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4 ``HEALTH INFORMATION TECHNOLOGIES: HOW INNOVATION BENEFITS

5 PATIENTS''

6 WEDNESDAY, MARCH 20, 2013

7 House of Representatives,

8 Subcommittee on Health

9 Committee on Energy and Commerce

10 Washington, D.C.

11 The subcommittee met, pursuant to call, at 10:00 a.m.,
12 in Room 2123 of the Rayburn House Office Building, Hon. Joe
13 Pitts [Chairman of the Subcommittee] presiding.

14 Present: Representatives Pitts, Burgess, Hall, Shimkus,
15 Blackburn, Gingrey, Lance, Guthrie, Griffith, Bilirakis,
16 Ellmers, Pallone, Green, Barrow, Christensen, Sarbanes, and

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17 Waxman (ex officio).

18 Staff present: Clay Alspach, Chief Counsel, Health; Matt
19 Bravo, Professional Staff Member; Debbie Hancock, Press
20 Secretary; Sydne Harwick, Staff Assistant; Sean Hayes,
21 Counsel, Oversight and Investigations; Robert Horne,
22 Professional Staff Member, Health; Carly McWilliams,
23 Legislative Clerk; Andrew Powaleny, Deputy Press Secretary;
24 Chris Sarley, Policy Coordinator, Environment and the
25 Economy; Heidi Stirrup, Health Policy Coordinator; Alli Corr,
26 Democratic Policy Analyst; Eric Flamm, FDA Detailee; Amy
27 Hall, Democratic Senior Professional Staff Member; Elizabeth
28 Letter, Democratic Assistant Press Secretary; Karen Nelson,
29 Democratic Deputy Committee Staff Director for Health; Rachel
30 Sher, Democratic Senior Counsel; and Matt Siegler, Democratic
31 Counsel.

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|
32 Mr. {Pitts.} The subcommittee will come to order. The
33 chair will recognize himself for an opening statement.

34 Today's hearing is part of a series of Energy and
35 Commerce subcommittee hearings this week that focus on
36 health, technology and innovation.

37 In the last few years, health information technologies,
38 including mobile medical applications, electronic health
39 records, personal health records, computerized health care
40 provider order entry systems, and clinical decision support,
41 have transformed the provision of health care in this
42 country. Electronic health records hold great promise for
43 the delivery of care given and the quality of care received
44 in this country. They have also been identified as key
45 components of future payment reforms such as those envisioned
46 for medical providers under the SGR.

47 There are now mobile medical apps for wireless
48 thermometers, apps that calculate body mass index, apps that
49 track the number of miles a runner has jogged and those that
50 can wirelessly transmit data to wearable insulin pumps.
51 These apps can range from the complex, like mobile cardiac

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52 outpatient telemetry that uses wireless sensors, to those
53 that allow users to count calories.

54 To give you a sense of the scope of their importance, it
55 has been estimated that 500 million people will be using
56 medical apps by the year 2015. Therefore, it goes without
57 saying that these technologies hold great potential for
58 patients and providers. However, with the proliferation of
59 these technologies have come concerns about how their use may
60 negatively impact patients. Some have argued that federal
61 oversight of these health information technologies is
62 important to safeguard patients from malfunctioning
63 technology.

64 In response to these concerns, the Office of the
65 National Coordinator in December of 2012 put out a proposal
66 for a risk-based regulatory scheme for electronic health
67 records that sought to address the needs of Americans both as
68 consumers and patients. The Food and Drug Administration has
69 also put forward a proposal, in the form of draft guidance
70 issued in July 2011, indicating its intent to regulate
71 certain apps as medical devices under section 201(h) of the
72 Federal Food, Drug and Cosmetic Act.

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73 While FDA's attention to the needs of patients is
74 commendable, its action requires very close scrutiny. This
75 subcommittee has examined in the past the negative impacts
76 that FDA regulation, with its uncertainty, high costs, and
77 long approval times, has had on the medical device industry.
78 If we allow the same to happen in this space, such negative
79 impacts could cripple a still evolving and promising
80 industry, where the average developer is small and the cost
81 of these apps is relatively inexpensive.

82 Some have also raised concern that the FDA may further
83 expand the definition of ``medical device'' in the future to
84 include other technologies, such as smartphones or tablets,
85 and thus the medical device tax passed in the Patient
86 Protection and Affordable Care Act could apply to them.

87 Therefore, this hearing is an appropriate place to
88 examine the extent to which the FDA and other federal
89 agencies should be involved in regulation of health
90 information technologies and what such a regulatory framework
91 might look like.

92 With these thoughts in mind, I want to thank our
93 witnesses for being here today and look forward to their

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94 testimony.

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

96 ***** COMMITTEE INSERT *****

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|
197 Mr. {Pitts.} And no one is seeking recognition. I will
198 close my statement and recognize the ranking member of the
199 Subcommittee on Health, Mr. Pallone, for 5 minutes for his
200 opening statement.

201 Mr. {Pallone.} Thank you. Thank you, Chairman Pitts.
202 Today is an important examination of the ways in which
203 health information technologies can benefit patients,
204 doctors, and the health care system as a whole. HIT is an
205 absolutely essential underpinning to the future of delivery
206 and payment reform.

207 The notion that if we can improve the coordination of
208 care, patient safety, disease management, and prevention
209 efforts, we can save money for the entire system. It is not
210 baseless. In fact, it has the utmost merit. Modernizing our
211 health care system and moving into an electronic era is part
212 of a national conversation that is occurring, and politicians
213 of both political parties, providers, and patients all agree
214 that HIT holds tremendous promise for improving the
215 performance of our healthcare system in a way that will
216 increase access, enhance quality, and indeed lower costs.

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117 That is why as chairman of this subcommittee, I worked
118 alongside many of my colleagues, Democrat and Republican
119 alike, and we passed the Health Information Technology for
120 Economic and Clinical Health Act, otherwise known as HITECH
121 or the HITECH Act. Together, we recognized with that bill
122 that there was a need for the Federal Government to commit to
123 expanding the use of information technology in the health
124 care sector, and that its widespread adoption would have
125 significant long-term benefits. This critical law contained
126 unprecedented funding to promote the adoption of health
127 information technology among hospitals, doctors, and health
128 care providers through initiatives by the Office of the
129 National Coordinator of HHS and through Medicare and Medicaid
130 incentives. This historic investment has begun to help
131 modernize our Nation's use of technology to truly ensure a
132 high-performing 21st century health system, and in building
133 an infrastructure of fundamental change.

134 The truth is that we have made great progress so far,
135 and there are even more opportunities that will be realized
136 in the future through the implementation of this law. As a
137 result of these programs, electronic health records, EHRs,

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138 and meaningful use of those records has increased
139 dramatically in recent years, and we will hear today from
140 some of the witnesses how it is working to make life better
141 for patients and serving as a catalyst for innovation.

142 Now I am afraid that my Republican friends are going to
143 spend this day making up false stories about how the
144 Affordable Care Act and FDA regulation is stifling
145 innovation--how our smartphones are going to be taxed and
146 Apple's manufacturing plants will be inspected, but I have to
147 say this is nonsense. The reality is the future of mobile
148 health is very bright. In fact, there is an effort underway
149 by the Federal Government to open up large sets of data to be
150 used by developers to create these mobile applications, and
151 many of these apps are designed to assist both individuals
152 and health care providers in managing health care decisions
153 and delivery. One industry analyst estimates that the total
154 revenues of the mobile medical app market will grow to \$26
155 billion by 2017, and because of the HITECH Act, this open
156 data will be able to be networked and shared with providers
157 to improve patient health and lower costs.

158 But I believe, and I think all of our witnesses today

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159 will agree with me, that if a technology developer is going
160 to make health-based claims, then there must be a role for
161 FDA to ensure it is safe and effective, and I hope that is
162 what comes out of today's hearing is a better understanding
163 of how the successful adoption of health information
164 technology will have a transformative effect on the quality
165 of health care in the United States, as well as the economy
166 of health care.

167 So I thank you all, thank the chairman, and I would
168 yield back the balance of my time.

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

170 ***** COMMITTEE INSERT *****

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|
171 Mr. {Pitts.} Chair thanks the gentleman, and now
172 recognizes the vice chair of the subcommittee, Dr. Burgess,
173 for 5 minutes for an opening statement.

174 Dr. {Burgess.} I thank the chairman for the
175 recognition. I am grateful to the chairman for holding this
176 hearing, grateful to our panel for presenting to us today.

177 The title of the hearing is fitting. As somebody who
178 worked in health care, I recognize the benefit that
179 innovation brings to patients. From the newest means to
180 detect and diagnose conditions, to the cures and diseases
181 that once were thought untreatable, innovation has led the
182 way to bettering the lives of patients.

183 Health care innovation doesn't always lower costs, but
184 it always holds the potential to improve the quality of life
185 and therefore is a goal worth pursuing in and of itself.

186 The tools that future doctors will have at their
187 disposal will be unparalleled in the history of medicine for
188 their ability to alleviate human suffering and improve lives,
189 but we need to get the tools in their hands. From custom
190 biologics to nanotechnology to the promises of the human

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191 genome, we are on the cusp of a medical revolution. The
192 President, in an Executive Order, ordered federal agencies to
193 review and remove outdated regulations. I absolutely agree
194 with Mr. President, but the proof really remains to be seen.

195 The biggest impediment to innovation is the uncertainty
196 of regulation. If the Federal Government thinks about
197 regulating something, that almost always means it is planning
198 to over-regulate. There is the difficulty, because the
199 lifeblood of innovation, venture capital, will be drained
200 away from the cures that might have been.

201 As a doctor, first do no harm. I don't want to do
202 anything that will harm a patient. But while the FDA
203 struggles with their core requirements that they propose to
204 venture into new areas like mobile apps and research only
205 products and health information technology, it really does
206 require a soft touch. Instead of talking to stakeholders,
207 including members of Congress, where updates may be needed
208 from time to time, and significant proposed regulatory
209 changes could stop innovation in their tracks, we are just
210 not seeing it happen. Companies will build it, doctors will
211 use it, patients will benefit if we could just get out of the

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212 way and ensure responsible regulation in a timely fashion.

213 The reason I care about this so much is because not just
214 today, this is about the future. This is about the men and
215 women that will follow after us in the practice of medicine.
216 These are about the ideas that somebody hasn’t even had yet.
217 The lack of a reliable and consistent regulatory process
218 signals an inability to handle the events for technology in
219 the future.

220 Mr. Chairman, this hearing is timely. It is in
221 conjunction with other hearings being done in other
222 subcommittees and the full committee. Technology had a
223 hearing yesterday. We will have a hearing in Oversight and
224 Investigations tomorrow. But it is part of a process.

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

226 ***** COMMITTEE INSERT *****

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|
227 Dr. {Burgess.} I would like now to yield the balance of
228 the time available to the gentlelady from Tennessee, the vice
229 chair of the full committee.

230 Mrs. {Blackburn.} I thank the gentleman for yielding,
231 and welcome to each of you. We are delighted that you are
232 here.

233 As Dr. Burgess said, we had a Telecom Subcommittee
234 hearing yesterday, and looked at the impediments to
235 innovation. It was fantastic to have a group of innovators
236 sitting at your table and talking to us about the problems
237 that they are seeing.

238 Now, one of my colleagues said that he feared we would
239 spend our time making up stories about how HHS and FDA kind
240 of get in the way, but we don't have to make them up. All we
241 have to do is read the testimony from yesterday.

242 One of the things that came through regularly in their
243 words was that the uncertainty that is there from the FDA,
244 this big gray area in the center, that you don't know if you
245 are going to be regulated as a medical device. If you don't
246 know how far that arm of government is going to reach and how

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247 massive the overreach will be, or will it be contained and
248 will there be some certainty?

249 Now, I don't think it is up to the FDA to provide that
250 certainty. I think it is up to Congress to decide what FDA's
251 role should be. We are seeking your thoughts and the panel
252 yesterday and tomorrow to make certain that we approach this
253 in the appropriate manner. What we want to be certain that
254 we do is allow the environment for innovation to take place.
255 As Dr. Burgess said, these are tools that today's doctors and
256 future doctors are going to be able to use. It is items--I
257 think 15 percent of apps are used by providers. That is
258 something that will yield to cost savings. At the same time,
259 patients are able to have a more active participation in
260 their health care, from managing diseases and chronic
261 conditions, by having access to an app that goes with them
262 everywhere they go.

263 So we look forward to hearing from you to setting the
264 right path forward, and we thank you for your time.

265 I yield back.

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

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267 ***** COMMITTEE INSERT *****

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|
268 Mr. {Pitts.} Chair thanks the gentlelady, and now
269 recognizes the ranking member of the full committee, Mr.
270 Waxman, for 5 minutes for an opening statement.

271 Mr. {Waxman.} Thank you, Mr. Chairman.

272 Today is our second day of hearings on this subject.
273 This is the week that this committee decided that in three of
274 its subcommittees, we would hold hearings to scare people
275 that they won't be able to develop what we want to see
276 developed, innovative ways to communicate in the health
277 space. The Energy and Commerce Committee has a history of
278 bipartisan accomplishments, and even in this area, and that
279 is one of the reasons, to me, why the partisan hyperbole we
280 have heard from some on this topic is so disappointing.

281 Yesterday, the Telecommunications Subcommittee examined
282 mobile medical applications and the FDA regulation of medical
283 devices. Both sides of the aisle agree we must promote
284 innovation in the dynamic mobile medical applications market.
285 Both sides agree that it is essential for the FDA to ensure
286 the safety and effectiveness of potentially dangerous medical
287 devices, even if they are also connected to a mobile

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288 platform. But we spent far too much of yesterday's hearing
289 debating an imaginary tax on smartphones, because in the
290 Affordable Care Act, there is a tax on medical devices. So
291 you have got two things to worry about. If you innovate, FDA
292 might look at it and regulate it, and two, if it is a medical
293 device, it may be taxed. Oh, you shouldn't sleep anymore at
294 night worrying about these problems Republicans are dreaming
295 up.

296 So they said FDA is going to regulate these iPhones, the
297 same way it regulates heart valves. Well, that is a
298 political talking point and it is just not real. I hope
299 today we can focus on this committee's real bipartisan
300 accomplishments in health information technology.

301 In the 111th Congress, the Congress before the last one,
302 our committee passed what was called the Health Information
303 Technology for Economic and Clinical Health Act as part of
304 the Recovery Act. They called this the HITECH--that is the
305 way we do it, so we got a new acronym. This law resulted in
306 an explosion of electronic health records and other advanced
307 health information technology--exactly what we wanted to see.
308 Physicians, hospitals, pharmacies, health care providers

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309 across the country are building an infrastructure network as
310 important to our Nation's future as the interstate highway
311 system. It is just like the construction of the interstates.
312 Building this infrastructure is challenging. Hundreds of
313 thousands of physicians, tens of thousands of hospitals,
314 clinics, pharmacies are going to connect to this network and
315 HHS is--made a lot of progress by engaging a wide variety of
316 stakeholders and driving coordination without mandating a
317 ``one size fits all'' solution. So we are trying to develop
318 the ability technologically to communicate, and it is an
319 ambitious goal. A seamlessly connected health information
320 infrastructure protects privacy while demanding the highest
321 quality, most efficient care. We haven't reached that goal
322 yet, but I believe we are on track to get there.

323 So given our enormous progress, it would be rash and
324 unwise to turn back now. This is worth doing. Similar to
325 the health IT, our approach to mobile health applications has
326 to strike the correct balance between innovation and patient
327 safety. Well, we had a hearing yesterday where we made it
328 clear that FDA wouldn't take mobile apps and regulate mobile
329 apps, even if they had information on general health and

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330 wellness, and even if it functioned as electronic health
331 record system. I think it is wise. We shouldn't regulate
332 this in any way as a medical device. But if you had
333 something on your iPhone that purports to help diagnose skin
334 cancer or congenital heart defects, well, you got to have
335 some appropriate regulatory scrutiny. You get a lot of false
336 positives, you get false negatives, people are being
337 confident in these devices, and we better know whether you
338 can be confident in these devices, if they are going to tell
339 you that a mole, don't worry about it, it is not cancerous,
340 when, in fact, it could be melanoma.

341 We don't believe in this country that buyer should
342 beware. Well, my colleagues in Congress should act.
343 Congress has acted, and in fact, when we had the Medical
344 Devices User Fee Act in the last Congress, we specifically
345 rejected in that bill a moratorium on FDA's use of its
346 authority over medical devices that happened to be
347 implemented as mobile applications.

348 My last point is even if it is regulated as a medical
349 device, it is not going to be charged with a tax. That tax
350 only goes to certain kinds of devices. So don't be scared.

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351 Look at the law, look at the reality, and don't listen to the
352 political rhetoric which this week has been orchestrated very
353 carefully by my Republican colleagues.

354 Yield back the balance of my time.

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

356 ***** COMMITTEE INSERT *****

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357 |
 Mr. {Pitts.} Chair thanks the gentleman.

358 That concludes our opening statements. We have one
359 panel today. I would like to thank our distinguished panel
360 of experts for providing testimony today, and I will
361 introduce them at this time.

362 First, Dr. Joseph Smith, Chief Medical and Chief Science
363 Officer, West Health Institute; secondly, Ms. Christine
364 Bechtel, Vice President, National Partnership for Women and
365 Families; third, Mr. Jim Bialick, Professor of Public Policy,
366 Georgetown Public Policy Institute; fourth, Dr. Jacqueline
367 Mitus, Senior Vice President, Clinical Development and
368 Strategy, McKesson Health Solutions; and finally, Dr. David
369 Classen, Chief Medical Information Officer, Pascal Metrics,
370 Associate Professor of Medicine and Consultant in Infectious
371 Diseases, University of Utah School of Medicine.

372 Thank you all for coming this morning. You will each be
373 given 5 minutes to summarize your testimony. Your written
374 testimony will be entered into the record.

375 Dr. Smith, we will start with you. You are recognized
376 for 5 minutes for your opening summary.

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|
377 ^STATEMENTS OF JOSEPH M. SMITH, M.D., Ph.D., CHIEF MEDICAL
378 AND CHIEF SCIENCE OFFICER, WEST HEALTH INSTITUTE; CHRISTINE
379 BECHTEL, VICE PRESIDENT, NATIONAL PARTNERSHIP FOR WOMEN AND
380 FAMILIES; JIM BIALICK, EXECUTIVE DIRECTOR, NEWBORN COALITION;
381 JACQUELINE MITUS, M.D., SENIOR VICE PRESIDENT, CLINICAL
382 DEVELOPMENT AND STRATEGY, MCKESSON HEALTH SOLUTIONS; AND
383 DAVID CLASSEN, M.D., CHIEF MEDICAL INFORMATION OFFICER,
384 PASCAL METRICS, AND ASSOCIATE PROFESSOR OF MEDICINE AND
385 CONSULTANT IN INFECTIOUS DISEASES, UNIVERSITY OF UTAH SCHOOL
386 OF MEDICINE

|
387 ^STATEMENT OF JOSEPH M. SMITH

388 } Dr. {Smith.} Chairman Pitts, Ranking Member Pallone,
389 and members of the subcommittee, thank you for the
390 opportunity to testify today. I am Dr. Joseph Smith, Chief
391 Medical and Science Officer for the West Health Institute, a
392 nonpartisan, nonprofit, applied medical research organization
393 dedicated to lowering the cost of health care for public good
394 by research and development of innovative, patient-centered

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395 solutions.

396 Our Nation's health care system is in dire need of
397 dramatic change as we lead the world in health care spending,
398 lag many of our peer nations in critical health outcomes, and
399 face into a growing aging population a tsunami of chronic
400 disease, with a relative shortage of physicians, it is
401 difficult to overstate our challenges, but suffice it to say
402 that our health care delivery system is exceeding both our
403 Nation's budget and our provider's bin without yet meeting
404 our patient's needs.

405 We see an enormous opportunity to use information
406 technology, device innovation, mobile and wireless
407 technology, and smart and learning systems to both transform
408 health care delivery and create empowered, informed consumers
409 of health care. Health care must be allowed and encouraged
410 to rapidly evolve using the same innovations that have
411 already revolutionized banking, education, retail, computing,
412 photography, and communication. We must take proactive steps
413 to assure that those technologies that have enabled a
414 revolution of decentralization, democratization, automation,
415 and personalization, and other aspects of our lives and our

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416 economy have the same beneficial impact on health care.

417 To enable this transformation, three elements appear
418 required. One, streamlined, predictable, transparent, risk-
419 based regulation that fosters innovation and investment for
420 the benefit of patients, as well as our ailing health care
421 system; two, a proactive regulatory and reimbursement stance
422 on true functional interoperability, not only EHR
423 interoperability, but specifically, medical device
424 interoperability to create an integrated, fully coordinated
425 web of patient-centered health care technology; and three,
426 reimbursement policy that aligns stakeholder incentives and
427 drives adoption of appropriate technology to improve safety,
428 efficiency, and cost of care.

429 At this point in time, when health care is truly a
430 ``burning platform,'' we need to stimulate innovation and
431 experimentation. This requires a clear, consistent, and
432 timely approach to regulation. Outside of health care, we
433 have witnessed a revolution in information, communication,
434 and device technology driven by innovation and investment,
435 all encouraged by a predictable regulatory posture. Within
436 health care, however, we have yet to fully exploit the potent

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437 intersection of these technologies.

438 With respect to medical apps, while we have witnessed an
439 explosion of innovation in the health and wellness
440 applications, we have seen relatively little activity in the
441 critically important, but more heavily regulated, areas of
442 remote monitoring, diagnosis and treatment of those chronic
443 diseases that burden patients, and make up the lion's share
444 of our health care spending. And for medical apps and
445 clinical decision support, it is an open question of whether
446 the existing medical device regulatory framework can be
447 sufficiently modified to provide the applicability, clarity,
448 predictability, and timeliness required.

449 The FDA's draft guidance on mobile medical apps offered
450 some improved clarity, but still described significant areas
451 of regulatory discretion, and now after lengthy delay without
452 becoming finalized has left an industry in limbo.

453 Going forward, considering the frequency with which both
454 general app user interfaces and medical treatment guidelines
455 used in clinical decisions support algorithms that are
456 routinely updated, the prospect of having all such changes
457 subject to the complex regulatory process for medical device

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458 revision seems more than daunting. Whatever the process, we
459 must drive regulation at the pace of innovation, and not
460 vice-versa.

461 The second priority is to use regulatory and
462 reimbursement policy to encourage true functional
463 interoperability of information systems, and medical devices.
464 Health care needs to exploit a truly connected and
465 coordinated med app technology that can be seen as
466 originating at the patient with those surrounding or even
467 implanted medical devices with seamless sharing of relevant
468 information among all such devices and the background EHR.
469 The current lack of such true functional interoperability
470 results in safety hazards and inefficiencies that we do not
471 tolerate in other less critical areas, and it creates
472 additional barriers for new innovative entrants.

473 Standards-based interoperability allows the information
474 required for commerce and banking and communication and
475 education to move at the speed of innovation, and yet, when
476 it comes to our health care, information is stuck in multiple
477 non-communicating silos as lifesaving devices are forced to
478 work independently, despite being inches apart, all in

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479 service of the same critically ill patient.

480 Today we released a study illustrating that true
481 functional medical device interoperability not only brings
482 improvements in patient safety and efficiency, but may also
483 result in savings of more than \$30 billion annually.
484 Established labeling for medical device interoperability and
485 inclusion of such stage three meaningful use could encourage
486 adoption of such functional interoperability for patient
487 benefit and health care savings.

488 The third priority area is regulation of reimbursement
489 policy that promotes aligned incentives. Reimbursement
490 systems that disproportionately reward hospital-based
491 procedures over office-based procedures, or face-to-face
492 encounters over remote encounters need to give way to
493 reimbursement based on outcome, not location, and value, not
494 volume. Only in this way will we unleash the power of
495 information communication and medical device technology.

496 In closing, the West Health Institute believes that
497 streamlined, predictable, transparent, risk-based regulation,
498 a proactive regulatory and reimbursement stance on medical
499 device interoperability, and realistic and actual policy to

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500 align stakeholder incentives can help to unleash a needed and
501 long overdue transformation of our health care delivery
502 system to allow it to sustainably address the needs of
503 today’s patients and meet tomorrow’s challenges.

504 Thank you very much.

505 [The prepared statement of Dr. Smith follows:]

506 ***** INSERT 1 *****

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|
507 Mr. {Pitts.} Chair thanks the gentleman, and now
508 recognizes Ms. Bechtel for 5 minutes for an opening
509 statement.

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|
510 ^STATEMENT OF CHRISTINE BECHTEL

511 } Ms. {Bechtel.} Good morning. I am Christine Bechtel
512 with the National Partnership for Women and Families. We are
513 a nonprofit, nonpartisan consumer advocacy organization. I
514 also serve on the Federal Health IT Policy Committee.

515 I am honored to speak today about how the EHR Incentive
516 Program, commonly known as ``Meaningful Use'', is catalyzing
517 fundamental change in our health care system and advancing
518 innovation.

519 Almost 3 years ago before this same subcommittee, I
520 shared a story of Susan Crowson, and she is a family
521 caregiver from Maryland, and she cared for her father, Pop.
522 Pop was seeing five different doctors, taking three different
523 prescription drugs, two over-the-counter drugs, and daily
524 vitamins to manage a host of complex conditions, including
525 Alzheimer's Disease, and arrhythmia. Susan diligently
526 tracked all of Pop's medications, tests, lab results, and
527 visits on a spreadsheet to help his doctors avoid medical
528 errors and provide the best care possible in our highly

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529 fragmented system.

530 Today, the Meaningful Use Program is making care better
531 for people like Pop and caregivers like Susan. Providers
532 with certified EHRs now maintain up-to-date electronic lists
533 of patient's health conditions, diagnoses, and medications,
534 and doctors can automatically track for drug interactions and
535 allergies. Pop and Susan can get a summary at every office
536 visit so they know the diagnosis and the plan. If Pop is
537 admitted to the hospital, they can send a summary of his
538 admission to his primary care doctor. These are just some of
539 the early innovations in health IT.

540 Sadly, many of these advances were not put in place
541 quickly enough to help the Crowson family. Since I last
542 testified, Pop has passed away. But thanks to Meaningful
543 Use, patients and family caregivers like Susan are less
544 likely to face these same struggles. They are now coming to
545 expect health IT, just as technology has revolutionized so
546 many other aspects of our life.

547 Indeed, the arc of adoption has surpassed our
548 expectations. At the last subcommittee hearing in 2010, we
549 wondered if incentive payments would be effective drivers of

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550 EHR adoption. We asked if providers would be able to achieve
551 Meaningful Use. Federal officials then offered a high end
552 estimate of 53 percent of office-based physicians would adopt
553 EHRs by 2015. But as of this February, 2 years before the
554 2015 projection, CMS reports that 40 percent of eligible
555 professionals have already completed phase one of Meaningful
556 Use, either in Medicare or Medicaid, and more than 70 percent
557 have registered for it. Hospitals have been even more
558 successful. Seventy percent are already Meaningful users,
559 and 85 percent have registered.

560 But there is much more work to do. To foster continued
561 innovation, we must deploy a wider array of standards through
562 HHS's certification program, which has been essential to
563 breaking down technical barriers to the secure sharing of
564 health information. It is this federal leadership which
565 occurs in collaboration with the private sector that is
566 critical to innovation.

567 We also need new approaches to payment that moves us
568 beyond fee-for-service and creative business case for care
569 coordination and improved health outcomes. This can only be
570 done by rewarding quality and value over volume. But we

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571 simply cannot measure and reward this kind of care without
572 health IT.

573 Even within these limitations, though, advancements in
574 standardization spurred by the Meaningful Use regulations are
575 catalyzing innovation. So for example, Medicare and the VA
576 implemented a feature called Blue Button that allows
577 individuals to securely view and download their health
578 information online, and this innovation is making a world of
579 difference for people like Beth Schindele, who cares for her
580 father, William Graves. With his permission, Beth went to
581 mymedicare.gov and downloaded his health information when he
582 was in the hospital. The data from Blue Button showed that
583 he had more than 63 providers caring for him over the course
584 of four hospitalizations in the last year and a half, and she
585 told me last week ``Having the data in my hands during his
586 hospitalization allowed me to prevent the hospital from
587 erroneously placing him on Coumadin, which is a blood
588 thinning medication, and he had stopped taking that 2 years
589 ago. I am so thankful that I did. Within hours of
590 discharge, he fell and he suffered severe head and arm
591 lacerations that would have been life-threatening had he been

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592 on Coumadin, and would have resulted in a readmission within
593 just 5 hours of leaving the hospital.' Blue Button is a
594 simple, yet powerful, innovation that will help consumers
595 play a critical role in promoting safer, more affordable, and
596 more coordinated care.

597 For this kind of innovation to accelerate, the challenge
598 before us is to ensure that every provider in the country has
599 health IT. We must expand the Meaningful Use program to
600 connect other providers like long-term care, behavioral
601 health, and home health. No other program in history has
602 done this much this quickly to advance the adoption of health
603 IT, and I am confident that along with payment reform, it
604 will result in better care at a lower cost. Thank you.

605 [The prepared statement of Ms. Bechtel follows:]

606 ***** INSERT 2 *****

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|
607 Mr. {Pitts.} Chair thanks the gentlelady and now
608 recognizes Mr. Bialick for 5 minutes for an opening
609 statement.

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|

610 ^STATEMENT OF JIM BIALICK

611 } Mr. {Bialick.} Chairman Pitts, Ranking Member Pallone,
612 members of the subcommittee, thank you for the opportunity to
613 testify on this important issue. And thank you, Mr. Pitts,
614 for the promotion, but I am actually the Executive Director
615 of the Newborn Coalition. We are an all volunteer
616 organization that came together to promote the development
617 and use of mobile apps and technology in newborn and infant
618 health.

619 The catalyst for our beginning was the birth of a baby
620 named Eve, who at 40 hours old was diagnosed with a critical
621 congenital heart defect, the most common birth defect in the
622 U.S. affecting nearly 1 in 100 births. Had it not been for
623 an attentive nurse, Eve would have been discharged with a
624 partially formed heart. While a simple screening tool, pulse
625 oximetry, exists to identify these conditions, there is still
626 no national requirement for routine screening. Her mother,
627 our co-founder, started a crusade to ensure that babies like
628 Eve would never again be sent home without first being

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629 screened.

630 We estimate that since our efforts began, the number of
631 babies screened for heart defects in the U.S. has increased
632 by 4,500 percent. To date, we have aided in the drafting of
633 legislation in 23 States and the enactment of nine laws. The
634 first was in New Jersey, where a baby was identified with a
635 heart defect before a discharge on the very first day of
636 screening, and most recently, in California.

637 We are very proud of these numbers, but we have learned
638 that it is not enough just to screen, but we also have an
639 obligation to accommodate the lifelong needs of those
640 diagnosed by the screening, and consumer technology, such as
641 mobile apps, play an important role in fulfilling that
642 responsibility.

643 It is important to remember that of the more than four
644 million babies born in the U.S. every year, the majority
645 aren’t born in advanced cardiac surgery centers. They may be
646 sent to several hospitals, be seen by more than a few
647 doctors, be given a number of medications, which in today’s
648 less than interoperable health care system means mom and dad
649 will be responsible for managing and reconciling most of this

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650 information on the best and worst day of their lives.

651 After leaving the hospital, babies can be monitored
652 continuously from home using a pulse oximeter. These babies
653 are special because they have heart defects, but they are
654 still just babies and their parents are still exhausted. So
655 what do parents do? They use the same smartphone or tablet
656 that they use to manage all of their other important
657 information. Families and providers have come to rely on
658 mobile apps to allow them to capture readings from remote
659 monitoring devices. This means less time having to focus on
660 being a nurse and more time available to be a parent.

661 The availability of these technologies has created a
662 revolution in how we interact with our data and engage in our
663 health, but it has also created legitimate safety concerns
664 that must be addressed. However, the FDA draft guidance as
665 written would seemingly attempt to regulate the future of
666 health care technology as a standalone medical device. In my
667 written testimony, I have laid out a model for a risk-based
668 framework that very intentionally delineates between health
669 information management apps and actual medical devices.

670 Applications and the platforms that support them have

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671 the ability to integrate and interoperate with any device
672 that will allow it. Consumer demand for integrated
673 technology solutions will drive the market to a wholly
674 interoperable system that can be accessed at any time,
675 anywhere, and by any device, and we would be foolish to
676 believe that this integration will happen and will not
677 include health information.

678 Consumer technologies have evolved to leverage the
679 Internet to share data, including with medical devices,
680 functionally eliminating the difference between being on a
681 network and physically linking devices with a cord. As a
682 result, we need to be thinking about the regulation of
683 technology differently. What we need is a new patient-
684 centered risk-based regulatory framework for evaluating
685 health technologies that is flexible enough to regulate what
686 we are using today and adaptive enough to accommodate the
687 technologies that have yet to be conceived.

688 I know the concept of a new regulatory process is
689 daunting, but an existing framework does not create the
690 certainty that the emerging health care technology
691 marketplace needs to flourish. I cringe when I hear from

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692 patient organizations that are dedicating a significant
693 amount of their budget to develop a mobile app, because I
694 know their product may have to go through a process that
695 would cost them more than they can afford, rendering their
696 initial investment worthless. I was disheartened when my
697 wife, who is now 4 months pregnant, asked me which app she
698 should use to track her pregnancy. I told her the one with
699 the fewest, least complex features, because I wanted to make
700 sure that she didn't lose all the data that she would enter
701 throughout the pregnancy in the event the manufacturer
702 depreciated certain functionalities to avoid the FDA. To me,
703 that is not certainty and that is not pro-patient.

704 This committee has the foresight to hold--has had the
705 foresight to hold this hearing because collectively, you
706 recognize that mobile apps are transforming how patients,
707 families, and providers engage in the delivery of health
708 care. Reform will not be without controversy, but it is far
709 better to address this issue now than to wait for traditional
710 approaches to fail at the expense of patients and families.

711 Thank you again for this opportunity to testify. I look
712 forward to working with you on this important issue, and I am

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713 happy to answer any questions.

714 [The prepared statement of Mr. Bialick follows:]

715 ***** INSERT 3 *****

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|
716 Mr. {Pitts.} Chair thanks the gentleman, and now
717 recognizes Dr. Mitus for 5 minutes for an opening statement.

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|
718 ^STATEMENT OF JACQUELINE MITUS

719 } Dr. {Mitus.} Good morning, Mr. Chairman and
720 distinguished members of the subcommittee. My name is Jackie
721 Mitus, and I currently serve as Senior Vice President of
722 Clinical Development and Strategy for McKesson Health
723 Solutions. I appreciate the opportunity to appear before you
724 today.

725 My background as a practicing hematologist/oncologist at
726 the Brigham and Women's Hospital in Boston, and faculty
727 member of Harvard Medical School, as well as my
728 responsibilities at McKesson, have provided me with a unique
729 perspective on health information technology. I have seen
730 first-hand how critical health IT is to advancing the care
731 and safety of patients.

732 As the largest health IT company in the world, McKesson
733 has actively engaged in the transformation of health care
734 from a system burdened by paper to one empowered by
735 interoperable electronic solutions.

736 I would like to make two key points today.

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737 First, health IT is foundational to improving the
738 quality, safety and affordability of healthcare.

739 Second, to ensure continued innovation and leverage the
740 power of health IT, we need a new regulatory framework that
741 is risk-based and specific to health IT.

742 Health care in our country is undergoing fundamental
743 changes to make it safer, better, and more efficient. Health
744 IT is the foundation of these efforts. It provides access to
745 current, accurate patient information such as medication
746 history, and it supports the clinician in preventing errors,
747 identifying gaps in care, and suggesting appropriate
748 diagnostic and treatment paths. Health IT does not replace
749 physician judgment, but rather, provides guidance and
750 support. The ultimate responsibility for the care and safety
751 of a patient always rests with the treating clinician.

752 Today, the FDA has authority to regulate medical devices
753 under amendments to the Food, Drug, and Cosmetic Act adopted
754 in 1976. The definition of a medical device in the Act is
755 broad and can be interpreted to include all health IT,
756 including medical software. The current regulatory approach
757 for medical devices, however, is not well-suited for health

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758 IT. For example, does an iPad that reminds a patient to
759 refill a prescription make it a traditional medical device?
760 What about an application that allows a clinician to access a
761 medical journal or review an x-ray online? Should these
762 applications and the iPad each be subject to FDA regulations?

763 Medical software is fundamentally different from medical
764 devices in two important ways. First, the safety of a
765 medical device is almost entirely dependent upon how it is
766 manufactured. The safety of health IT, on the other hand,
767 hinges upon how it is developed and perhaps more importantly,
768 on how it is implemented. Thus, health IT cannot safely be
769 ensured simply through good manufacturing practice.

770 Second, medical devices, unlike health IT, are directly
771 involved in the treatment of a patient with little, if any,
772 opportunity for a clinician to intervene. The majority of
773 medical software does not directly or independently act upon
774 a patient, but rather, provides data and guidance. The
775 ability of a learned intermediary to utilize professional
776 judgment distinguishes this technology from traditional
777 medical devices.

778 Mr. Chairman, we risk using a law enacted nearly a half

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779 century ago to regulate a rapidly changing and dynamic era of
780 technology.

781 In closing, I would like to highlight the work of the
782 Bipartisan Policy Center, BPC, which last month released a
783 report in response to the FDA Safety and Innovation Act.
784 With the input of nearly 100 organizations, including
785 McKesson, the BPC recommended dividing health IT into three
786 risk categories. The first and highest risk category
787 includes technology linked to or used to operate a medical
788 device. This technology would continue to be regulated as a
789 medical device. The second category includes medical
790 software that merely guides the physician, such as clinical
791 decision support or electronic health records. This group
792 would be subject to rigorous accreditation by an independent
793 third party, or perhaps ONC. Finally, the third category,
794 non-clinical technology, such as billing and scheduling
795 software, would not be subject to regulatory oversight. The
796 BPC approach is flexible, protects patient safety, promotes
797 innovation, and leverages existing quality and safety
798 standards.

799 In conclusion, health IT is imperative to the successful

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800 transformation of health care. It improves the quality of
801 patient safety, enables payment and delivery reform, and
802 promotes efficiency and lower cost. That is why it is so
803 important that we regulate health IT thoughtfully to advance
804 care and support innovation. That is why we need a new risk-
805 based framework such as that proposed by the BPC.

806 On behalf of McKesson, I thank you for the opportunity
807 to share our thoughts.

808 [The prepared statement of Dr. Mitus follows:]

809 ***** INSERT 4 *****

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|
810 Mr. {Pitts.} The chair thanks the gentlelady, and now
811 recognizes Dr. Classen for 5 minutes for an opening
812 statement.

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|

813 ^STATEMENT OF DAVID CLASSEN

814 } Dr. {Classen.} Good morning, Chairman Pitts and Ranking
815 Member Pallone, members of the subcommittee. Thank you for
816 the opportunity to testify on this very important issue. I
817 am a practicing infectious disease physician at the
818 University of Utah School of Medicine, and I am the Chief
819 Medical and Informatics Officer at Pascal Metrics, a patient
820 safety organization. I also chair the AHRQ Formats Committee
821 at the National Quality Forum. My background is as an
822 infectious disease physician, medical informaticist and
823 patient safety researcher. As such, I have been on several
824 Institute of Medicine committees that have focused on how to
825 improve patient safety, most recently, the one I will draw my
826 testimony from today, Health IT and Patient Safety: Building
827 Safer Systems for Better Care. One of the focuses of that
828 report was how do we improve the safety of care for our
829 patients most effectively with health IT? How do we do it in
830 a way that doesn’t injure our patients or harm them, and how
831 do we do it in a way that does not stifle innovation?

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832 From that report, we looked back through the original To
833 Err is Human report from the Institute of Medicine that
834 suggested that as many as 98,000 lives a year are lost due to
835 medical errors. In our most recent report, we suggest that
836 those estimates of patient safety problems are probably lower
837 than is really the story, based on newer detection problems
838 both in hospitals and in the ambulatory setting of care. So
839 there clearly is a large opportunity for us to use health IT
840 to improve safety of care, both on the inpatient setting in
841 hospitals and on the ambulatory setting.

842 So one strategy that the Nation has turned to for safer,
843 more effective care is the widespread use of health IT. As
844 we have heard from other panel members, this really is the
845 case over the last several years. We are investing billions
846 of dollars in Meaningful Use to more broadly adopt this
847 health IT. It is clearly playing an ever larger role in the
848 care of patients, and clearly there is evidence that it has
849 improved health care and reduced medical errors.

850 Continuing to use paper records places patients at
851 unnecessary risk for harm and substantially concerns the
852 ability to reform health care. However, there are concerns

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853 about harm that has come from the use of health IT that led
854 to the generation of this IOM report. In this IOM report,
855 health IT and patient safety was defined broadly to include
856 EHRs, patient engagement tools, personal health records,
857 secure patient portals, health information exchanges, and
858 mobile applications.

859 Practicing clinicians, such as myself, expect health IT
860 to support the delivery of high quality in several ways,
861 including storing comprehensive health data, providing
862 clinical decision support, facilitating communication, and
863 reducing medical errors. It is widely believed that health
864 IT, when designed, implemented, and used appropriately, can
865 be a positive enabler to transform the way care is delivered.
866 Designed and applied inappropriately, health IT can add
867 complexities to the already complex delivery of health care,
868 which can lead to unintended consequences, for example,
869 dosing errors, failing to detect fatal illnesses, and
870 delaying treatment due to poor human to computer error,
871 actions or loss of data. Merely installing health IT in
872 health care organizations will not result in improved care or
873 safety. Taking together the design, implementation, and use

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874 of health IT affects its performance on improving the safety
875 of care.

876 Safe implementation and safe use of health IT is a
877 complex, dynamic process that requires a shared
878 responsibility among vendors, health care workers, and health
879 care organizations, a partnership, if you will. Many
880 features of software contribute to its safe use, including
881 usability and interoperability, and can also contribute to
882 patient safety problems if we have poor user design, poor
883 work flow, or complex interfaces, which could be a threat to
884 patient safety. The lack of system operability is clearly a
885 major problem in patient safety. We do have some success
886 stories here. Laboratory standards have added--actually
887 facilitated the free flowing of laboratory information.
888 However, we are not there yet and information such as problem
889 lists and medication lists are not currently easily
890 transmitted between health IT systems.

891 Safety considerations need to be embedded throughout the
892 whole health IT implementation process, including planning,
893 deployment, stabilization, optimization, and transformation.
894 Vendors take primary responsibility for the design and

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895 development of technologies ideally with iterative feedback
896 from users. The users assume responsibility for safe
897 implementation at work with vendors throughout the health IT
898 implementation process. This partnership to develop,
899 implement and optimize system is a shared responsibility
900 where vendors and users help each other achieve the safest
901 possible applications of health IT.

902 It is important to recognize that health IT products
903 generally cannot be installed out of the box. Users often
904 need to ensure that products appropriately match their needs
905 and capabilities in both functionality and complexity of
906 operation. So therefore, in operation health IT can look
907 very different from what it looked like on the shelf.

908 Ongoing safe use of health IT requires diligent
909 surveillance of evolving needs, gaps, performance issues, and
910 mismatches between user needs and system performance, unsafe
911 conditions, and adverse events. The IOM report believes
912 certain actions are required by both private and public
913 entities to monitor safety in order to protect the public's
914 health, and provided the following recommendations to improve
915 health IT nationwide. In my testimony, I have the

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916 recommendations in that report, but in the interest of time,

917 I will leave them in the testimony and conclude my remarks.

918 Thank you very much.

919 [The prepared statement of Dr. Classen follows:]

920 ***** INSERT 5 *****

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|
921 Mr. {Pitts.} The chair thanks the gentleman.

922 Let me ask--start a question. I recognize myself for 5
923 minutes for this purpose. I will ask each of you this
924 question.

925 Do you believe that data, Dr. Smith, for the purposes of
926 regulation should be classified as a medical device?

927 Dr. {Smith.} Data, no, sir.

928 Mr. {Pitts.} Ms. Bechtel?

929 Ms. {Bechtel.} I have to say this is not my area of
930 expertise.

931 Mr. {Pitts.} Mr. Bialick?

932 Mr. {Bialick.} Data, no.

933 Mr. {Pitts.} Dr. Mitus?

934 Dr. {Mitus.} Data per se, no.

935 Mr. {Pitts.} Dr. Classen?

936 Dr. {Classen.} Data, no.

937 Mr. {Pitts.} Thank you.

938 Now, Mr. Bialick, do you believe that the newborn
939 patients you are here representing today will be best served
940 by the FDA classifying medical apps as medical devices?

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941 Mr. {Bialick.} As the draft guidance is written, no.

942 Mr. {Pitts.} Speaking of the FDA draft guidance, many
943 have argued that the FDA is proposing to only regulate apps
944 that are essentially medical devices and does not intend to
945 go any further. And while I may disagree with this
946 presumption, I do think it is very instructive for the
947 purposes of today's hearing. Many years of dealing with the
948 FDA have taught me that it is not what they say they are
949 going to regulate today, but what they could regulate
950 tomorrow.

951 Are you familiar--I will stay with you, Mr. Bialick--
952 with the term regulatory creep?

953 Mr. {Bialick.} I am.

954 Mr. {Pitts.} And what could regulatory creep mean for a
955 combination who seek to innovate in this space and to the
956 patients whose lives may depend upon this innovation for
957 their health and welfare?

958 Mr. {Bialick.} The draft guidance, as it was written, I
959 think refers or relies on terminology like an app that even
960 now is a little bit outdated. The concept of an app is a
961 discreet piece of software on a device. That is really being

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962 changed by how the market has embraced cloud technology. The
963 idea that you would have a discreet piece of an app or
964 software that is one little piece, that is different now when
965 an app is also the browser on your smartphone. These
966 technologies are becoming platform agnostic, and so how do we
967 talk about that in reference of, you know, when the draft
968 guidance was written, even the definition of an app has
969 changed during this time, so the idea that we can regulate an
970 app--but these apps are expanding, we need to have clearer
971 lines as to how these things are--where the regulation is
972 going to stop.

973 Mr. {Pitts.} Okay. Well, let me ask, and each of you
974 can respond. Do you believe the FDA has the expertise to
975 regulate medical app technology, and do you foresee them
976 gaining that expertise in the foreseeable future? Let's just
977 start and go down the line. Dr. Smith?

978 Dr. {Smith.} I think it is, to a point in my testimony,
979 making sure that regulation moves at the speed of innovation.
980 I think it is quite challenging for the FDA and for many
981 reasons to stay as current as possible on those things which
982 are simply just emerging. And so the simple answer to your

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983 question is no. I think the opportunity for external
984 expertise needs to be exploited much more thoroughly than it
985 has been to date.

986 Mr. {Pitts.} Mr. Bialick?

987 Mr. {Bialick.} I think that the FDA absolutely has the
988 experience and knowledge in-house to evaluate apps that are
989 actually medical devices. When it talks about just some of
990 these apps that are connecting, sharing information on
991 networks, then no, they don’t have the regulatory expertise
992 in-house.

993 Mr. {Pitts.} Dr. Mitus?

994 Dr. {Mitus.} Concur with my colleagues. Today, the FDA
995 plays a very, very important role in health care. McKesson
996 has many solutions that are regulated by the FDA, whose
997 expertise really is in the regulation of medical devices.
998 Health IT, we believe, it really requires a different
999 paradigm that is not well-suited to the current
1000 infrastructure and process under the FDA. It is less about
1001 the organization and more around the process.

1002 Mr. {Pitts.} Dr. Classen?

1003 Dr. {Classen.} Just citing from the IOM report, the IOM

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1004 said that if the FDA were to get further involved in the
1005 oversight of HIT beyond medical devices, a new framework to
1006 do that should be created.

1007 Mr. {Pitts.} Okay. Now Mr. Bialick, can you share any
1008 real world examples of patient's lives being changed through
1009 the application of new medical technologies?

1010 Mr. {Bialick.} Absolutely. I think, you know, from my
1011 own experience that I can talk to you with our spread of
1012 legislation around congenital heart defect screening, like I
1013 said, you know, not everybody is born in a city center so
1014 access to some of these remote home monitoring devices is
1015 very functional. Not only that, but the telemedicine
1016 capacity that we are seeing, especially through some of these
1017 devices, is really expanded. You know, it is--someone said
1018 in the hearing yesterday, it is the new house call, and that
1019 is absolutely true. We want to keep making sure that these
1020 devices are getting to the patients that need them.

1021 Mr. {Pitts.} My time is expired. Chair recognizes the
1022 ranking member for 5 minutes for questions.

1023 Mr. {Pallone.} Thank you, Mr. Chairman.

1024 I wanted to ask some questions of Ms. Bechtel. You

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1025 testified before this subcommittee in July, 2010, in the
1026 early days of the HITECH Act and the Meaningful Use Program,
1027 and at that point, the program was just getting off the
1028 ground and we heard estimates from CMS that between 21
1029 percent and 53 percent of the eligible providers would adopt
1030 EHRs by 2015, and we have come a long way since then. As of
1031 February, 2013, 2 years before the 2015 deadline, CMS data
1032 shows that more than 70 percent of eligible providers have
1033 registered and nearly 40 percent have already successfully
1034 completed the first phase of Meaningful Use. The data for
1035 hospitals is even more promising. Eighty-five percent of
1036 those that are eligible have registered, and more than 70
1037 percent are Meaningful Users today. So Ms. Bechtel, these
1038 adoption rates have exceeded expectations, if you would, you
1039 know, confirm or talk about that, and are we just seeing
1040 providers purchase an EHR to check a box or are we actually
1041 seeing real Meaningful Use, and then finally, other than
1042 adoption of EHRs, what other signs of progress do you see? I
1043 will throw those all into one question.

1044 Ms. {Bechtel.} Great. Thank you so much, Congressman.

1045 Yes, I think it is really remarkable that we have made

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1046 the progress that we have, and it is a testament to the hard
1047 work of health care providers and vendors, and the regional
1048 extension centers who are helping primary care doctors and
1049 critical access hospitals every day to adopt and to implement
1050 and really use EHRs in a meaningful way. I think there are
1051 some terrific additional signs of progress, like the fact
1052 that in 2006 there were almost no e-prescribers, which is
1053 really key to eliminating handwriting errors. It creates an
1054 enormous amount of efficiency for consumers and their
1055 families, and today there are more than a half million. So
1056 there is really some amazing work that has been done, and I
1057 think number one, it is the key to helping us get to this
1058 system we all want through payment reform, and getting there
1059 faster, and number two, we have to keep up the pace and we
1060 have to keep up the progress. The design of the Meaningful
1061 Use Program is such that in the beginning, providers are
1062 adopting and they are beginning to implement and use it in
1063 some ways like I outlined in my testimony that are very
1064 meaningful to patients and families. But as they stay in the
1065 program, it is designed to create even more capabilities that
1066 benefit patients and families, improve quality, and lower

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1067 costs, and so future stages will deliver even more societal
1068 benefits. I think the key now is just keeping up the pace.

1069 Mr. {Pallone.} All right, let me ask you another
1070 question about the mobile apps. I am afraid this hearing is
1071 really missing the forest for the trees when it comes to the
1072 government's role in the growth of mobile apps and health
1073 information technology. Far from inhibiting the growth of
1074 mobile health applications, the Administration has taken
1075 unprecedented steps to open up federal data to app developers
1076 and coders, and this public-private collaboration has led to
1077 extraordinary growth in the mobile health application space.
1078 One example is iTriage, an application created using HHS data
1079 that helps consumers locate nearby health care providers.
1080 The app has over three million downloads from the iTunes
1081 store, far from being slowed down by the Federal Government.
1082 If iTriage and scores of other apps have grown and they have
1083 grown enormously because of cooperation and openness of the
1084 Federal Government. So if you could just tell us about how
1085 open government data has contributed to the growth of mobile
1086 medical apps, and what that has meant for patients.

1087 Ms. {Bechtel.} Yes, I think this is a terrific example

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1088 of federal leadership that is really driving innovation.
1089 Three years ago, HHS launched the Open Health Data
1090 Initiative. They created a website called healthdata.gov,
1091 and if you think about the absolute richness of health data
1092 that HHS as an agency has, it is really phenomenal, whether
1093 it is FDA or CDC or NIH or even CMS. And so the model for
1094 this work was actually NOAA, the National Oceanic and
1095 Atmospheric Administration, where once NOAA began to release
1096 their weather data publically, we use it in weather forecasts
1097 on television, we have it on our smartphones, and so the
1098 innovation that occurred is really the model for opening up
1099 health data. The Blue Button functionality that I talked
1100 about earlier is a great example. That was one of the first
1101 initiatives of the open health data effort, and application
1102 developers have taken what is claims data--it is not even the
1103 rich clinical data from EHRs yet, but it will be next year.
1104 They have taken the claims data and built applications that
1105 enable consumers to view their own health information online,
1106 but also now, the next step is that they are going to
1107 automate it so that I, as a consumer, can decide that I want
1108 an automatic feed anytime there is new data, and I can say I

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1109 would like you to also send it to my primary care doctor. So
1110 when we talk about care coordination, which is so essential
1111 to consumers, this is a great innovation and they have held
1112 more than 20 code-a-thons where application developers and
1113 entrepreneurs and different communities have come together to
1114 create applications in real time using HHS health data that
1115 are really making a difference. U.S. News and World Reports
1116 uses it in their health insurance, their best health
1117 insurance plans. Health Grade uses it to help consumers pick
1118 the best health care providers out there. So there is
1119 really, you know, no limit to the innovation that I think can
1120 occur, because of the collaboration with the Federal
1121 Government and entrepreneurial innovators.

1122 Mr. {Pallone.} Thank you.

1123 Mr. {Pitts.} Chair thanks the gentleman and now
1124 recognizes the vice chairman, Dr. Burgess, for 5 minutes for
1125 questions.

1126 Dr. {Burgess.} Thank you, Mr. Chairman. Well, it begs
1127 the question then, is there going to be an app for the
1128 regulatory apps, and I guess that is what we are here to
1129 answer today.

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1130 Dr. Smith, you brought up an intriguing issue about--
1131 when speaking about electronic health records and I guess
1132 Meaningful Use and where outcomes, not location actually
1133 ought to be considered. I had a physician in the office this
1134 morning, a gastroenterologist who said look, I got a problem.
1135 You know, I have got an EHR in my office, I use it and it
1136 meets all the criteria for Meaningful Use. I go to the
1137 ambulatory surgery center. I access the same record online
1138 and use it, but because I am in an ambulatory surgery center,
1139 it does not count toward Meaningful Use, and in fact, if I
1140 spend more than 50.01 percent of my time in the surgery
1141 center, which is where I spend my time because I am doing
1142 procedures on patients who need them, then suddenly I fall
1143 out of the criteria to meet the criteria for Meaningful Use.
1144 Is that what you were referring to where you said outcome,
1145 not location?

1146 Dr. {Smith.} It is in part that. It is also the notion
1147 that until we realize that it is all about the outcome and
1148 really irrelevant about how we get to that outcome, we will
1149 drive rather bizarre behavior, and so when one thinks about
1150 telemedicine and the opportunity to--

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1151 Dr. {Burgess.} He is a gastroenterologist. Bizarre
1152 behavior goes with the territory. I am sorry, go ahead.

1153 Dr. {Smith.} So I am a cardiologist, and I resemble
1154 that remark.

1155 Until we focus entirely on the outcome, we will drive--
1156 first incentive will drive instead of taking care of patients
1157 at a distance and keeping them on the straight and narrow, we
1158 will facilitate the system we have had, which is one of
1159 really emergency rescue as opposed to health care.

1160 And so I think with respect to information flow, it has
1161 to be seamless. With respect to the burden of chronic
1162 disease that we have in this country, the notion that we are
1163 best off taking care of folks only when they show up in the
1164 emergency room or in the doctor's office is clearly wrong-
1165 headed when those patients need the kind of day-to-day
1166 iterative care that some of these remote technologies and
1167 integrated interoperable systems can provide. And so that is
1168 really the point of that comment.

1169 Dr. {Burgess.} Now there is a difference between what a
1170 lot of us would consider traditional medical advice, and an
1171 app. I mean, an intercardiac defibrillator, a traditional

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1172 medical device, can you sort of delineate the difference
1173 there for us?

1174 Dr. {Smith.} Oh, absolutely. So, you know, I spent
1175 much of my life in the either implementation or even design
1176 of implantable defibrillators, and you know, the company I
1177 was working for at the time kind of led a charge in making
1178 sure that that information that is resonant in those devices
1179 could get back to doctors wherever they were when it was most
1180 needed, instead of using the patient as a vehicle for
1181 bringing that information back to see you in the office. And
1182 so there is a huge difference between the one-to-one patient
1183 encounter that you can have--and I will point out that you
1184 can now have technology mediated encounter versus the
1185 information that you can get on the web. I mean, so whether
1186 it is an app or whether it is the web, those are really quite
1187 different things. And so I think as a physician yourself,
1188 you would realize the important differences.

1189 Dr. {Burgess.} Well, and the ownership of that data is
1190 important as well, and when we talk about an HHS website, but
1191 that is, at least in theory, the identified data, but you are
1192 talking about data that is specific to that patient, specific

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1193 to that patient encounter.

1194 Dr. {Smith.} Absolutely.

1195 Dr. {Burgess.} Dr. Mitus, I was fascinated by your
1196 testimony. I remember a few years ago in the middle of the
1197 chaos of the Haitian earthquake, it was either on CNN or
1198 reading a Time magazine article where a doctor who was not an
1199 OB doctor was helping take care of a pregnant woman after the
1200 earthquake. She had a hypertensive crisis. His reflex
1201 action was to reach for an angiotensin converting enzyme
1202 inhibitor, but he looked it up on his mobile app and found
1203 that that was contraindicated in pregnancy and used something
1204 else. I think the story had a happy outcome, but it
1205 certainly underscores the power of having that medical
1206 information at your fingertips, and you know, you just go
1207 into the app store--even as we sat--not that I wasn't paying
1208 rapt attention to all of the testimony, but you can download
1209 Harrison's Principles of Internal Medicine. You can download
1210 the Merck Manual. You can download the Washington Manual,
1211 and have that literally at your fingertips in as odd a place
1212 as a congressional hearing.

1213 So how, you know, how does the regulatory environment

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1214 affect that?

1215 Dr. {Mitus.} I completely concur that health IT has
1216 really revolutionized our ability to provide timely and safe
1217 care to patients in ways that that we could never have
1218 envisioned even 10 years ago. The power of technology
1219 enables us and is very different than a medical device. I
1220 believe, though, there is an important distinction, to return
1221 to your prior question. A device, in our mind, sits directly
1222 connected to a patient and has automation that allows it to
1223 independently act upon that patient. It is really replacing
1224 that human judgment. Whereas a physician who intervenes and
1225 accesses medical guidelines, such as a textbook online or
1226 receives an alert to potentially prevent a fatal drug
1227 interaction is allowed to use their own common sense and
1228 judgment, and that is fundamentally different than a device.

1229 Dr. {Burgess.} But the FDA looks at it as decision
1230 support, so therefore, it is open to regulation. Is that
1231 correct?

1232 Dr. {Mitus.} That is our understanding, and we believe
1233 a risk.

1234 Dr. {Burgess.} Thank you, Mr. Chairman. I will yield

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1235 back.

1236 Mr. {Pitts.} Chair thanks the gentleman and now
1237 recognizes the ranking member of the full committee, Mr.
1238 Waxman, for 5 minutes for questions.

1239 Mr. {Waxman.} Thank you very much, Mr. Chairman.

1240 Dr. Mitus, as I understand, you are a
1241 hematologist/oncologist. Is that right?

1242 Dr. {Mitus.} Correct.

1243 Mr. {Waxman.} Okay. So let's say you had software that
1244 could--claims to diagnose a mole and whether it is melanoma
1245 or not. Do you think the FDA ought to regulate that?

1246 Dr. {Mitus.} That is a very interesting question, and
1247 one that I pondered last night after you asked that
1248 yesterday. I actually looked up Dr. Mole online to
1249 understand, as I was not familiar with that technology. I
1250 think that really delineates the challenge that we have
1251 before us. What a wonderful piece of technology--

1252 Mr. {Waxman.} Excuse me. I really have a limited time.
1253 Do you think it ought to be regulated by the FDA or FDA ought
1254 to review it before it is widely used? Yes or no.

1255 Dr. {Mitus.} I believe that there is risk and there is

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1256 intelligence in that application, as I understand it, and it
1257 is--should be considered a high risk piece of software, and
1258 we believe in a risk-based system and it could potentially be
1259 regulated by the FDA, much the way mammography software is
1260 today.

1261 Mr. {Waxman.} Okay. Now you raised a bunch of points
1262 in your testimony, and you pose a number of questions.
1263 Should an iPad application that helps track the number of
1264 steps you walk per day be regulated as a medical device, and
1265 FDA says no in their guidance. You asked if it is a reminder
1266 time to refill a prescription. FDA's guidance said no, that
1267 is not a medical device. You asked a question whether
1268 digital versions of a physician's desk reference would be
1269 subject to regulation, and FDA says no. Those are not going
1270 to be subject to regulation. So I found it puzzling, because
1271 FDA addressed them specifically in their draft guidance, a
1272 specific list of these examples of what should not be
1273 regulated. Is your concern that FDA is going to change its
1274 mind and regulate it?

1275 Dr. {Mitus.} My concern is that there is a spectrum of
1276 capabilities that is increasingly delivered through

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1277 technology, whether on a mobile app or on a desktop, and that
1278 gray area as we just described, the ability for a doctor to
1279 receive an alert or a warning is not something in my mind
1280 that should be regulated as a medical device.

1281 Mr. {Waxman.} Well, I can understand that point of view
1282 but you would see the point of view that some things ought to
1283 be regulated as a medical device, wouldn't you?

1284 Dr. {Mitus.} Medical devices certainly should be
1285 regulated as medical devices.

1286 Mr. {Waxman.} Well, there is a judgment to be drawn.
1287 My colleague said well, that judgment ought to be up to
1288 Congress. Do you think Congress should make those
1289 distinctions, or should it be the FDA or some government
1290 regulatory agency that has some expertise on these kinds of
1291 issues? There is a line to be drawn. Who should draw that
1292 line?

1293 Dr. {Mitus.} It is a difficult line to be drawn. I am
1294 not--I won't presume to be able to tell you who should draw
1295 that line. What we would like to point out--

1296 Mr. {Waxman.} Well, knowing that it is difficult
1297 doesn't help. Who should draw the line? There is some that

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1298 should be regulated as medical devices and some shouldn't. I
1299 agreed with your testimony. Those things that are
1300 informational based shouldn't be regulated, and FDA agrees
1301 with that, but there are some that ought to be diagnosed.

1302 Mr. Bialick, there is a device that remotely monitors
1303 infants with congenital heart defects using a pulse oximeter.
1304 Pulse oximeters monitor the oxygen saturation of a patient's
1305 blood, and especially in the case of newborns with congenital
1306 heart defects, they are a critical tool to monitor cardiac
1307 health. This is obviously a sensitive and important device.
1308 If the device provides the wrong reading or provides faulty
1309 information, it can lead to disastrous results. Do you
1310 believe that FDA should play a role in ensuring that these
1311 types of devices are safe and effective?

1312 Mr. {Bialick.} That is why FDA does evaluate pulse
1313 oximeters.

1314 Mr. {Waxman.} And you think that is appropriate?

1315 Mr. {Bialick.} Pulse oximeters as medical devices, yes.
1316 The app that has the potential to connect to a covered
1317 device, that is a different story because it is not a
1318 traditional medical device. You are talking about medical

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1319 software at that point. So I would like to talk about
1320 drawing the delineation here. That is the delineation I
1321 would like to make.

1322 Mr. {Waxman.} Well, the app transmits the information,
1323 but the information is based on this pulse oximeter.

1324 Mr. {Bialick.} Right, and--

1325 Mr. {Waxman.} And the pulse oximeter ought to be
1326 reviewed by the FDA because if it is giving false
1327 information, it can have serious consequences, right?

1328 Mr. {Bialick.} I agree. Medical devices should be
1329 evaluated by the FDA.

1330 Mr. {Waxman.} So say, Dr. Mitus--

1331 Mr. {Bialick.} I am sorry.

1332 Mr. {Waxman.} I am switching to Dr. Mitus. If somebody
1333 takes a picture of a mole and they say don't worry, you don't
1334 have cancer, and they are wrong, that is a serious disaster
1335 waiting to happen. We need somebody other than members of
1336 Congress to say that ought to be regulated, and the law
1337 requires, I think, FDA appropriately to regulate it.

1338 My point to all of you is there is a distinction that
1339 has to be made, and the points you raised, Dr. Mitus, were

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1340 all scary things that just aren't being considered for
1341 regulation, and FDA has been very explicit about it. So I am
1342 somewhat disappointed that you would say these things are
1343 going to be regulated when FDA says they have no intention of
1344 regulating them, and so that is why I asked do you think FDA
1345 is going to reverse its stand. Is that what you are worried
1346 about?

1347 Mr. {Pitts.} You may respond.

1348 Mr. {Waxman.} To Dr. Mitus, are you worried the FDA is
1349 going to change its mind and suddenly regulate those things?

1350 Dr. {Mitus.} We are worried that there is a large gray
1351 area of medical health IT that could be subject to
1352 regulation.

1353 Mr. {Pitts.} Mr. Bialick, you wanted to say something?

1354 Mr. {Bialick.} To your point, Mr. Waxman, you said is
1355 this Congress's decision to make this or is this FDA's
1356 decision or is this another agency? I would like to say that
1357 this is such a big issue and such a dynamic market that no
1358 one entity should be making these decisions. There is a
1359 clear need for a framework of experts to convene to talk
1360 about what is going on at FDA, what is going on at ONC, what

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1361 is going at FCC, especially as these things consider mobile
1362 apps, as well as what Congress's role is in regulating that?
1363 So the framework, absolutely Congress has a role. Congress
1364 has a role to develop this framework.

1365 Mr. {Waxman.} Well, FDA is required to bring in a group
1366 like that and give them guidance, but if you are giving an
1367 amorphous group to look at it with nobody having clear
1368 responsibility, nothing is going to happen and that is a very
1369 dangerous thing if a device can do harm.

1370 My time is expired.

1371 Mr. {Pitts.} The chair thanks the gentleman and
1372 recognizes the gentleman from Illinois, Mr. Shimkus, for 5
1373 minutes.

1374 Mr. {Shimkus.} Thank you, Mr. Chairman. I enjoy
1375 following Mr. Waxman, who is obviously very thoughtful. We
1376 had part of this debate yesterday in the other hearing, and I
1377 think--and I am going to go off script just because Mr.
1378 Bialick, on this pulse oximeter--I am not a health care guy
1379 but I did read it in your testimony--your point is that that
1380 device is a taxed and monitoring. So as I was trying--you
1381 are trying to say that data is being formed by the medical

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1382 device as certified. The transmission of that data to a
1383 handheld device is a concern, especially if it gets
1384 classified as a Tier III medical device.

1385 Mr. {Bialick.} Absolutely.

1386 Mr. {Shimkus.} What happens if it gets classified as a
1387 Tier III medical device?

1388 Mr. {Bialick.} It would be evaluated as such through
1389 the FDA process.

1390 Mr. {Shimkus.} And what else happens to it?

1391 Mr. {Bialick.} It gets pulled off the market. It has
1392 to go through the entire process. I mean--

1393 Mr. {Shimkus.} And what else happens to it? It gets a
1394 big freaking tax on it, you know, a gross tax, not a net tax.
1395 So anyway, it is always exciting to be on this committee with
1396 my friend from California.

1397 Because we talked about the chips and the shoes, too.
1398 Obviously for general fitness, just measuring steps, no, but
1399 what if that is a device that has been prescribed?

1400 Mr. {Bialick.} Another case.

1401 Mr. {Shimkus.} And my friend, Mr. Pallone, mentioned
1402 HHS health and one app. Good for them. How many apps are

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1403 there? Ninety-seven thousand apps. How are the other 96,999
1404 developed? By the private sector, by individual capital, by
1405 people assuming risk. I pulled this up--you know, pull up
1406 your page. How many new apps are there to, you know, change
1407 your app? Notifications, you got to update your app. What
1408 happens if this whole process falls into that? So now you
1409 have an app, it has had technical problems, maybe it is a
1410 Tier II and now you want to update the app. Does that have
1411 to go back through the entire process again? These are very,
1412 very important--they belittle--the fact that we are having
1413 these questions, but the fact that we are having these
1414 questions means that we don't have answers.

1415 So what does FDA do when they go to the Institute of
1416 Medicine, right, they commission a report, which they did on
1417 MDUFA, and they kind of follow that a lot of times. Well,
1418 what did the Institute of Medicine just come out on this?
1419 Well, one member disagrees with the committee and would
1420 immediately regulate health IT as a Class III medical device
1421 as outlined in Appendix E. So they are saying all health IT-
1422 -or this guy, this one respondent says this should be, and
1423 there is a fear about that, is there not, because of the

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1424 things we issued before.

1425 So Mr. Bialick, if FDA regulated health IT as medical
1426 devices, would they be subject to the device tax as written
1427 in law?

1428 Mr. {Bialick.} I default to Congress on that.

1429 Mr. {Shimkus.} I already asked that. The answer is
1430 yes. What could this mean for patients, especially for
1431 telemedicine and other advancements that are starting to
1432 improve the quality and access to care for patients in rural
1433 areas, like my district, who are sometimes hours away from
1434 the care they need?

1435 Mr. {Bialick.} It is a very important question. I
1436 think that as telemedicine develops, we are starting to also
1437 see a development of our networks of care. So it is not just
1438 we go to the one rural doctor that we have access to--

1439 Mr. {Shimkus.} Right.

1440 Mr. {Bialick.} --but rather, we have access to many
1441 professionals.

1442 Mr. {Shimkus.} Anybody else want to jump in real quick
1443 on this?

1444 Dr. {Mitus.} I believe it could significantly delay and

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1445 put at risk the deployment--

1446 Mr. {Shimkus.} Here is what I observed in my district.

1447 I have a large rural district. There are 102 counties in the

1448 State of Illinois. I represent 33. Where a lot of hospitals

1449 are moving to is obviously nurses on site, doctors at

1450 computer screens monitoring the real data, and also what they

1451 can do is--so the nurse says doc, calls him up, Doc, check

1452 this patient X. So they go into the room, the patient is

1453 laying there and he will have the nurse open up the eyelid

1454 and the camera will zoom in on the eye to make a

1455 determination. Now if you follow this debate, now you have

1456 got data flowing over in a picture form, i.e., like the mole

1457 debate, but it is a camera in essence taking a real time

1458 picture. How does that get regulated? And if it, as my

1459 colleague from California said, if that should be a Tier III

1460 because then do I not have the access to real time picture of

1461 the pupil of a patient, and an immediate doctor intervention,

1462 versus calling one from 20 miles away?

1463 My time is expired. I thank you all and I yield back my

1464 time.

1465 Mr. {Pitts.} Chair thanks the gentleman, and now

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1466 recognizes the gentlelady from Virgin Islands, Dr.

1467 Christensen, for 5 minutes for questions.

1468 Dr. {Christensen.} Thank you, Mr. Chairman, and thank
1469 you to the panelists for being here this morning. I am sorry
1470 I missed yesterday's hearing.

1471 But this hearing--this series of hearings is centered on
1472 the relationship between innovation and public--and patient
1473 safety, and I think the Meaningful Use EHR program is a great
1474 example of how government can promote technological
1475 innovation that has the potential to significantly improve
1476 patient care.

1477 Phase one of the program already enables providers to
1478 maintain up-to-date electronic lists of the health
1479 conditions, diagnoses, medication, and medication allergies.
1480 They can automatically check for drug interactions and drug
1481 allergies, as we have heard, and have the ability to send
1482 prescriptions electronically to a patient's pharmacy,
1483 reducing wait time and eliminating handwriting errors.

1484 Ms. Bechtel, can you give us some information about--
1485 some more information about how electronic health records are
1486 already helping to improve patient care, and how future

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1487 phases of Meaningful Use advance our ability to improve that
1488 care, and would you add into your answer how it--how HIT--the
1489 role it can play in eliminating health disparities?

1490 Ms. {Bechtel.} Absolutely. So let me start with health
1491 disparities, because I actually think that that is one of the
1492 ways that the Meaningful Use Program is making a real
1493 difference for patients and families.

1494 In the first stage of Meaningful Use, there were a
1495 couple of things that were really important to help
1496 disparities. One was collecting better and more granular
1497 data about race, ethnicity, language, and gender, because
1498 those are categories where we see vulnerable populations and
1499 the greatest amount of health disparities, as you know. And
1500 so we have now created the ability to collect information
1501 like that in a standardized way, and when you do that in a
1502 computer system, you can then stratify other information by
1503 those data types to identify disparities, and the first step
1504 in eliminating them has to be identifying them. We also
1505 created a capability for electronic health records to report
1506 quality measurement, and which is key to payment later, and
1507 so the ability to look at the kind of care that you are

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1508 providing for different populations that you are serving is
1509 really instrumental, and that was not standardized prior to
1510 Meaningful Use.

1511 In future stages as well, we are going to see things
1512 like a population health dashboard that is going to allow you
1513 to look at multiple populations. My hope is that, you know,
1514 well into the future we will see things like more advanced
1515 intelligence systems that will look for disparities that we
1516 didn't even know to look for, for example. So there are some
1517 really terrific things.

1518 I think I would say that in terms of what is happening
1519 today already right now, the Commonwealth Fund, an
1520 independent organization, looked at several different
1521 hospitals and they concluded that health IT adoption has led
1522 to faster, more accurate communications, streamlined
1523 responses that have improved patient flow. It has reduced
1524 duplicative testing and sped up responses to patient
1525 inquiries, and that has been, you know, really phenomenal.

1526 Yesterday there was a study released by the Quest
1527 Collaborative, which Premiere reads, and it is really an
1528 indication of what can happen when you blend not just the

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1529 health IT infrastructure that the Quest hospitals have, but
1530 the quality measurement and the public reporting and the
1531 payment and all of these things that have bipartisan support,
1532 they saved 92,000 lives and \$9.1 billion over 4-1/2 years.

1533 Dr. {Christensen.} Let me try to get another question
1534 in. You sat on the Federal HIT Policy Committee and you
1535 reported that 70 percent, I think, of physicians are
1536 utilizing HIT, but have you seen the adoption in minority
1537 practices, practices in rural and poor communities, and if
1538 so, if not, is that a concern and is the committee doing
1539 anything to address that?

1540 Ms. {Bechtel.} Yes, and I think that is also a great
1541 question for federal officials tomorrow as well. But yes, we
1542 are. So 40 percent of rural primary care providers are
1543 working with regional extension centers and are therefore
1544 more likely to achieve Meaningful Use, so that is really good
1545 news. In terms of providers serving vulnerable populations,
1546 many of them will receive payments under the Medicaid
1547 program, and every State has, in fact, designed and has begun
1548 to implement their programs, and that is really the first
1549 step to make sure.

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1550 So I think there is very good news, but it is something
1551 we must continue to monitor.

1552 Dr. {Christensen.} Okay, thank you. I guess I will
1553 yield back the balance of my time. I don't--

1554 Mr. {Pitts.} Chair thanks the gentlelady and now
1555 recognizes the gentleman from Texas, Mr. Hall, 5 minutes for
1556 questions.

1557 Mr. {Hall.} Mr. Chairman, I would like to use part of
1558 my time thanking you for bringing this up. It is something I
1559 am very, very interested in. I would ask Mr. Bialick, I
1560 guess--I hope I pronounced it right. I don't believe anyone
1561 has got around to the newborns. If they have, I will wait
1562 and write--and ask for written testimony.

1563 But if not, Mr. Bialick, a lot of us remember the
1564 sleepless nights and exhausting routines that go along with a
1565 newborn at home, and if we are blessed with a child without
1566 medical problems, we have sleepless nights also but not like
1567 others. Can you share with the committee the additional
1568 challenges and/or stresses of medical problems and how
1569 technology can be utilized to make their lives better, or--
1570 let me shorten it. How do you envision mobile medical

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1571 technology devices being used to improve care for newborns,
1572 and if these technologies are subject to a lengthy
1573 bureaucratic approval process, how will that impact patients
1574 and families? Because if they apply or register when their
1575 newborns are newly born, they won't be newborns when they get
1576 around to them.

1577 Mr. {Bialick.} Sure. Thank you for that question.
1578 Babies with congenital heart defects are super users of the
1579 health care system. They are not only going to be using
1580 imaging services very early, they are going to need, in
1581 critical cases, either immediate intervention, maybe
1582 surgically, and then follow-up care with additional imaging
1583 throughout their lives.

1584 Now, it happens to be that, like I said, not all babies
1585 are born in advance cardiac care centers. They are not all
1586 born in coordinated care environments. Half of births in
1587 many States are Medicaid births as well, so care can often be
1588 fragmented. Right now, the way the health care system has
1589 developed, really to stay at the center of your care, you
1590 have to be the one that is coordinating it yourself, and
1591 mobile apps have allowed us to do that. We are able to hold

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1592 in our hand the electronic record now, because of something
1593 like the Meaningful Use Program of Medicaid providers and
1594 maybe several different hospitals, several different
1595 specialists. And that not only is comforting to know that
1596 you have access to this information, but it is also very
1597 valuable because sometimes when you go back into a care
1598 situation, it is for a very critical reason, and having this
1599 information will help you and your provider and your care
1600 team get to answers much faster.

1601 Mr. {Hall.} I thank you for that. I was a father to
1602 three boys, three sons, and I was amazed because they were so
1603 intelligent. They could count. If they didn't count four
1604 eyes, they wouldn't go back to sleep.

1605 Thank you. I yield back my time.

1606 Mr. {Pitts.} Chair thanks the gentleman, and now
1607 recognizes the gentleman from Virginia, Mr. Griffith, 5
1608 minutes for questions.

1609 Mr. {Griffith.} Thank you, Mr. Chairman. I appreciate
1610 that very much.

1611 You know, I have gotten a sense from some of the
1612 questions that somehow this is a partisan thing, and I don't

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1613 think it is, and so I am taking a step back. I am not sure
1614 really where that is coming from, but I think it is very
1615 interesting, you know, as a lawyer and I am learning all this
1616 medical stuff, and I thank you all for educating me. But it
1617 seems to me that the real question is, and what everybody
1618 seems to have agreed on is that we as Congress need to make
1619 sure there is a framework that then you can put the
1620 complicated does this fit, does that not fit, into that
1621 framework. Am I correct in that, Dr. Mitus?

1622 Dr. {Mitus.} Absolutely.

1623 Mr. {Griffith.} Dr. Smith?

1624 Dr. {Smith.} I might add, if you would let me. I think
1625 that we if we whisk overprescribing this framework, and I
1626 think at some point there is a role for not drawing the
1627 sharpest of line, but to give latitude to the bedside where
1628 the patient and physician can decide whether technology is
1629 appropriate in use, as opposed to trying to draw one line for
1630 the broad population.

1631 Mr. {Griffith.} And I think we all want to see this
1632 technology being used. It is great stuff and whatever we can
1633 do to encourage folks to use it, but I do think there is a

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1634 difference if--in the case of a picture of a mole, if the
1635 mobile app is actually running it through a computer and
1636 telling you it is cancerous or not cancerous, then yes, I
1637 want the FDA looking at that. If the mobile app is getting
1638 that to an expert doctor to take a look at it, I don't see
1639 that as being a medical device, and if there is a problem
1640 with the diagnosis--and I would think that Mr. Waxman would
1641 appreciate this--there are a slew of trial lawyers who would
1642 be more than happy to help you figure out what you need to do
1643 next if there is a misdiagnosis. You know, so I think we go
1644 from there.

1645 I am concerned that the FDA sometimes tends to be slow,
1646 and if we have got something that doesn't fit the norm,
1647 obviously if it is something serious like the app is making
1648 the decision on whether or not that mole is cancerous, yes,
1649 then I want that top thing and I kind of like the framework
1650 that you pointed out, Dr. Mitus. If we don't have that kind
1651 of a framework and they decide to review everything, wouldn't
1652 you all--and I guess I will ask Dr. Mitus and Dr. Smith this
1653 question, and Mr. Bialick and others can chime in if they
1654 wish. But isn't there a real concern that the slowness of

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1655 the FDA, particularly if you are looking at something that
1656 just transmits the data, can actually slow down innovation in
1657 this area where we really want the innovation to go forward?

1658 Dr. Smith?

1659 Dr. {Smith.} So you know, as a practicing cardiologist,
1660 I would often get records to make decisions based on
1661 transmission through a fax machine, and at that time, it was
1662 difficult to tell the difference between a three, a five, and
1663 an eight. And so one could make wildly different decisions
1664 based on that communication transfer, which no one regulates.
1665 Now that we make it so crisp and so clear and so error-free,
1666 now I don't believe is necessarily the time to regulate that
1667 particular flow of information. I think the market has
1668 served the need in this case, and so if it is really just
1669 about transmission of information, it is difficult to see
1670 even though that information may be clinically relevant, that
1671 that is necessarily something that requires FDA oversight.

1672 Mr. {Griffith.} It is funny how sometimes people can
1673 interpret old rules with new technology and get it wrong or
1674 get a different answer. In my law practice, if I had a book,
1675 I got taxed on it. If it was a disc, it didn't get taxed.

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1676 If I could subscribe to an online site, it didn't get taxed.
1677 But if it was a book, by golly, I had to pay tax on that
1678 book.

1679 Let me ask this about the smaller creative
1680 entrepreneurs, Mr. Bialick.

1681 Mr. {Bialick.} Bialick.

1682 Mr. {Griffith.} Bialick, thank you. In your opinion,
1683 if the FDA is successful in classifying all these medical
1684 apps, those particularly that I know we are talking about
1685 data are essential data's medical devices, do you think that
1686 might discourage some of the app makers to go into something
1687 that is easier to get their capital back out, or a quicker
1688 return on their investment?

1689 Mr. {Bialick.} Absolutely. The threshold for a
1690 blockbuster app is gigantic now. I mean, it is millions of
1691 dollars, and so even to get the investment now to--let's say
1692 you are going to develop it beyond just in your garage and
1693 have a large scale launch. The concern that you will have
1694 the potential for or if it is known that you will have
1695 additional regulation on top of that cuts out the bottom
1696 line, so there is an investment side to it, too.

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1697 Mr. {Griffith.} So they are more likely to try to find
1698 the next Angry Bird as opposed to finding the next Angry
1699 Mole?

1700 Mr. {Bialick.} Well said.

1701 Mr. {Griffith.} And last--and I only have a couple of
1702 seconds left. I am just going to make a statement. I think
1703 a lot of us on this committee feel that the FDA is not only
1704 risk averse, but they are at the point of no risk. We don't
1705 want to approve something if there is any risk, and obviously
1706 every human being is a little bit different and whatever you
1707 do, there is going to be at least some risk. And so I would
1708 just encourage the FDA to work with you all and hopefully we
1709 will pass that framework that you want and get it done.

1710 Thank you, sir, and I yield back.

1711 Mr. {Pitts.} Chair thanks the gentleman, and now
1712 recognizes the gentleman from Texas, Mr. Green, for 5 minutes
1713 for questions.

1714 Mr. {Green.} Thank you, Mr. Chairman. I would like to
1715 thank our witnesses for appearing today.

1716 As mobile technology has gotten more sophisticated,
1717 applications relating to health have become more complex, but

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1718 also hold more potential. The possibilities of innovation
1719 are tremendous, but there is potential risk to health safety
1720 as well. Mobile applications such as glucose monitors are
1721 being sold as a way to monitor critical health issues, or
1722 other applications having direct effect on health should be
1723 regulated in a way that ensures their effectiveness and
1724 trustworthiness.

1725 Regulation through the FDA comes with challenges. The
1726 agency is oftentimes far too slow. Obtaining approval can be
1727 costly. I worry about stifling innovation and bringing in
1728 unnecessary levels of regulation onto clever people with
1729 limited startup capital, but unlimited potential. However,
1730 even big companies have made high profit mistakes developing
1731 mobile apps. Had the recent mishap with a mapping software
1732 been a glucose monitor, there could have been serious
1733 consequences. But we must protect patient and consumer
1734 safety at all costs, but properly determining what poses as a
1735 safety risk may prove difficult.

1736 Dr. Mitus, the Bipartisan Center framework focuses on
1737 clinical and nonclinical software. It also recognizes the
1738 role for FDA oversight for medical device software. Do you

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1739 agree with that approach and that FDA does have a role for
1740 the oversight of riskier MMAs?

1741 Dr. {Mitus.} Yes, absolutely.

1742 Mr. {Green.} Okay. In what ways can the FDA regulate
1743 mobile medical applications as mobile devices without slowing
1744 innovation?

1745 Dr. {Mitus.} We believe that if a device, again, is
1746 defined as something that directly touches a patient or
1747 independently acts on a patient, that is a medical device and
1748 the software that runs that device would be considered a
1749 medical device, and subject to the current regulatory
1750 process. I think it is very important to distinguish that
1751 from the vast bulk of health IT, which is really not best
1752 categorized as a medical device.

1753 Mr. {Green.} Okay. Dr. Classen, a lot has been
1754 discussed about risk-based framework for regulation. As I
1755 read it, there are a lot of similarities between FDA's and
1756 the Bipartisan Policy Center's approaches. In what ways do
1757 the BPC recommendations differ from the draft guidance issued
1758 by the FDA?

1759 Dr. {Classen.} The guidance that we focused on in our

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1760 report at the Institute of Medicine, a lot of the FDA
1761 guidance excluded what we were focused on there from their
1762 oversight on mobile medical apps, and we had recommended that
1763 a new framework be created for oversight of these areas. So
1764 we would agree with BPC Center approach and framework as a
1765 next step, creating more specificity around a future
1766 framework as we have outlined.

1767 Mr. {Green.} I do have concerns about the capacity of
1768 the FDA to properly and efficiently regulate mobile apps.
1769 This is a topic that deserves more scrutiny by Congress and
1770 the FDA. We must find a way to ensure that the safety and
1771 effectiveness of the applications regulate only the
1772 application that posed a risk, and do so in a way that is
1773 efficient and effective.

1774 Mr. Chairman, members of Congress always doesn't do
1775 things that are efficient and effective, but in this case,
1776 because it affects the health care and how we can deliver and
1777 monitor health care in the future, it is so important not
1778 only for our subcommittee, but the full committee and
1779 Congress.

1780 Thank you, Mr. Chairman. I yield back my time.

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1781 Mr. {Pitts.} Chair thanks the gentleman and now
1782 recognizes the gentleman from New Jersey, Mr. Lance, for 5
1783 minutes for questions.

1784 Mr. {Lance.} Thank you, Mr. Chairman, and good morning
1785 to you all.

1786 I have heard from at least one app developer in my
1787 district who has been attempting to work with the FDA to
1788 approve the medical app. This involves a smartphone and
1789 corresponding app that helps patients with diabetes monitor
1790 the diabetes and so they can track their glucose levels. It
1791 is my understanding that while the procedure is currently
1792 under review at the FDA, the approval process is slow moving
1793 and there are some levels of uncertainty as to how the agency
1794 can address or regulate the technology. Your testimony this
1795 morning has involved this type of discussion. Do you
1796 believe that the experience of companies such as the one with
1797 whom I have been speaking in my district are common
1798 experiences that companies have, and should we be concerned
1799 about the FDA as it goes forward to regulate mobile apps as
1800 medical devices? To whoever wishes to respond to the
1801 question.

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1802 Dr. {Smith.} So I do believe it is about clarity and
1803 speed, and I think, you know, we are in part here today
1804 because it was in the middle of 2011 when draft guidance was
1805 issued in this space, and we still don't have the clarity and
1806 certainty of even that guidance, which by itself, still has
1807 elements in it which maintains some vaguery. And so, you
1808 know, I believe we are suffering the confusion of successive
1809 clarification, as opposed to enjoying the speed of
1810 appropriate regulatory efforts. And so I think it is both
1811 slow for the folks who are engaged, but perhaps even slower
1812 for those who are hesitating to engage and are finding other
1813 things to do with their time, treasure, and talent. And so I
1814 think it is fundamentally about clarity and speed, and at
1815 times, even willing to accept the imperfect now as opposed to
1816 waiting interminably for some other perfected notion of
1817 regulation.

1818 Mr. {Lance.} Of course.

1819 Mr. {Bialick.} I would like also just to say, I won't
1820 comment on the frequency with which that is a common
1821 occurrence, but I would like to say that that viewpoint and
1822 the experience of a developer like that is critical to this

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1823 process. You know, we talk about large apps, we talked about
1824 the apps that are being developed in a garage or a basement
1825 or an attic. We want to also make sure that those that are
1826 going to be engaging in this process and those that have made
1827 this market so dynamic, their viewpoint and their experience
1828 is brought into the process as well.

1829 Mr. {Lance.} It is clear to me that this would be
1830 helpful to those who have the condition of diabetes, and this
1831 is a well-respected group and wants to move forward in a
1832 medically responsible way. What would you suggest that we as
1833 the legislative branch do to help the FDA move through this
1834 situation to benefit the American people, particularly as it
1835 relates to such health concerns as diabetes?

1836 Dr. {Mitus.} We would like to reiterate what you have
1837 just articulated so well. There is a risk, barriers to
1838 entry and to this important space, the delay of important
1839 advances into health care, and really we support a risk-based
1840 approach where we continue to manage devices as they are
1841 today, and then develop other mechanisms for the important
1842 oversight of health IT that is not a device.

1843 Mr. {Lance.} Yes, Dr. Smith?

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1844 Dr. {Smith.} I would like to draw attention to the
1845 impact that the delay between draft guidance and formal,
1846 permanent guidance provides. So it goes well beyond the
1847 current issue. The next draft guidance offered, if there is
1848 a doubt that that will become final, you will have no
1849 movement based on the draft. No companies will engage based
1850 on those recommendations, for fear that that process will be
1851 again derailed. And so imperfect as it may be, I think there
1852 is a value proposition that says fulfill that draft promise,
1853 or else we risk the notion that the regulatory cloud becomes
1854 even larger. And so I think there is a calculus to be
1855 performed here, but one that has implications well beyond the
1856 current discussion.

1857 Mr. {Lance.} Thank you. Let me say, I do not view this
1858 as a partisan issue, and I want to work in a bipartisan
1859 capacity with colleagues on the other side of the aisle, as
1860 well as with those on this side of the aisle which I am
1861 involved, because we want to do this in a responsible way,
1862 making sure that the American people can have access to these
1863 marvelous new portions of improving the health of the Nation.

1864 Thank you, Mr. Chairman. I yield back the balance of my

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1865 time.

1866 Mr. {Pitts.} Chair thanks the gentleman and now
1867 recognizes the gentleman from Maryland, Mr. Sarbanes, for 5
1868 minutes for questions.

1869 Mr. {Sarbanes.} Thank you, Mr. Chairman. This is a
1870 fascinating hearing.

1871 When we were doing the health care reform effort here,
1872 which resulted in the Affordable Care Act, one of the things
1873 that I was most excited about was this turn in the direction
1874 of prevention with our health care system and trying to come
1875 up with a system that is a health care system, rather than a
1876 sick care system, which in many ways is what we had until
1877 now. But the promise of it is that patients can become full
1878 partners in their care, and at a time when we worry about
1879 whether there is going to be enough caregivers to provide the
1880 services out there, if you begin to identify the patient
1881 themselves as a potential caregiver, you get a little less
1882 anxious. Now, you have to approach that in a sensible way,
1883 but you know, if we are focused on so the acute care side of
1884 things, I can't help my surgeon perform surgery on me, but I
1885 can certainly help my primary care physician make me more

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1886 sensible about prevention. So I really become a partner in
1887 that, and this technology holds that real promise.

1888 There was--Dr. Francis Collins, who is the director of
1889 NIH, recently highlighted the results of a mobile health
1890 clinical trial in his personal blog, and this was a trial
1891 conducted over a year by University of Maryland School of
1892 Medicine, which utilized a diabetes mobile health technology
1893 of a company that I am very familiar with called WellDoc,
1894 which is based in Baltimore. And they showed that these
1895 patients were able to demonstrate a reduction in terms of the
1896 percentage result on their blood sugar test that they would
1897 take on a regular basis, and the same system was studied in a
1898 demonstration project of Medicaid patients, where patients
1899 used this diabetes self-management system, with the result of
1900 reducing the number of diabetes-related hospital admissions
1901 and emergency room visits among that population that was
1902 using it by approximately 57 percent, which is really
1903 incredible. And a lot of times people do end up in the
1904 hospital because they have missed some basic precaution they
1905 need to be taking in their own self-management, so it just
1906 shows how important these opportunities to use technology are

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1907 in terms of self-management by patients, and you have all
1908 spoken to that.

1909 My question, and I offer it to anyone here on the panel,
1910 is as we continue this effort to reduce our health care
1911 costs, and there is real potential using this technology to
1912 do that, can you point to instances where federal programs
1913 are beginning to adopt these validated technologies across
1914 the spectrum of government health care? And you can--if you
1915 want to point to Medicaid and Medicare, please do, to the
1916 Federal Employees' Health Benefits Program, TRICARE,
1917 Veterans' Affairs, what have you, because obviously we are
1918 very interested in that, given the cost and scope of those
1919 programs.

1920 Ms. {Bechtel.} So I will start, and I say that I think
1921 it is a terrific question, and my testimony really focused on
1922 the Meaningful Use Program in Medicare and Medicaid, because
1923 of the work that it is doing to make patients full partners
1924 in their health. Giving patients access to electronic tools
1925 is really making them members of the care team now. We are
1926 moving from a point where we used to do things to patients
1927 and for patients to now doing things with patients, and that

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1928 is essential to lowering costs and making care better for
1929 them. And the online tools are really facilitating important
1930 things like shared decision making, population health
1931 outreach so that we can get reminders about, you know, being
1932 overdue for a mammography screening or immunization or--you
1933 know, whether it is pneumonia or flu shot or something like
1934 that. And it is also facilitating the provision of education
1935 resources for patients that are very specific to their needs.
1936 So we are moving to a health care system that is much more
1937 customized and personalized and engaging for patients and
1938 families, and so that is why I think that it is essential as
1939 we move forward in the Meaningful Use Program to really keep
1940 up the pace. In the next phase, we are going to give
1941 patients online access that they can download their health
1942 information and transmit it to other care providers who need
1943 it. We are going to give them the ability to securely send
1944 an e-mail to their doctor. I mean, there are some really
1945 important advancements that are coming down the pike if we
1946 just keep our foot on the gas pedal.

1947 Mr. {Sarbanes.} Mr. Chairman, would you indulge one
1948 more response from Dr. Smith?

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1949 Mr. {Pitts.} Go ahead.

1950 Dr. {Smith.} So I point to the VA here. Adam Darkins
1951 runs the VA telehealth program. In 2012, I think there were
1952 1.5 million telehealth visits. The net impact of that at 150
1953 VA medical centers is to drop emergency room visits by 40
1954 percent, hospital admissions by 63 percent. Patients
1955 experienced a 60 percent reduction in hospital days. Nursing
1956 home admissions dropped by 63 percent, and patients reported
1957 a 95 percent satisfaction rate with their care. And that is
1958 the largest functioning telehealth program that we have in
1959 the country, and it is run by the Veterans' Administration.
1960 I think it is one of the best kept secrets of excellence
1961 inside the Veterans' Administration, and it speak to the
1962 potent opportunity that this has when we align the incentives
1963 system so that this technology is fully realized.

1964 Mr. {Sarbanes.} Thank you. Those are powerful
1965 statistics. I yield back.

1966 Mr. {Pitts.} Chair thanks the gentleman and now
1967 recognizes the gentlelady from North Carolina, Mrs. Ellmers,
1968 for 5 minutes for questions.

1969 Mrs. {Ellmers.} Thank you, Mr. Chairman, and thank you

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1970 to all of our panelists today for this very important
1971 subcommittee hearing.

1972 You know, first I would like to just say that across the
1973 board, health IT is so important. We have got to do
1974 everything we can to make it move forward quickly, you know,
1975 for our patients. You know, as you all have pointed out, you
1976 know, the very helpful information that we are gaining from
1977 it and how this truly will improve upon health care in this
1978 country, with all the hurdles that it has faced. However,
1979 having said that, I think it is incumbent upon myself to
1980 point out that it isn't quite the nirvana that has been
1981 discussed here. For instance, when we are talking about the
1982 Meaningful Use, as Ms. Bechtel, you know, you had cited some
1983 of the statistics, the number of physicians, the number of
1984 hospitals, however, we do have to remember that this is a
1985 mandate that was put forward and physicians are participating
1986 in it because if they do not, they will receive a Medicare
1987 reimbursement cut. So it is not only very beneficial and
1988 very important; however, it is very costly and at a time in
1989 this economy when you see what we are faced with, physicians
1990 being small business owners themselves, hospitals having

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1991 difficulty functioning, you know, physicians--you know, tens
1992 of thousands of dollars that they are having to incur to put
1993 this into place, hospitals, millions of dollars. It is a
1994 challenge. And again, the importance being duly noted,
1995 however, very difficult for many physicians to be incurring
1996 this cost.

1997 With that, I do have a question. Ms. Bechtel, you had
1998 mentioned that this situation--you know, that we are moving
1999 forward and it is very important, and that there are many of
2000 these physicians, but you do acknowledge the fact that it is
2001 a mandate?

2002 Ms. {Bechtel.} Absolutely, and I think it points to the
2003 problem that we have in the larger system, which is a
2004 complete lack of payment, that really drives quality and the
2005 development--

2006 Mrs. {Ellmers.} Absolutely.

2007 Ms. {Bechtel.} --of functionality, as you well know,
2008 and I know you are a big supporter of health IT, when we have
2009 fee-for-service, of course we are going to see the
2010 proliferation of billing systems, and we have no problems in
2011 interoperability or adoption rates of billing systems that

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2012 are designed to, you know, really focus on services.

2013 Mrs. {Ellmers.} And two, this is my next question. We
2014 had also discussed the fact--and I think you had mentioned
2015 that at some point in the future, patients will be able to
2016 download their own information. Now, there again, I see a
2017 big problem and this feeds into the reason that we are having
2018 this subcommittee hearing, which is the future, you know,
2019 where are we going to go, how is FDA regulation going to
2020 affect these things, how is medical device tax going to keep
2021 technology from innovating and moving forward?

2022 One of the issues that I continuously hear about is the
2023 fact that communication or software is different, the
2024 different systems that physicians, hospitals, and others use,
2025 so there really is a communication problem right now. What
2026 timeline do you--number one, do you acknowledge that, and
2027 two, what timeline do you see that happening for patients to
2028 be able to download information on their own so that they can
2029 be, you know, partners in this?

2030 Ms. {Bechtel.} So you can do this if you are a veteran
2031 through the VA right now, or through the Medicare program.
2032 The ability to do it through the Meaningful Use Program,

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2033 which will be from the EHRs, is going to start in October of
2034 this year for hospitals, and in January for physicians.

2035 Mrs. {Ellmers.} But do you--have you also heard that
2036 there is a communication problem between, you know, different
2037 facilities, physician offices and hospitals, different health
2038 care--

2039 Ms. {Bechtel.} Yes. It is one of the most common
2040 complaints we hear from consumers is the lack of coordination
2041 and the lack of communication. They say over and over again,
2042 I just want my doctors to talk to each other. The problem is
2043 they are not paid to talk to each other, so Meaningful Use
2044 has done a couple of things. One is there is an open
2045 standard now called the Direct Protocol, which is essentially
2046 like secured g-mail. Physicians and soon patients can
2047 actually use it right now to talk to each other, so you can
2048 have a hospital send a care summary to a primary care
2049 clinician--

2050 Mrs. {Ellmers.} Okay. Can I just--I need--I only have
2051 like 30 seconds left here, and I do have a question for Dr.
2052 Mitus. Now, you had mentioned that doctors are not paid to
2053 talk to each other. How do you describe that?

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2054 Ms. {Bechtel.} Because they are not paid for care
2055 coordination, they are paid on volume for services and
2056 procedures. So my doctor doesn't get reimbursed for picking
2057 up the phone and calling my cardiologist and coordinating--

2058 Mrs. {Ellmers.} So you are basing that on payment?

2059 Ms. {Bechtel.} Under fee-for-service.

2060 Mrs. {Ellmers.} Okay, fee-for-service, okay.

2061 Dr. Mitus, and again, I apologize because this is such
2062 an important issue for me. The Commonwealth Alliance that
2063 you put together, what do you see Meaningful Use not doing
2064 that you feel is an issue that needs to be addressed? In
2065 other words, you know, where are your areas of concern and
2066 the Commonwealth Alliance's concern?

2067 Dr. {Mitus.} May I take a few moments to answer?

2068 Mr. {Pitts.} You may proceed.

2069 Mrs. {Ellmers.} Thank you.

2070 Dr. {Mitus.} Thank you for raising an issue that we are
2071 very proud of, that we announced with an intention to launch,
2072 led by McKesson, Athena Health, Allscripts, Cerna, and
2073 Greenway. We are really trying to create to solve the very
2074 difficult problem of disparate health systems and the ability

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2075 to communicate across those health systems. It is one thing
2076 to gather data from an electronic medical record within an
2077 individual physician's office, but that ability to aggregate
2078 information from all the sites of care is a tremendous
2079 problem. We are attempting to solve that and create
2080 interoperability and seamless communication by setting
2081 standards and creating an infrastructure to support those
2082 important processes.

2083 Mrs. {Ellmers.} Is there a government HHS or any other
2084 agency that is hampering this availability that you are aware
2085 of?

2086 Dr. {Mitus.} Not that I am aware of.

2087 Mrs. {Ellmers.} Okay. Thank you so much, and again,
2088 thank you, Mr. Chairman, for indulging me for a few moments.

2089 Mr. {Pitts.} Chair thanks the gentlelady and now
2090 recognizes the gentleman from Georgia, Dr. Gingrey, for 5
2091 minutes for questions.

2092 Dr. {Gingrey.} Mr. Chairman, thank you very much.

2093 This is really for all of the panelists. Some have
2094 suggested that the mobile apps may be a game changer for
2095 health care delivery and consumer engagement. Do you agree

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2096 with that statement, or do you believe they have already
2097 changed? Why don't we start at the end and--

2098 Dr. {Smith.} It would be sad if where we are is where
2099 we are going, and so I have to believe that we are looking at
2100 the front end--on the cusp of a transformation in health care
2101 where engaged consumers work with a coordinated and
2102 integrated health care system, and so we can realize the
2103 important benefits of having ambient health care as opposed
2104 to having the model of health care delivery that we have been
2105 living with since my grandparents.

2106 Dr. {Gingrey.} Sure, thank you.

2107 Mr. {Bialick.} I 100 percent agree with that,
2108 absolutely agree with that.

2109 Dr. {Mitus.} I support the comments of my colleagues.

2110 Dr. {Classen.} And I would agree.

2111 Dr. {Gingrey.} All right. Excuse me, I didn't realize
2112 my phone was alive. I apologize for that, panelists.

2113 Dr. Smith, who makes mobile apps? It is sophisticated,
2114 big developers or are we talking about the little developer
2115 working out of the garage, the entrepreneur types, or is it
2116 both engaged in this activity?

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2117 Dr. {Smith.} So over the last 3 years, I have probably
2118 met with 1,000 companies that are interested in this space,
2119 all small, all largely unaware or incompletely aware of the
2120 regulatory framework that they are kind of naively entering,
2121 and find a bit of frustration as they realize that there is
2122 this other burden that they are not yet aware of. It is not
2123 enough to solve the problem; one must then engage a system
2124 with its own set of rules. And so it is often a fresh
2125 graduate out of graduate school, or even an undergrad who
2126 identified a problem in his family, the health care that they
2127 see, and are trying to figure out a way to solve it.

2128 Dr. {Gingrey.} The next question is for Mr. Bialick.
2129 Today, there are roughly 97,000--I can't believe that, but
2130 this is a statistic that I have. Today, there are roughly
2131 97,000 medical apps in the Apple app store, 97,000. These
2132 apps have generated more than three million free downloads.
2133 If the FDA regulates medical apps as medical devices and
2134 these products have to go through regulatory review at the
2135 agency and then they become subject to the 2.3 percent
2136 medical device tax, how likely do you believe it is that
2137 these apps will remain free to the public?

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2138 Mr. {Bialick.} I would just say that any additional
2139 costs added to the development process is going to change the
2140 marketing approach for them. This is a very capitalist
2141 market that we have created in health care apps. I would say
2142 that if you are going to increase the startup cost, if you
2143 are going to recoup that cost within a reasonable amount of
2144 time, you are likely going to have to change how money is
2145 coming in, and so that is either going to be to stop offering
2146 them for free, or require that end users pay for additional
2147 functionality within the app itself.

2148 Dr. {Gingrey.} Well sure, exactly, and I will stay with
2149 you, Mr. Bialick. You know, the death toll for chronic
2150 conditions is a staggering number. More than 10,000 people
2151 die every day because of chronic conditions. Not only is the
2152 human toll large, but of course, the economics behind it are
2153 driving up health care costs, they are harming our household
2154 and national finances, and as these costs for health care go
2155 up, more money is diverted from other programs. It is
2156 diverted from job creation, indeed, from consumers' pockets.
2157 How can health information technologies such as medical apps
2158 or electronic health records, if not classified by the FDA as

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2159 medical devices, how can they address these problems and how
2160 do we accelerate their use?

2161 Mr. {Bialick.} So to address the--let's look at a
2162 really high cost problem specifically to get to your
2163 question, which would be something like dually eligible
2164 beneficiaries between Medicare and Medicaid programs. Even
2165 if you target a specific issue like using these mobile apps
2166 to provide very high touch care, so we are not talking about
2167 managed care, but rather, we are talking about a direct way
2168 for the patient to be reminded for something, like imagine,
2169 taking their medication, some of these issues that could
2170 avoid the number of costly returns to the hospital. That is
2171 a very direct and tangible way that people can interact with
2172 their health care. That is what should be accelerated.

2173 Dr. {Gingrey.} Well, and that is the point I wanted to
2174 make to the witnesses and to my colleagues on the
2175 subcommittee. These devices, these medical apps, they don't
2176 draw blood. They don't take a biopsy. They are not
2177 invasive. They are just giving information to people in a
2178 timely fashion, and if permitted, to members of their family
2179 so that they know what is going on with mom or dad who 5,000

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2180 miles away and maybe very elderly, or maybe even in a nursing
2181 home. I mean, this is a hugely important subject and I
2182 commend the chairman for assembling this panel of witnesses
2183 and discussing this subject.

2184 So Mr. Chairman, I thank you for letting me go over a
2185 little bit, but I appreciate it and I yield back.

2186 Mr. {Pitts.} Chair thanks the gentleman, and now
2187 recognizes the gentleman from Florida, Mr. Bilirakis, for 5
2188 minutes for questions.

2189 Mr. {Bilirakis.} Thank you, Mr. Chairman. I appreciate
2190 it very much. Thank you to the panel for their testimony. I
2191 was over in VA. I apologize, but that is very important as
2192 well.

2193 I want to--question to Mr. Smith. You mentioned in your
2194 testimony the potential cost savings benefits of telehealth.
2195 Do you believe it is feasible to expand the use of telehealth
2196 to Medicare to effectively lower its costs?

2197 Dr. {Smith.} It is a simple word, absolutely. I could
2198 go on, but we have seen the impact of telehealth and
2199 telemedicine--New England, the Health Care Institute, the VA
2200 program, there is a rich history of information, some of

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2201 which I provided in my written testimony, about the
2202 beneficial impacts not only on outcome but also on costs.
2203 And so it seems obvious that we can extend that to patients
2204 struggling with chronic disease, independent of how their
2205 health care bills are paid.

2206 Mr. {Bilirakis.} Very good, thank you.

2207 Follow up again to Mr. Smith. With doctors showing an
2208 increase of reluctance to accept new Medicare patients, for
2209 obvious reasons, do you believe that allowing doctors to use
2210 telehealth will enable them to expand their reach in not only
2211 treating existing patients, but also increase access by
2212 enabling them to treat new beneficiaries? If you could
2213 elaborate a little bit.

2214 Dr. {Smith.} Sure. I think the technology obviously
2215 enables that notion of care at a distance in ways that are
2216 much more efficient than, say, in addition to the costs
2217 associated with travel, say, many of the costs associated
2218 with--in unnecessary or untimely ER visits or doctor's office
2219 visits. But I think it is not enough to have the technology
2220 enabled, we also have to have payment mechanisms that provide
2221 appropriate incentives for use. And so I was talking to a

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2222 colleague who is a dermatologist and I asked about this--the
2223 world of teledermatology. And he says, you know, it is never
2224 going to take off because I don't get paid for it. I think
2225 that is an unfortunate, but rational, statement.

2226 Mr. {Bilirakis.} Very good. Anyone else on the panel
2227 wish to comment?

2228 Mr. {Bialick.} I would like to just specifically on
2229 that point about taking on more Medicare providers. I think
2230 that when we talk about telemedicine, we think about it in a
2231 traditionally rural setting, so it is the idea of someone
2232 that lives in the country that doesn't have access to
2233 advanced care facility that is using telemedicine to connect
2234 to that. But especially from what we have learned from the
2235 VA around telestroke interventions as well as a number of
2236 other occupational therapy style interventions that you are
2237 able to do via telemedicine, this is absolutely something
2238 that can be leveraged to not only increase--improve outcomes,
2239 but save money in the urban setting as well.

2240 So we shouldn't be thinking about this as a purely rural
2241 situation, but this is also something that can be done in an
2242 urban situation as well, and still much like we are talking

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2243 about with the idea of regulation of apps, there are major
2244 regulatory barriers in place that are limiting the amount
2245 that Medicare providers are able to do that.

2246 Mr. {Bilirakis.} Thank you. Anyone else?

2247 Thank you very much. I yield back, Mr. Chairman. I
2248 appreciate it.

2249 Mr. {Pitts.} Chair thanks the gentleman. That
2250 concludes the questioning.

2251 At this time, I would like unanimous consent to place
2252 two documents into the record. The first is a letter from
2253 Carson McCarthy, the second is a statement from the
2254 Bipartisan Policy Center. I think you have seen these. So
2255 without objection, so ordered.

2256 [The information follows:]

2257 ***** COMMITTEE INSERT *****

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|
2258 Mr. {Pitts.} This has been a very interesting hearing,
2259 very important issue, very informative. We would like to
2260 thank all the witnesses for taking time and presenting
2261 testimony and answering all the questions. Members may have
2262 follow-up questions. I will remind members they have 10
2263 business days to submit questions for the record, and I ask
2264 the witnesses to respond to the questions promptly.

2265 With that--and members should submit their questions by
2266 the close of business on Wednesday, April 3. With that,
2267 thank you very much. Without objection, the subcommittee is
2268 adjourned.

2269 [Whereupon, at 12:00 p.m., the subcommittee was
2270 adjourned.]