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4 ``HEALTH INFORMATION TECHNOLOGIES: HARNESSING WIRELESS

5 INNOVATION''

6 TUESDAY, MARCH 19, 2013

7 House of Representatives,

8 Subcommittee on Communications and Technology

9 Committee on Energy and Commerce

10 Washington, D.C.

11 The subcommittee met, pursuant to call, at 10:37 a.m.,
12 in Room 2123 of the Rayburn House Office Building, Hon. Greg
13 Walden [Chairman of the Subcommittee] presiding.

14 Present: Representatives Walden, Latta, Terry, Shimkus,
15 Terry, Blackburn, Scalise, Lance, Guthrie, Gardner,
16 Kinzinger, Long, Ellmers, Matsui, Lujan and Waxman (ex

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17 officio).

18 Staff present: Ray Baum, Senior Policy Advisor/Director
19 of Coalitions; Matt Bravo, Professional Staff Member; Andy
20 Duberstein, Deputy Press Secretary; Neil Fried, Chief
21 Counsel, Communications and Technology; Debbie Hancock, Press
22 Secretary; Sydne Harwick, Staff Assistant; Brittany Havens,
23 Staff Assistant; Sean Hayes, Counsel, Oversight and
24 Investigations; Robert Horne, Professional Staff Member,
25 Health; Andrew Powaleny, Deputy Press Secretary; David Redl,
26 Counsel, Telecom; Charlotte Savercool, Executive Assistant,
27 Legislative Clerk; Roger Sherman, Democratic Chief Counsel;
28 Shawn Chang, Democratic Senior Counsel; Patrick Donovan, FCC
29 Detailee; Margaret McCarthy; and Kara van Stralen, Democratic
30 Special Assistant.

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|
31 Mr. {Walden.} We are going to call to order the
32 Subcommittee on Communications and Technology for our hearing
33 on ``Health Information Technology: Harnessing Wireless
34 Innovation.''

35 I want to welcome our witnesses and our participants in
36 today's hearing. It is not every day that the Subcommittee
37 on Communications and Technology holds a hearing addressing
38 FDA regulation, but the fact that we are having such a
39 hearing is a testament to the breadth of innovation using
40 wireless smartphones and tablets and all that that is
41 bringing to nearly every aspect of our lives. There are
42 literally thousands of apps in the various smartphone and
43 tablet app stores in the health and wellness categories,
44 actually tens of thousands, everything from simple calorie
45 counters to complex analytical tools. The more than 300
46 million wireless devices we depend on every day are
47 revolutionizing health and wellness.

48 If I stopped here, this hearing could be about the
49 success of bringing the innovation and investment of the
50 wireless ecosystem to bear on the ever more costly health

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51 care system. And make no mistake about it, that could still
52 be the outcome. But the specter of costly and time-consuming
53 regulation, to say nothing of a 2.3 percent excise tax, looms
54 large over this industry. We have heard from investors,
55 wireless device manufacturers and application developers that
56 are concerned about the uncertainty of an FDA regulatory
57 regime that may or may not apply to them and the possibility
58 of an additional excise tax that cuts into already thin
59 margins.

60 The collision of worlds in the mobile health, or
61 mHealth, is a study in contrasts. The app economy is
62 characterized by low barriers to entry, quick time to market,
63 and the ability to adapt to quickly changing user needs.
64 Medical devices, on the other hand, face a long and costly
65 premarket approval process at the FDA. Now, we all want to
66 make sure that patient safety is taken care of first, but why
67 would we treat mobile applications the same as a dialysis
68 machine? These are the kinds of questions we need to get
69 answers to about where that sweet spot is and that fine.

70 The answer may be that the wireless economy represents a
71 tempting target for the 2.3 percent excise tax that the

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72 President's health care law placed on medical devices. While
73 the IRS and the FDA have provided some draft guidance on how
74 they will apply the medical device definition and the medical
75 device tax, their analysis is not a poster child of clarity
76 and it leaves large parts of the economy wondering if they
77 will be on the hook for what is essentially a tax on
78 innovation, and we certainly are hearing that from our
79 witnesses and others.

80 The FCC and the Obama administration have both joined
81 the wireless industry in trumpeting the virtuous cycle of
82 innovation and investment in mobile technologies: investment
83 in wireless networks and devices creates opportunities for
84 app developers to create new and innovative uses for wireless
85 services, which in turn spurs further investment in networks
86 and devices. MHealth is part of this virtuous cycle that is
87 driving faster speeds, lowering costs, spurring innovation
88 and creating patient benefits. Given the interconnected
89 nature, we should be aware that an impact on one segment of
90 this industry has the potential to slow the entire cycle.

91 The overbroad application of FDA regulation and the
92 health care law's medical device tax are not, as some have

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93 suggested, outside the realm of possibility. In a 2012
94 report by the Institute of Medicine, one expert author
95 suggested that all health IT products should be treated as
96 class III medical devices, which receive the highest level of
97 regulatory scrutiny and therefore should be subject to the
98 tax. Now, that is just one person's opinion but it is in the
99 prestigious Institute of Medicine report.

100 Luckily, while these are not hypothetical concerns, they
101 are also by no means foregone conclusions, which is why we
102 are having a hearing today. Wireless has and can continue to
103 be a system that brings the mobile revolution to our Nation's
104 health and wellness sector, but we must ensure that as we
105 bring the innovation of the wireless economy to health and
106 wellness that we not place unnecessary hurdles in the way of
107 the developers and investors that are fueling mHealth.

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

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

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|
110 Mr. {Walden.} So I want to thank our witnesses for
111 being here, and I would now recognize the vice chair of the
112 subcommittee, Mr. Latta.

113 Mr. {Latta.} I thank the chairman for yielding, and I
114 also thank our distinguished panel for testifying today.

115 The mobile application industry is a modern American
116 economic success story. Just this year alone, mobile apps
117 were projected to be a \$25 billion industry. No one, at
118 least no one in Washington, could have predicted the
119 incredible growth and the extraordinary uses for these apps,
120 particularly in the mobile health world. The health and
121 wellness opportunities for mobile apps have great potential
122 for our health care delivery system.

123 I am concerned that the regulatory uncertainty coming
124 from the FDA will discourage innovation and investment in
125 mobile apps and that Americans will lose out on potentially
126 lifesaving technology. This climate of regulatory
127 uncertainty could also have adverse effects on the overall
128 wireless ecosystem, which continues to drive economic growth
129 in this country. Furthermore, I believe the medical device

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130 tax will be extremely detrimental to our economy. The
131 potential application of the medical device tax to mobile
132 apps will only further deter investment and development in
133 the industry.

134 Mr. Chairman, I look forward to our testimony today and
135 our witnesses, and I yield back.

136 [The prepared statement of Mr. Latta follows:]

137 ***** COMMITTEE INSERT *****

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|
138 Mr. {Walden.} I thank the gentleman for his comments.
139 We now recognize the ranking member of the subcommittee
140 today, Ms. Matsui of California.

141 Ms. {Matsui.} Thank you, Mr. Chairman, and I would like
142 to thank the witnesses for being here today.

143 Technology is changing health care as we know it. A
144 smart spectrum policy that is driving wireless revolution is
145 also transforming our health care sector. We are seeing the
146 benefits of health care providers utilizing WiFi and high-
147 quality, unlicensed spectrum to spur the development of next-
148 generation patient care monitoring applications that could
149 transmit patients' vital health data to their doctor or
150 hospital. Whether it is monitoring diabetes, glucose levels,
151 tracking blood pressure or providing real-time hydration
152 levels, the list goes on and on.

153 We are seeing cloud technologies transforming health IT
154 through the creation of select community health clouds
155 forming in regions across the country, enabling hospitals to
156 better treat patients while ensuring HIPAA-compliant
157 transfers of secure medical information. It will only become

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158 more important as the mobile app economy continues to drive
159 consumer demand for smartphones and tablets.

160 The fact is, the ever-evolving app economy is helping to
161 transform the health care sector, integrating science,
162 medicine and technology to provide individuals with real-time
163 access to vital health information, much of which was
164 previously unavailable outside of a hospital or a doctor's
165 office. House calls are becoming a thing of the past.
166 Virtual checkups are becoming the new digital-age house call.
167 Doctors are using iPads to issue prescriptions and diagnose
168 patients. Smartphones are creating new paths of virtual
169 interactions between doctors and patients. Texting your
170 doctor has become a more common practice as more Americans,
171 particularly young people, are finding greater comfort and
172 accessibility in communicating electronically with their
173 doctors.

174 The Affordable Care Act also has allowed the health care
175 industry to become more innovative using technology. I
176 believe we will see a growing ecosystem of health IT
177 innovation now that the Affordable Care Act is here to stay.

178 My home State of California has been a pioneer in ACA

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179 implementation. Our exchange, Covered California, has
180 already begun using mobile devices to launch online features
181 so consumers can estimate their monthly premiums and compare
182 health care options. Physicians and hospitals in my district
183 of Sacramento are using the exchange to improve their health
184 IT capabilities. For example, the Live Health Online
185 Initiative already permits doctors to care for patients
186 through a secure online visit using laptop Web cams and
187 ultimately through video-enabled tablets and smartphones
188 regardless of where the doctor and patient are located.

189 With more than 50 million additional Americans expected
190 to obtain health insurance this year due to the law, an
191 efficient and effective health IT network is even more
192 imperative. In order to realize the full potential of
193 innovative health technologies, the regulatory environment
194 must keep pace with rapidly changing technology.

195 In 2011, the FDA released draft guidance to provide
196 rules of the road for medical app developers clarifying which
197 medical apps would require its attention and which would not.
198 I believe the draft guidance attempts to strike the
199 appropriate balance between enabling innovative medical apps

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200 and ensuring patient safety, and I urge the agency to move
201 forward expeditiously. Now, moving forward, I believe the
202 FDA must be mindful of the fact that technology continues to
203 evolve at a rapid pace and the need for them to provide
204 clarity to the marketplace.

205 Another way to foster greater innovation in the health
206 sector is through creating a workable federal definition for
207 telehealth services. I am developing legislation to do just
208 that. I believe having certainty here would spur innovation
209 and research in the private sector and in programs like
210 Medicare. We must continue to chart a technology-friendly
211 course that promotes better patient care for all Americans.

212 And Mr. Chairman, I would like to ask unanimous consent
213 to enter into the record the following three items: a report
214 from the Center on Budget and Policy Priorities on the
215 medical device excise tax, a letter from SDI Diagnostics, a
216 small medical device manufacturer, regarding FDA regulatory
217 oversight of the medical device market, a study published in
218 the peer-review journal, JAMA Dermatology, identifying risks
219 and depending on smartphone apps for diagnosis.

220 Mr. {Walden.} Without objection.

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221 [The information follows:]

222 ***** COMMITTEE INSERT *****

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|
223 Ms. {Matsui.} Thank you. And I look forward to working
224 with my colleagues to continue to promote health IT. I look
225 forward to hearing from our witnesses today. Thank you. I
226 yield back.

227 [The prepared statement of Ms. Matsui follows:]

228 ***** COMMITTEE INSERT *****

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229 Mr. {Walden.} The gentlelady yields back the balance of
230 her time. The Chair now recognizes the gentlewoman from
231 Tennessee, Ms. Blackburn, for 5 minutes.

232 Mrs. {Blackburn.} Thank you, Mr. Chairman, and I want
233 to thank our witnesses for being here today. We are deeply
234 appreciative that you all are here, and we are appreciative
235 of what you are doing in the industry and in this space in
236 which you are working.

237 You know, I was stunned in doing some work on this and
238 talking with some of the innovators in Nashville. Five
239 hundred thousand jobs are attributed to your sector, and you
240 are one of the few areas where there has actually been some
241 job growth since the misery that was there in 2008 and 2009
242 and, you know, when you look at mHealth, you are talking
243 about a \$27 billion industry within the next couple of years,
244 so we thank you for this. Not only is it productive and not
245 only is there opportunity to profit from your innovations,
246 there is the opportunity to encourage R&D and to provide
247 better outcomes and better wellness and maintenance of effort
248 in health to expand the use of telemedicine and mobile

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249 health. So hearing from you where you think we need to
250 travel with this is going to be helpful and it is going to be
251 instructive as we look at this entire space for health care
252 informatics and the opportunities that exist there.

253 I think that, you know, we are all concerned about what
254 would help with the medical device tax being applied to this.
255 Of course, it is muddy as muddy water when you are trying to
256 figure out where the FDA is actually looking to go. I know
257 there are about 300,000 apps that are available, or 50,000
258 apps, I think it is, and 300,000 downloads, that are through
259 the Apple app store. So people like the convenience of this,
260 and we want to do what we can to make certain that it remains
261 accessible and affordable and is not levied with a tax that
262 is going to end up being a hindrance.

263 So we appreciate your ability to make way for us in your
264 schedules to be here, and Mr. Chairman, I yield back.

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

266 ***** COMMITTEE INSERT *****

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267 Mr. {Shimkus.} Would the gentlelady yield?

268 Mrs. {Blackburn.} Yes.

269 Mr. {Shimkus.} Thank you. I would just like to weigh
270 in.

271 The medical device tax is a very pernicious tax by
272 itself. One of the problems I have is the gross nature,
273 taxing just gross versus obviously net after costs and
274 expenses. I mean, where else but in Washington can you dream
275 up such a bad tax provision? But as was stated earlier by my
276 colleagues, what is critical for you all in your testimony
277 today is to help us sort through your concerns, your risks,
278 your level of being able to capitalize or not, and then where
279 is this line? I mean, it is very vague, and so when there is
280 uncertainty, there is higher risk. When there is higher
281 risk, there is more cost of capital and it could be damaging
282 to any business model that you would address.

283 So we really appreciate you being here. We are probably
284 going to ask some pretty specific questions, especially for
285 those of you who are in that space innovating and creating
286 jobs. We thank you for coming.

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287 And with that, I yield back to my colleague.

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

289 ***** COMMITTEE INSERT *****

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|
290 Mrs. {Blackburn.} I thank the gentleman for yielding
291 back. Did Mr. Lance, one of my other colleagues, want any of
292 the remaining time? Okay. Mr. Chairman, I yield back.

293 Mr. {Walden.} The gentlelady yields back. The Chair
294 now recognizes the former chairman of the committee, the
295 gentleman from California, Mr. Waxman.

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

297 This is a hearing to look at mobile medical
298 applications, and this is the first of three hearings on this
299 subject this week. The high-speed wireless broadband access
300 is creating new opportunities in consumer services in nearly
301 every segment of our economy including health care, and
302 mobile medical applications hold incredible promise for
303 patients and health care providers, potentially reducing
304 costs, improving health care delivery and saving lives. That
305 is why we made a significant investment in medical
306 communications, because this is a really important area. We
307 all want to see this exciting innovation continue.

308 At the same time, we have to be cognizant of the need to
309 protect patient safety. That is why the Food and Drug

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310 Administration has released a draft guidance regarding mobile
311 medical applications. So their guidance says if it is a
312 dietary tracking app or a reminder service for medical
313 appointments, they certainly don't need FDA approval for
314 that. But an app that purports to diagnose cancer? Well
315 there ought to be some review and have regulatory scrutiny.

316 Let me give an example. A group of dermatologists
317 recently published a study of four apps that claim to be able
318 to diagnose melanomas. Well, the dermatologists found that
319 three of the four incorrectly classified 30 percent or more
320 of melanomas as benign when they were actually malignant.
321 Well, we can't tell the American people buyer beware when
322 potentially life-and-death care decisions are at stake.

323 My Republican colleagues say that FDA is hoping to
324 subject smartphones and tablets to the medical device tax.
325 Well, that doesn't really hold up to scrutiny. I think they
326 have their facts wrong. Allegations that ordinary
327 smartphones and tablets could be subject to added red tape or
328 new taxes under Obamacare are absolute myths. In fact, FDA's
329 draft guidance specifically states that the agency does not
330 intend to regulate distributors of mobile medical apps like

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331 the iTunes store or the makers of smartphones or tablets like
332 Apple. Smartphones and tablets are not listed with FDA as
333 medical devices, so they are completely outside the scope of
334 the medical device tax.

335 Furthermore, it is my understanding that most mobile
336 medical apps would also be exempt from the medical device tax
337 because of the IRS ``retail exemption.'' This provision says
338 that devices are exempt from the tax if they are regularly
339 available for purchase and use by ordinary consumers,
340 including over the Internet, and if they are not primarily
341 intended for use in a medical institution or by a medical
342 professional.

343 To go back to the case of the dermatologists, those apps
344 would not be subject to the medical device tax, but they
345 would be subject to FDA scrutiny to be sure that the patients
346 are not being harmed.

347 There are legitimate concerns that we ought to examine,
348 instead of using today's hearing to invent new fallacies to
349 attack the Affordable Care Act. We have already had a number
350 of hearings this year on a tax on Obamacare. Well, my
351 Republican colleagues didn't like it. They all voted against

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352 it. They hoped that the Supreme Court would have thrown it
353 out. The Supreme Court upheld it. They hoped the election
354 would replace the President so they could have repealed it.
355 The electorate voted for President Obama. This is all going
356 to go into effect at the end of this year and it will be
357 fully in place by January of 2014. We have already seen a
358 lot of improvements in health care by virtue of the
359 Affordable Care Act.

360 The Affordable Care Act is going to serve a very
361 important purpose. It is not going to require mobile apps to
362 be regulated or to be taxed. FDA released a draft guidance
363 for mobile medical apps, and we should commend them for this
364 action. Both industry and consumers would benefit from the
365 clarity of final guidance. I hope that FDA is working
366 expeditiously toward that goal.

367 You have to make distinctions. You don't blur it all to
368 serve the political point of view to attack the Affordable
369 Care Act. We have got to look at the law, draw the
370 distinctions, and make sure that the public is protected
371 while innovation is still encouraged. And I think that we
372 are looking to a lot of very important innovation and we want

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373 to see that come into action.

374 Thank you, Mr. Chairman. Yield back.

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

376 ***** COMMITTEE INSERT *****

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377 Mr. {Walden.} The gentleman yields back the balance of
378 his time. The Chair would ask unanimous consent to enter
379 into the record a letter from the CTIA CEO and former
380 Representative Steve Largent raising concerns of the wireless
381 industry, and a letter from Keith Brophy, CEO of IDA-Med from
382 Grand Rapids, Michigan. It is a medical app device
383 developer, and also has concerns about the uncertainty, which
384 is why we are having this hearing today. Without objection.

385 [The information follows:]

386 ***** COMMITTEE INSERT *****

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387 Mr. {Waxman.} Mr. Chairman, I certainly have no
388 objections. I just wanted to point out to the witnesses that
389 there is another hearing going on so I will be back and
390 forth, and I apologize for not being here.

391 Mr. {Walden.} No problem. Feel free to take the full
392 time in the other hearing if you like. No, I am just--we
393 actually have a little fun together here, so it is fine.
394 Thank you. And we have got other members that are going to
395 be coming and going. It is a good reminder, because there is
396 an Energy and Power Subcommittee meeting as well.

397 So with that, we welcome our witnesses, and I know Dr.
398 Dagi's plane was a little delayed getting out of Boston,
399 apparently a little snow up there, but he has arrived, and he
400 will be joining us momentarily, but we will go ahead, and
401 again, we thank you all for being here. I have read through
402 your testimony. It is most helpful in our efforts to shine
403 some light on this issue.

404 So we are going to start with Mr. Robert Jarrin, Senior
405 Director of Government Affairs for Qualcomm. Mr. Jarrin, we

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406 are delighted to have you here this morning and look forward
407 to your testimony, sir.

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|
408 ^STATEMENTS OF ROBERT JARRIN, SENIOR DIRECTOR, GOVERNMENT
409 AFFAIRS, QUALCOMM; BRADLEY MERRILL THOMPSON, GENERAL COUNSEL,
410 MHEALTH REGULATORY COALITION; BEN CHODOR, CHIEF EXECUTIVE
411 OFFICER, HAPPTIQUE; JONATHAN SPALTER, CHAIRMAN, MOBILE
412 FUTURE; T. FORCHT DAGI, MD, MPH, DMEDSC, PARTNER, HLM VENTURE
413 PARTNERS; AND DR. GEORGE FORD, CHIEF ECONOMIST, PHOENIX
414 CENTER FOR ADVANCED LEGAL AND ECONOMIC PUBLIC POLICY STUDIES

|
415 ^STATEMENT OF ROBERT JARRIN

416 } Mr. {Jarrin.} Thank you. Good morning, Chairman
417 Walden, Ranking Member Matsui and members of the
418 subcommittee. First and foremost, I would like to thank you
419 for having me participate as a witness in today's hearing. I
420 have worked in various capacities over the span of two
421 decades, at times preparing others to sit before you. Today
422 I am truly honored to be the one sitting here.

423 I will begin by starting with mobile technology. It is
424 the largest platform in the history of mankind. The
425 population of the world is approximately 7 billion people,

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426 and there are nearly 6.6 billion mobile connections. In the
427 United States alone, there are 323 million mobile
428 subscriptions for a population of 315 million people.

429 Consumer research suggests that two-thirds of people
430 sleep with their mobile device next to them, and one-third
431 interact with their device before they even get out of bed.
432 Those with a mobile phone tend to check it about 150 times
433 per day, roughly about once every 6-1/2 minutes.

434 Mobile devices are powerful and sophisticated. Today, a
435 typical smartphone has more computing power than Apollo XI
436 did when it landed on the moon. Computing devices are now
437 built around mobile experiences with always-on connectivity,
438 location awareness, augmented reality and powerful
439 processing. Soon there will come a day when virtually
440 everyone and everything in our world will be connected
441 through a ubiquitous wireless technology.

442 Let me also share some startling statistics of a
443 different nature yet related, chronic disease in America.
444 According to the CDC, about out of every two adults in the
445 United States has at least one chronic illness. Seven out of
446 10 deaths among Americans are due to chronic disease.

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447 Obesity, for example, affects one in three adults as well as
448 one in three children who are either overweight or obese.
449 Although chronic diseases are among the most common, they are
450 also the costliest of all health problems. The CDC states
451 they are also among the most preventable.

452 This presents an interesting opportunity. Many
453 Americans are sick yet more have access to a personal,
454 powerful, mobile computing device. Hence, it was only a
455 matter of time before the health care technology innovators
456 would take notice of the potential to personalize a mobile
457 platform and facilitate the delivery of affordable health
458 care. Nowhere is this growth more obvious than in the mobile
459 health applications landscape. Quite simply, the growth of
460 mobile health apps has skyrocketed. Approximately 27,000
461 unique health apps are available. Over 7,000 health apps are
462 specifically intended for use by students and health care
463 professionals. Five hundred new mobile health apps launch
464 every month. Interestingly, however, a survey conducted by
465 MobiHealthNews shows that to date, FDA has only cleared fewer
466 than 80 mobile medical apps through its 510(k) process. They
467 further estimate that as little as 5 percent of all health-

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468 related apps could potentially be considered medical and
469 possibly subject to FDA regulation.

470 On July 21, 2011, the FDA issued a draft guidance on
471 mobile medical applications. The agency went on to receive
472 more than 700 pages of comments from over 100 interested
473 stakeholders. They also held a 2-day workshop and engaged
474 the public at large in briefings and events. FDA officials
475 have expressed their views that the final MMA guidance would
476 be deregulatory. In fact, it would delineate how the agency
477 would exercise enforcement discretion to not proactively
478 regulate many low-level-risk mobile medical apps. However,
479 it is now March 19, 2013, and unfortunately, FDA has yet to
480 release a final MMA guidance document. Qualcomm and others
481 are concerned that the failure to release final guidance has
482 created uncertainty among countless budding entrepreneurs and
483 large corporations that fear the prospect of facing FDA
484 regulation. Qualcomm offers the following recommendations
485 for consideration.

486 First, FDA should promptly finalize the MMA draft
487 guidance document. Second, the final guidance should offer
488 specific examples of low-risk regulated mobile medical

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489 devices that FDA, through enforcement discretion, would not
490 regulate. Third, there should be clarity on intended use in
491 light of ambiguous and general health claims and terms.
492 Fourth, for apps that do not warrant listing as low-risk
493 class I medical devices--rather, that do warrant listing as
494 low-risk class I medical devices, the agency should consider
495 how it will assess exemption from Good Manufacturing
496 Practices. Fifth, accessories should be classified according
497 to their individual level of risk and not according to the
498 device with the highest classification level. Sixth, FDA
499 should continue its commitment to consistency, predictability
500 and transparency by coordinating internal and external
501 efforts through a single dedicated office within FDA the
502 agency. Seventh and lastly, the agency would benefit to
503 utilize external facing resources such CDRH Learn, Device
504 Advice and the Division of Small Manufacturers, International
505 and Consumer Assistance to work with app developers and their
506 communities.

507 FDA has a proven and successful policy, regulatory and
508 legal framework that has been formed from over 100 years of
509 innovation, science and learning, a framework that puts the

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510 patient first and ensures the safety and effectiveness of all
511 health and medical products in the U.S. marketplace. We
512 recommend that FDA be given the fullest support it needs to
513 continue doing its fine work while allowing innovation to
514 drive the U.S. healthcare system.

515 In closing, I would like to say a few words about
516 Qualcomm. Qualcomm, Inc., is the leading supplier of
517 wireless chips, having shipped worldwide well over 11 billion
518 chips to date. Qualcomm is the leading developer of 3G, 4G
519 and other next-generation wireless technologies. In
520 addition, Qualcomm has a wholly owned medical device
521 subsidiary focused on producing medical device data systems.
522 We are committed to the health care space through various
523 public and private efforts as further described in my written
524 testimony and on Qualcomm's Web site.

525 Thank you, and I look forward to answering your
526 questions.

527 [The prepared statement of Mr. Jarrin follows:]

528 ***** INSERT 1 *****

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|
529 Mr. {Walden.} Mr. Jarrin, thank you for the thought you
530 put into your testimony and for being here today.

531 We will now go to Mr. Bradley Merrill Thompson, General
532 Counsel, mHealth Regulatory coalition. Mr. Thompson, thank
533 you for being here today. We look forward to hearing your
534 testimony.

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|

535 ^STATEMENT OF BRADLEY MERRILL THOMPSON

536 } Mr. {Thompson.} Well, thank you very much for inviting
537 me. As you can tell from the name of our organization, the
538 topic today is of very great interest to us.

539 Our coalition is a very diverse coalition, which is both
540 fun and challenging. It is fun, because we have a lot of
541 spirited discussions. It is challenging because it
542 represents a lot of different points of view. We have folks
543 in there from the traditional medical device industry, we
544 have app developers in there, we have the telecommunication
545 firms in there, patient groups and so forth. And frankly,
546 the way I navigate consensus-building in our group is to say,
547 look, we only have one rule, and that is, put the patient
548 first, leave economics at the door and let us figure out what
549 policy puts the patient first.

550 In that vein, I have three simple points that I want to
551 make this morning in my testimony. The first one is that we
552 would urge FDA to publish its guidance just as soon as
553 possible and indeed expand on that guidance in the future. I

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554 cheated a little bit, and I read the testimony of my other
555 fellow witnesses here, and it seems like there is going to be
556 good agreement on that score. What I would offer as the
557 nerdy lawyer maybe among the panel is that I think that maybe
558 FDA is delaying because they are going for the complete and
559 final definitive for-all-time answer to these questions, and
560 it is really tough because the industry changes on almost a
561 daily basis. So they write a draft, it goes through a couple
562 of months of review. By that couple months, the environment
563 has changed a bit and they want to go back and erase some of
564 what they wrote previously.

565 I think what they need to do is get a final version out
566 there and then use the guidance process to update it
567 periodically as the environment changes, as the regulatory
568 issues shift, as the questions shift, simply update the
569 guidance periodically. We have talked about creating a Web
570 site where they would on a more real-time basis offer some
571 guidance. There are some tools that are available to them
572 but bottom line is, I think FDA is struggling a bit with how
573 to get hits guidance out, and in our opinion, it needs to get
574 out because there is an awful lot of business that is frozen

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575 on the sidelines waiting to see what that guidance says.

576 The second point I want to make to you is a bit
577 counterintuitive probably for someone from industry to say,
578 and that is, we would like to see more FDA enforcement in
579 this area, and particularly more balanced FDA enforcement in
580 this area. And the way I can make this point is best through
581 an example, and it is an example I read about of a new app
582 just a few weeks ago announced from India where you can do
583 urinalysis with your iPhone, and everyone was talking about
584 it on the Internet because I think a lot of people were
585 trying to figure exactly where you pee on this thing in order
586 to get the reading, and it turns out you do a very
587 traditional technique: you pee in a cup and put a strip in
588 that cup, it changes color, and then use the camera on the
589 iPhone to more accurately assess what the color changes were.
590 And they introduced this thing. It hasn't yet hit the U.S.
591 market but they have announced their intention to go through
592 the Apple app store in introducing it. The problem is, FDA
593 has regulated urinalysis for 30-some years. That is a very
594 traditional medical device, and the typical one looks about
595 the size of a cash register, so I got to tell you, doing it

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596 on an iPhone, that is cool, that is really cool, but what
597 they did is, on the front page, at the bottom of the front
598 page they basically said in legalese this is not a medical
599 device. Well, honestly, if it were that simple, I know a lot
600 of other companies that would like to do that same thing,
601 right? If you could avoid FDA by putting a disclaimer at the
602 bottom of your home page and yet the whole rest of the Web
603 site explains how it is used in urinalysis, that is a
604 problem.

605 So this is in part a competitive issue, right? Because
606 different companies are held to different standards. But it
607 is a public health issue because this is an important app,
608 and if it gets the urinalysis reading wrong, people with
609 diabetes, people with serious conditions could be relying on
610 that app. So either deregulate it, which would take an act
611 of Congress, I believe, because it is clearly a medical
612 device, or more evenly enforce the rules.

613 The third and final point that I want to make is that we
614 favor sticking with FDA as the regulator for both the
615 traditional device industry and the less traditional mHealth
616 area. There was a rumor circulating, and who knows where

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617 these start, that people wanted to move mobile health
618 regulation away from FDA. We couldn't support that. We
619 couldn't support it because it would create two systems where
620 if you do it on an iPhone system, if you do it on a cash
621 registered-sized machine, you have a completely different
622 system. To us, that actually increases the uncertainty and
623 the complexity and the confusion, and so we have found that
624 FDA has the knowledge that they need. This is a new
625 technology. We are all learning the technology, but they
626 have the public health knowledge in order to do this and to
627 do it right, so we favor sticking with the agency.

628 Those are the three points I wanted to make this
629 morning, and I appreciate the time.

630 [The prepared statement of Mr. Thompson follows:]

631 ***** INSERT 2 *****

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|
632 Mr. {Walden.} Mr. Thompson, thank you for your
633 testimony. We will now go to Mr. Ben Chodor, who is the
634 Chief Executive Officer of Happtique, like health app
635 boutique.

636 Mr. {Chodor.} Exactly.

637 Mr. {Walden.} Everybody with me now. All right, Mr.
638 Chodor, you are on.

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|
639 ^STATEMENT OF BEN CHODOR

640 } Mr. {Chodor.} Good morning, Mr. Chairman Walden and
641 Ranking Member Matsui and members of the subcommittee. My
642 name is Ben Chodor and I am the CEO of Happtique. It is an
643 honor to testify today on mobile health technology, which
644 Happtique believes can change health care delivery systems.
645 My testimony addresses two important issues in our industry--

646 Mr. {Walden.} Will you make sure your microphone is on?

647 Mr. {Chodor.} Is that better?

648 Mr. {Walden.} There we go.

649 Mr. {Chodor.} My testimony addresses two important
650 issues facing our industry: questions about regulations, and
651 the applicability of medical device tax to mobile devices.
652 Happtique is a mobile health solution company whose mission
653 is to integrate mobile health into patient care and daily
654 life. Happtique is owned and operated by GNYHA Ventures, a
655 business arm of Greater New York Hospital Association. GNYHA
656 has a robust family of companies to assist its members in
657 addressing business and operational issues. Happtique, the

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658 newest member of the companies, was established in direct
659 response to members' needs to develop comprehensive mobile
660 health strategies to support clinicians, facilitate patient
661 engagement and improve their own operations. Happtique's
662 principle offerings include individually branded, secure,
663 multiplatform applications for hospitals, physician and
664 patient: our MRX, it is our patent pending technology that
665 enables physicians to actually prescribe apps to their
666 patient, a unique system of classifying apps in more than 300
667 categories, and our brand-new private sector solution to a
668 big problem, we have just launched our certification program
669 for health apps.

670 Happtique created these solutions to harness the
671 unprecedented potential for mobile health technologies.
672 Think about it: 87 percent of physicians use smartphones or
673 tablets every day. One out of five smartphone users has at
674 least one health app on it. There are over 40,000 health
675 apps on the market and it is growing every day, and there is
676 little to no barrier of entry for these apps. This has
677 incredible opportunity for innovation in health care but
678 comes with certain concerns, namely how credible is this app

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679 for myself or for my patient.

680 So who should monitor, you know, the mobile health
681 industry? Clearly, the industry needs to balance three
682 things: innovation, safety and effectiveness. The FDA
683 released its guidelines in 2011, which Mr. Jarrin went over,
684 and Happtique's belief is that the FDA is in the best
685 position of any agency to regulate health apps because of its
686 long health expertise in assuring patient safety, but we have
687 to say from our point of view, the FDA has to release these
688 guidelines sooner than later. It is about time that they
689 come out.

690 We don't believe the FDA should regulate mHealth
691 products that are not considered medical devices. The FDA's
692 draft guidance addressed which mobile apps the FDA does not
693 anticipate classifying as mobile apps for purpose of
694 regulation. The industry is pleased that the FDA recognizes
695 its own limits.

696 Complementary to the FDA regulatory framework,
697 Happtique, our company, has created a certification program
698 with industry stakeholders to offer clinicians and patients a
699 way to identify technically and validation of an app.

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700 Happtique developed a health app certification standard under
701 the direction of a blue ribbon panel, and we are reviewing
702 operability, privacy, security and content. In the
703 development of the standards, we consulted with key public-
704 private sector organizations--the FDA, the FTC, the FCC, the
705 AMA, the AAMC and many, many other organization. This
706 conducted the certification process. Again, Happtique is an
707 engaged, well-known security company to ensure operability,
708 privacy and security, and we are engaging specialists, so if
709 it is a cardiology app, cardiologists should review the
710 material. Apps that pass both the technical and testing
711 content review will be awarded the Happtique certification
712 seal. Our goal here is that the users will be reassured that
713 a certified app delivers credible content, safeguards user
714 data and functions as described.

715 I would like to switch gears for a second and now talk
716 about the medical device tax and how it relates to mobile
717 apps since I know several members of the committee also care
718 a great deal about this issue. Happtique does not believe
719 that Congress intended to impose a device tax on iPhones,
720 iPads, Android phones or tablets or BlackBerrys or apps that

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721 run on these devices. If congressional intent is ambiguous,
722 we firmly believe the retail exemption applies. If the IRS
723 wants to implement this tax on this technology, Congress
724 needs to pass a law that specifically states that tax
725 applies. Imposing a device tax on apps will undoubtedly
726 stifle innovation, developers and publishers, and frankly,
727 the threat of tax stifles innovation too.

728 In closing, thank you for my allotted time, and I would
729 like to thank the chairman and ranking member and the
730 subcommittee for asking me to testify today.

731 [The prepared statement of Mr. Chodor follows:]

732 ***** INSERT 3 *****

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|
733 Mr. {Walden.} Mr. Chodor, thank you for your very good
734 testimony, and that is why we are having this hearing is to
735 try and shine some light and bring some clarity.

736 Mr. Jonathan Spalter is next. He is the Chairman of
737 Mobile Future. Mr. Spalter, thank you for being here.

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|

738 ^STATEMENT OF JONATHAN SPALTER

739 } Mr. {Spalter.} And thank you, Chairman Walden and
740 members of the subcommittee for giving me the opportunity to
741 testify on behalf of Mobile Future and our member companies.
742 My name is Jonathan Spalter and I am Chairman of Mobile
743 Future. We represent innovators across the wireless
744 ecosystem, and I sit before you, I think, at a very, very
745 hopeful time for our community.

746 It is now believed by many scientists that there has
747 already been a child born in the world who will live to 150
748 years old. What an exciting notion for our children and our
749 grandchildren. These leaps and bounds in the quantity and
750 the quantity of our lives are in no small part due to the
751 astounding progress we are all witnessing at the nexus that
752 we are talking about today of health care and mobile
753 innovation.

754 This morning I would like to very focus very practically
755 my comments on what mobile innovators need from government to
756 help us all advance our health. We know that the virtuous

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757 cycle of investment in the mobile ecosystem from networks to
758 devices to applications provides an unparalleled foundation
759 for health innovation, and I believe government can help
760 build on it by providing our mobile health innovators four
761 key and achievable certainties. First, a clear understanding
762 of where regulation begins and where it ends. The mobile
763 medical app guidance now has been pending for 2 years. Clear
764 guidelines and regulatory certainty are needed now,
765 commonsense and affordable approval processes that are
766 measured in months, not in years, timely decisions across
767 government that of course encourages a careful balance to
768 safeguard patient safety and privacy on the one hand, which
769 we all care about, without inhibiting the development and use
770 of mobile medical apps, and finally, basic fairness when it
771 comes to the taxes we pay, all consumers pay, on wireless
772 services and applications. Bottom line: Americans would
773 benefit from clear guidelines on when applications go to
774 which government agency and for what set of approvals.

775 But let us also not forget that none of this progress
776 would be possible without spectrum and without investment,
777 and therefore it is imperative that the incentive auctions

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778 which are being designed now at the FCC are open and
779 inclusive so that all Americans can take advantage of
780 wireless health applications, and it is also worth noting
781 that the needed spectrum is held by government agencies,
782 significantly held by government agencies, so all of our
783 eyes, all of America's eyes are on the federal agencies who
784 hold much of this underutilized spectrum hoping they will
785 make a meaningful contribution.

786 I know that all of us can personalize this progress that
787 we are talking about today. My daughter Willa was diagnosed
788 2 years ago at age 8 with type 1 diabetes. She has been
789 extremely fortunate that from her very first week with the
790 disease to have been in a clinical trial at Stanford
791 University that is pursuing the holy grail of diabetes
792 research: the artificial pancreas. Even having worked in
793 mobile innovation and technology myself for years, I wasn't
794 prepared, my family wasn't prepared for just how personally
795 and profoundly relevant mobile innovation would become so
796 quickly to my daughter. On the first day of her trial, there
797 was her endocrinologist, Bruce Buckingham, and her research
798 nurse, Jen Block, explaining the research and the hope that

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799 it holds for 3 million Americans who are dealing with this
800 disease. And then Dr. Buckingham, not really knowing what I
801 do for a living, spoke about the importance of spectrum as he
802 explained the wireless sensors that were all around my
803 daughter's hospital room and the wireless glucose monitor
804 that she now wears in her body. The medical team included
805 software coders, application developers, algorithm writers,
806 network engineers, all pushing together towards what could be
807 and I indeed hope will be nothing short of a revolution in
808 diabetes management, and this is the future of American
809 health care. We all have a personal stake in speeding its
810 process, and ultimately this is not about government stepping
811 away, rather it is a profound opportunity for government to
812 lean in and demonstrate that it too can innovate, that it can
813 act flexibly, that it can move quickly with common sense and
814 with the understanding that innovation is born of many, many
815 things including a healthy dose of humility and restraint
816 when it comes to regulation.

817 So on behalf of application developers and wireless
818 innovators across our country, on behalf of my little girl
819 and the millions of Americans who are managing chronic

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820 diseases, I really thank you for the opportunity to testify
821 about our Nation's promising mobile future, and I really look
822 forward to your questions.

823 [The prepared statement of Mr. Spalter follows:]

824 ***** INSERT 4 *****

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|
825 Mr. {Walden.} Mr. Spalter, thank you for sharing your
826 very powerful story with us. It really sheds clear light on
827 our task here, and of course, it also shows that we are the
828 most important subcommittee in the Congress because we did
829 make available new spectrum and we are continuing to pursue
830 the government excess spectrum as we might find.

831 Mr. {Spalter.} And that has the added advantage of
832 being true, Mr. Chairman.

833 Mr. {Walden.} Thank you. You are welcome to come back
834 on a weekly basis. Seriously, thank you very much and thanks
835 for the work you are doing.

836 We will now go to Dr. T. Forcht Dagi, I believe, MD,
837 MPH, DmedSC--I will let you explain all of those things--
838 Partner at HLM Venture Partners. We are delighted you were
839 able to get another flight and get down here from Boston.
840 Thank you very much. Go ahead and push that button in front
841 of you there.

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|
842 ^STATEMENT OF T. FORCHT DAGI

843 } Dr. {Dagi.} Thank you, Mr. Chairman. Chairman Walden,
844 Ranking Member Eshoo, members of the subcommittee, I am Dr.
845 T. Forcht Dagi. I am a Partner of HLM Venture Partners based
846 in Boston, Massachusetts, and San Francisco, California. I
847 am a board-certified neurosurgeon trained at Johns Hopkins
848 and the Massachusetts General Hospital and hold or have held
849 leadership positions in clinical and academic medicine for
850 over 20 years. I am Chair of the Committee on Perioperative
851 care of the American College of Surgeons at present, and I
852 hold a professorial appointment at Harvard Medical School.

853 On behalf of HLM Venture Partners, the venture industry
854 and the entrepreneurial community, and also as a physician
855 devoted to the betterment of health care, it is my privilege
856 to testify before this committee on the subject of mobile
857 medical apps, MMAs.

858 Venture capitalists are committed to the funding of
859 American's best and most innovative entrepreneurs. They work
860 closely to transform breakthrough ideas and to emerging

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861 growth companies that drive job creation and economic growth
862 in the United States.

863 One of the top priorities for health care and life
864 science investors is to work and discover innovative
865 solutions that address unmet medical needs, enhance health
866 care outcomes and lower overall health care costs while
867 preserving the safety and the quality of the American health
868 care system.

869 For investment to grow in the formative stages of
870 emerging medical mobile applications, there need to be well-
871 defined regulatory pathways to market. Uncertainties in the
872 regulatory environment create significant risk for innovative
873 companies and deter investment in many promising ideas. We
874 believe that regulatory pathways should be risk based,
875 transparent, consistent, predictable, and above all, balance
876 the problem of patient safety and its protection against
877 innovation.

878 I believe that medical mobile applications will prove to
879 be a central, important and potentially critical tool in
880 optimizing communications among clinicians and especially
881 between clinicians and patients. Also, they will help

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882 broaden and sustain shared decision making, which is a
883 critical part of any type of health care reform. I believe
884 that MMAs will prove invaluable for patient engagement in
885 education. They can materially enhance integrated strategies
886 for health care, help coordinate the management of chronic
887 disease and promote patient safety while lowering health care
888 costs. Here are some examples of the critical roles they
889 already play. They are used to help diabetics follow and
890 refine insulin regimens. Mr. Spalter, I didn't know you were
891 going to speak to that. Thank you. They are used to screen
892 for diseases of the retina, for telemedical consultations, to
893 help patients with congestive heart failure avoid
894 readmission, to diagnose moles and screen for cancer, and to
895 coordinate across groups of physicians in different
896 institutions. They provide a means for sending sentinel
897 emergency alerts to providers. They also facilitate home
898 health care and remote monitoring of patients in other
899 settings like the intensive care unit. They hold tremendous
900 promise in patient care, and I emphasize, safety.

901 I would also like to emphasize my concern about the 2.3
902 percent medical device tax with regard to medical innovation

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903 and U.S. job creation. We also believe Congress did not
904 intend to burden the emerging MMA companies with this new
905 tax. Their products are not included in the traditional
906 medical devices. The 2.3 percent tax on revenue has already
907 started to have detrimental effects on early-stage medical
908 device companies. They are regressive and repressive. It
909 creates a major market inefficiency by increasing the capital
910 intensity of innovation and discourages venture capitalists
911 from investing in these companies now and in the future. The
912 tax would be even more devastating for companies developing
913 MMAs because of their revenue structure.

914 The tax of 2.3 percent sounds modest but it is not.
915 This is a tax on revenue. It is not a tax on profits. The
916 vast majority of entrepreneurial ventures developing MMAs are
917 very small and very early. Some of the companies in which we
918 invest may in fact generate some revenue but very unlikely to
919 generate profit. Revenues are plowed back into the company
920 for growth, and therefore the 2.3 percent tax on small
921 startup companies delays their ability to reach profitability
922 and increases the amount that must be invested before a
923 company can become cash flow positive.

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924 Venture capitalists and entrepreneurs stand ready to
925 participate along with other public and private stakeholders
926 to find solutions that will help move these important
927 innovations into the health care system. We would like to
928 offer the following recommendations to help stimulate
929 investment in this very important sector.

930 First, promote a regulatory framework that is
931 predictable, consistent, transparent and risk based. The
932 Food and Drug Administration issued draft guidance for mobile
933 medical applications on the 21st of July 2011. This guidance
934 addresses some regulatory concerns and reduces some
935 regulatory uncertainty but leaves open questions around
936 enforcement discretion decisions. The uncertainty must be
937 resolved. Second, the FDA and other stakeholders are
938 encouraged to collaborate and formulate alternative oversight
939 frameworks that meet the goals of patient safety and mobile
940 medical applications but also encourage and foster innovation
941 and invention. Third, we would ask that the FDA solicit very
942 broad input in evaluating new regulatory frameworks,
943 especially from those at the forefront of the innovation that
944 promotes health care transformation. And finally, we would

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945 ask that mobile medical applications that are defined as
946 medical devices be exempted from the 2.3 percent medical
947 device tax.

948 Mr. Chairman, Member Eshoo, members of the subcommittee,
949 thank you for the opportunity to testify. I look forward to
950 working with you to address these critical issues.

951 [The prepared statement of Dr. Dagi follows:]

952 ***** INSERT 5 *****

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953 Mr. {Walden.} Dr. Dagi, thank you very much for your
954 very learned testimony.

955 We will now go to Dr. George Ford, who is the Chief
956 Economist, Phoenix Center for Advanced and Legal Economic
957 Public Policy Studies. Dr. Ford, we are delighted to have
958 you. Please go ahead with your testimony.

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|
959 ^STATEMENT OF GEORGE FORD

960 } Mr. {Ford.} Chairman Walden, Ranking Member Matsui and
961 members of the committee, thank you for the invitation to
962 speak today and appear before this committee again.

963 At issue in this hearing is the role of FDA oversight in
964 health-related applications for mobile devices and the
965 platforms on which they run. MHealth applications are
966 believed to have great potential to promote better health and
967 improve the efficiency of the health care system. MHealth
968 can also help address the documented health in lower-income
969 segments of the population where the provision of health
970 services and treatment compliance can be challenging. In my
971 testimony today, I touch upon a couple of thoughts about the
972 possible regulation of mobile applications and platforms as
973 medical devices by the FDA.

974 First, by its very nature, regulatory intervention into
975 mHealth by the FDA will have direct implications for the
976 Nation's mobile communications industry. Mobile
977 applications, mobile devices and mobile networks are all part

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978 of the mobile communications ecosystem. In a greater or
979 lesser degree, to touch one, is to touch them all. United
980 States mobile industry is a true American success story, and
981 the mobile app economy is said to employ about a half a
982 million persons. Many believe that the continued growth in
983 the mobile sector both in size and innovative capacity is
984 critical for the U.S. economy. One study suggests that the
985 diffusion of new technology and mobile wireless
986 communications supports about 400,000 jobs annually, and the
987 billions invested annually in mobile and fixed networks
988 supports and creates hundreds of thousands of jobs.

989 Accordingly, regulating mobile applications is not only
990 a health care issue but a much broader economic one. The
991 difference between a good decision and a bad decision
992 regarding the FDA's regulation of the mobile sector may have
993 significant economic impacts. Indeed, economic theory and
994 ample literature demonstrate that the inevitable and arguably
995 intended effect of FDA involvement is to raise the cost of
996 innovation, to alter the trajectory of innovation, to reduce
997 competition and to favor larger firms that can afford the
998 overhead of dealing with a federal regulatory agency. In a

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999 tradeoff with efficiency and efficacy and safety, these
1000 negative effects may be acceptable. Gains from improvements
1001 in safety and quality may be sufficient to offset the lost
1002 innovation and higher prices from less competition.
1003 Normally, the cost-benefit tradeoff is limited to the health
1004 sectors, but in the mobile ecosystem, the FDA's intervention
1005 could spill over into the entire mobile broadband industry.
1006 The dangers are significant, and I applaud this committee for
1007 taking this matter seriously.

1008 Second, while the scope of the FDA's regulation of
1009 mHealth is a complex issue on its own, the decision is made
1010 ever more complex by the Affordable Health Act's medical
1011 device excise tax. Regulation and taxation are completely
1012 different questions, and there is no reason to believe and
1013 every reason to suppose that the proper methodologies for
1014 choosing when is appropriate or not will be quite different
1015 in scope and severity. Taxes may or may not raise revenues,
1016 but taxes always discourage the activity being taxed and play
1017 no apparent role in ensuring the safety of the product being
1018 sold. Yet the role of the FDA in assessing mobile health
1019 applications cannot be treated today as independent of the

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1020 tax question since defining applications medical devices may
1021 very well lead to the taxation of such applications under the
1022 Affordable Health Act.

1023 In addition, given health disparities for low-income
1024 Americans and given the expectation that mHealth will be
1025 particularly effective with low-income Americans, the medical
1026 device tax may prove to be a regressive tax.

1027 Moreover, the medical device can be described, or what I
1028 describe as a virtue tax. Normally, the government applies
1029 taxes to items it wants people to consume less of, that is,
1030 sin taxes. The medical device tax, in contrast, applies to
1031 items a government agency has declared to be good for people.
1032 If we want innovation to drive a healthier America, then why
1033 tax such innovation? It doesn't seem to be very good policy,
1034 perhaps doing more harm than good.

1035 Finally, and perhaps most significantly, I believe the
1036 FDA's draft guidance leaves the door wide open for inserting
1037 the FDA into the innovation flow of mobile handsets, tablets
1038 and other devices, or what we refer to as platforms. There
1039 are good reasons to believe that formal role for the FDA in
1040 the mobile handsets and tablets would significantly curtail

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1041 the pace of innovation in that sector, an innovative pace
1042 that is rapid and highly beneficial. My written testimony
1043 discusses this concern in detail.

1044 A critical question is: could a regulator or tax
1045 collector or even an overzealous regulator or tax collector
1046 make a legally defensible argument that these general purpose
1047 devices or even the entire mobile network are medical devices
1048 and thus subject to regulation or the medical device tax? In
1049 an ecosystem like the wireless industry where all the
1050 components are tightly intertwined, where does the line get
1051 drawn on what is and what is not a medical device?
1052 Obviously, clarity is needed, and there needs to be some
1053 limitations on the scope of the FDA's reach lest regulation
1054 and taxation become very broad in a mobile ecosystem and do
1055 significant damage to innovation in the sector.

1056 Mr. Chairman, thank you again for the invitation to
1057 testify today. I welcome any questions.

1058 [The prepared statement of Mr. Ford follows:]

1059 ***** INSERT 6 *****

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|
1060 Mr. {Walden.} Dr. Ford, thank you very much for your
1061 testimony and that of all of our witnesses today. I think it
1062 has helped explain why we are doing this hearing to begin
1063 with because we kept hearing that there is a lot of
1064 uncertainty in the marketplace that may indeed be slowing
1065 down, stifling investment, innovation and new U.S. job growth
1066 and technologies, so that is why we are doing this hearing,
1067 and I know Mr. Waxman, who had to leave, and I understand
1068 that we all have to juggle here, thinks the law is very
1069 clear. Obviously, you all don't, especially when it comes to
1070 the FDA's lack of a final rule in this area. Look, we are
1071 all for patient safety, and there is no separation here. We
1072 are all patients eventually. We want patient safety. We
1073 don't want fraudulent devices on the market. We recognize
1074 the importance of appropriate regulation.

1075 But Dr. Ford, you reminded me of something I always was
1076 told, that if you want less of something, tax it more, and
1077 you know, you really summed it up and basically said, look,
1078 you are taking innovation in health care, don't we want more
1079 of that. Is that not what you were--

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1080 Mr. {Ford.} Yes.

1081 Mr. {Walden.} And a gross-receipts tax, which could
1082 completely stifle innovation.

1083 Mr. {Ford.} The gross-receipts tax will significantly
1084 deter involvement of companies in this space. It is a fairly
1085 severe tax, particularly when we are dealing with innovation,
1086 new products, new companies and even hospitals and doctors
1087 themselves have entered into the business to design their own
1088 applications. This virtue-tax issue is an interesting one,
1089 and I think it is weird when you have a government agency say
1090 okay, here is the good stuff and now we want you not to use
1091 it so much.

1092 Mr. {Walden.} We have run into that in my own State of
1093 Oregon. There was a medical device manufacturer who for
1094 various reasons, but they said including the new gross-
1095 receipts tax, I believe laid off, what a couple hundred
1096 people already, and I am hearing about it around the country.

1097 Dr. Dagi, are you seeing a move to take this offshore in
1098 terms of innovation and development and offshore these jobs
1099 and all that now, or not?

1100 Dr. {Dagi.} I am, sir, seeing two things. We are

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1101 seeing that many companies attempted to take this offshore,
1102 and they are also attempting--they are also thinking about
1103 launching offshore where profits will not be taxed and where
1104 the regulatory path is both simpler and more direct.

1105 Mr. {Walden.} So is it accurate to say that Obamacare
1106 is driving this sort of medical technology and innovation to
1107 other countries because of this tax?

1108 Mr. {Ford.} I am not expert enough to say that it is
1109 Obamacare specifically.

1110 Mr. {Walden.} Well, but the 2.3 percent tax is part of
1111 the President's health care law.

1112 Mr. {Ford.} Yes, sir.

1113 Mr. {Walden.} All right. And so Mr. Spalter, what does
1114 that mean, people like your daughter and the innovation that
1115 could come from that? Are you concerned about a reduction in
1116 innovation in this area and that these really smart people
1117 who are probably, I don't know, 14 sitting in a garage
1118 somewhere creating apps are going to create another Angry
1119 Birds as opposed to something in this area? And I would open
1120 that up to anybody here. That is my concern is that public
1121 policy has an impact. Is it going to have a negative impact

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1122 here, which is not what we want.

1123 Mr. {Spalter.} America's wireless consumers, all of are
1124 actually paying roughly 17 percent of our monthly bill of our
1125 wireless services to taxes. Wireless services are taxed at
1126 two and a half times other goods and services on average
1127 across our country. We are very concerned, Mr. Chairman,
1128 that these types of taxes, if they are applied to mobile
1129 medical applications and devices, will stifle innovation,
1130 will tempt entrepreneurs to pursue, as you suggested, other
1131 types of innovation and apply their genius and their efforts
1132 to other parts of the mobile ecosystem rather than efforts to
1133 make our children, our families, our parents healthier. So
1134 there is an impact and we need to be very, very vigilant and
1135 cautious about going down this path.

1136 Mr. {Walden.} Mr. Jarrin, in your testimony you
1137 mentioned that as many 5 percent of the 27,000 health-related
1138 apps could be subject to regulation, yet as our data would
1139 indicate, fewer than 80 medical apps have gone through the
1140 FDA process. I was a journalism major, not a math major, but
1141 I think that leaves 1,200 apps in a state of regulatory
1142 uncertainty, roughly.

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1143 Mr. {Jarrin.} Correct.

1144 Mr. {Walden.} Is that accurate, and are you concerned
1145 about the time delays and all of that?

1146 Mr. {Jarrin.} Yes, we are very concerned about the fact
1147 that we haven't found any clear guidance. The draft guidance
1148 document needs to be finalized, and we were hoping that
1149 through that finalized document we would have a better
1150 understanding of whether or not these apps that are on the
1151 market should be regulated or the agency will use their
1152 enforcement discretion to not regulate them. That is a very
1153 important thing, because when you are talking about a device,
1154 a medical device will always be a medical device. It is up
1155 to the agency whether or not they are going to proactively
1156 regulate that medical device, and I am speaking about the
1157 very low risk end of devices, not medium risk or higher risk
1158 devices, which I think we all agree are not the ones that we
1159 are discussing. But when we are talking about a mobile
1160 application, a health application, there is a lot of
1161 ambiguity. For example, if I were to use some of the terms
1162 like ``well being'' in my marketing claims or ``heart
1163 health'' or ``sleep deprivation'' or ``patient

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1164 satisfaction'', ``stress'', even mentioning--

1165 Mr. {Walden.} Do those trigger FDA?

1166 Mr. {Jarrin.} Unsure, and that is the kind of clarity
1167 that we are looking for from the agency, and they seemingly
1168 were ready to deliver that clarity. I believe in this very
1169 building, less than a year ago, Dr. Jeffrey Shuren, the
1170 center director, spoke about some of the things they were
1171 contemplating to take off the table, and they spoke about
1172 some of the things like medication adherence software
1173 potentially could be off the table, BMI calculators, I mean
1174 body mass index calculators, drug-drug formula, drug dosing
1175 calculators. That would have been very helpful for the
1176 industry.

1177 Mr. {Chodor.} Can I add something?

1178 Mr. {Walden.} If you are real quick, because I am over
1179 my time.

1180 Mr. {Chodor.} Well, we are hearing from developers and
1181 hospitals and docs that a lot of them are waiting on the
1182 sidelines until there is final--when are the guidelines going
1183 to come out, is there going to be a tax until they start
1184 developing in the space.

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1185 Mr. {Walden.} And those are separate issues?

1186 Mr. {Chodor.} Separate issues, but they are not going
1187 forward because they are waiting.

1188 Mr. {Walden.} All right. Thank you all, and I thank
1189 the courtesy of the committee, we went over, but we will turn
1190 now to Ms. Matsui for 5 minutes.

1191 Ms. {Matsui.} Thank you, Mr. Chairman.

1192 Let me just go through this. You know, the Affordable
1193 Care Act was carefully drafted so not to add to the deficit.
1194 It imposes a small tax on a wide range of industries that
1195 will benefit from expansion of health insurance coverage for
1196 nearly 30 million Americans under the reform. Now, one such
1197 levy is the 2.3 percent excise tax on medical devices. Now,
1198 let me just--without getting into the merits of the device
1199 tax, I would like to ask some questions to clarify quickly
1200 the applicability to smartphones, tablets and app stores.

1201 Mr. Thompson, is FDA proposing to regulate devices like
1202 smartphones and iPads or app stores like the iTunes store?

1203 Mr. {Thompson.} I think in the draft guidance, they did
1204 about the best they could to explain no, that they don't want
1205 to regulate those articles if they can avoid it. Admittedly,

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1206 it is not the model of crafting but I think their intent came
1207 through.

1208 Ms. {Matsui.} Okay. So if the FDA is not regulating
1209 smartphones, tablets or app stores, would they be subject to
1210 the medical device tax?

1211 Mr. {Thompson.} So if they are not medical devices,
1212 they would not be subject to the medical device tax.

1213 Ms. {Matsui.} So Mr. Thompson, it is also my
1214 understanding that IRS looks at something called the retail
1215 exemption when examining the applicability of medical device
1216 devices.

1217 Mr. {Thompson.} Right.

1218 Ms. {Matsui.} Could you explain that exemption?

1219 Mr. {Thompson.} Well, the exemption is meant to cover
1220 medical devices that are basically sold at retail for use by
1221 laypeople in managing their health, and so those are exempt
1222 from the tax, and it covers most things other than, for
1223 example, the professional use apps that we have referred to a
1224 few times. So whether it is for reading an ultrasound image
1225 for a doctor or whatever, those apps would be subject to the
1226 tax. But stuff sold to consumers through the app store would

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1227 not, as I understand it.

1228 Ms. {Matsui.} Okay. Mr. Chodor, you state in your
1229 testimony that a fair reading of the final regulations
1230 implementing the tax should lead one to conclude that the
1231 retail exemption applies to all smartphones and tablets that
1232 are on the market today. So do you agree with Mr. Thompson
1233 that based on current IRS rules, smartphones and iPads are
1234 not subject to the medical device tax?

1235 Mr. {Chodor.} Absolutely, Happtique agrees with that.

1236 Ms. {Matsui.} Okay. So from all you have stated then,
1237 smartphones and tablets will not be taxed as medical devices.

1238 Now, I understand, you know, the frustration here, and I
1239 am frustrated too regarding the draft of 2011, and I agree
1240 the FDA needs to move swiftly to finalize the mobile medical
1241 app guidance. I understand that. The clarity of the final
1242 guidance can improve confidence for investment and bringing
1243 new innovative applications to the consumer, and I wholly
1244 agree with you there, and I think we really need to encourage
1245 that in a very expeditious manner.

1246 I want to move on to something else here. Spectrum is
1247 something that I am very much involved in, and we are all

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1248 involved on this committee. We understand how important that
1249 is and how important it is to free up the federal spectrum.
1250 Mr. Spalter, your testimony discusses the importance of
1251 making more spectrum available to expand mobile broadband,
1252 and I couldn't agree more. Do mHealth applications have
1253 particular spectrum needs? Are hospitals and other health
1254 care providers going to be affected if we do not address the
1255 looming spectrum crunch?

1256 Mr. {Spalter.} I believe profoundly yes. Mobile health
1257 applications are at their nascent stage now. We are
1258 expecting there are going to be extraordinary levels of
1259 adoption, innovation, new products, new services, new
1260 applications brought to the market, and we need to have a
1261 predictable and reliable continuum of access to spectrum for
1262 enabling and deploying these innovations. Similarly, for
1263 hospitals, patient communities, professional health care
1264 providers, the need for secure, reliable, profoundly strong
1265 and scalable networks is only going to become more important,
1266 and that is based on the availability of spectrum.

1267 Ms. {Matsui.} Right, exactly, but the unlicensed
1268 spectrum is also necessary for you too, correct?

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1269 Mr. {Spalter.} Both unlicensed and licensed spectrum
1270 are going to be critical to advancing the prospect and the
1271 promise of innovation in America's health care.

1272 Ms. {Matsui.} So you think that this is going to be the
1273 future, and in essence, as fast as we can do this, the better
1274 it is going to be?

1275 Mr. {Spalter.} The President has spoken about the
1276 fierce urgency of now for the sake of our patients, for the
1277 sake of our families. Nowhere is that urgency more important
1278 than in the health care of our citizens, and mobile
1279 innovation based and built on spectrum assets and reliable
1280 networks is what will get us there.

1281 Ms. {Matsui.} Well, thank you very much. I see my time
1282 is exceeded. I yield back. Thank you.

1283 Mrs. {Ellmers.} [Presiding] Thank you. I now turn to
1284 Vice Chairwoman Blackburn for her questions.

1285 Mrs. {Blackburn.} Thank you, Madam Chairman, and thank
1286 you all again for being here with us.

1287 You know, listening to you all and listening to some of
1288 the questions, I think that we are kind of walking through a
1289 period of the what-ifs, and some of the what-ifs are, well,

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1290 if it is light touch, if they stay out of our business, we
1291 are going to do this, and if it is overregulating, talk to
1292 me. If the FDA says, you know, we are going to go after the
1293 device, you know, all of our mobile devices as well as go
1294 after some of these 80,000 apps, what is that going to do?
1295 Because we are talking about a gross-receipts tax, not a tax
1296 on your profits. So talk to me. If they go heavy-handed on
1297 this, does it stifle all the innovation? Does it shut it
1298 off? Anybody that wants to speak, raise your hand and then I
1299 will recognize you. Go right ahead.

1300 Dr. {Dagi.} The problem is that there is a risk to
1301 developing any kind of a medical application or medical
1302 device. For investors to come in and to provide the
1303 investment capital, they have to see a reward. Sooner or
1304 later, reward is going to be based on profits, but in the
1305 early stages it is going to be based on gross revenues. If
1306 you cut the gross revenues, first of all, you cut the
1307 valuations of the company. They become less valuable and
1308 less likely to be--

1309 Mrs. {Blackburn.} So it is like anything else? The
1310 money is going to find an easier path?

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1311 Dr. {Dagi.} It will find an easier path.

1312 Mrs. {Blackburn.} Okay. I appreciate that.

1313 Anybody, anything else to add to that? No? Okay. I
1314 want to--Mr. Chodor, I think that probably you are the one to
1315 go to on this. I saw the national coordinator's Patient
1316 Safety Action Plan, and of course, with all of your health
1317 information management systems, a lot of that work is done
1318 down in my district in Tennessee, and we appreciate that they
1319 are there, and I know that for the HIMS members, many times
1320 with meaningful use, you have got the private certifications
1321 that are working in that space. Do you think a similar model
1322 would work for the mobile medical apps and have it go through
1323 that process as opposed to a more lengthy regulatory process?

1324 Mr. {Chodor.} From Happtique's point of view, we don't
1325 think it would be the same because when you take an app, as
1326 we were mentioning earlier today, where it takes a mole and
1327 takes a picture of it and says is it a melanoma or not, and
1328 someone is going to make a clinical decision based on an app,
1329 we believe that is something that should go in the hands of
1330 the FDA, an organization that has done that, and that should
1331 be done by, you know, the government as opposed to private

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1332 sector. Just like Happtique's certification program, we
1333 aren't covering apps that should be FDA. We think those
1334 apps, you know, that are really making clinical decisions
1335 should be regulated.

1336 Mrs. {Blackburn.} Okay. Anybody else want to add to
1337 that? No? Nothing else?

1338 Okay, Mr. Jarrin. The IOM recommendations, when did you
1339 suggest FDA move forward with its draft guidance?

1340 Mr. {Jarrin.} When did we suggest?

1341 Mrs. {Blackburn.} Yes.

1342 Mr. {Jarrin.} We suggested when we offered comments to
1343 the agency back in October of 2011. The agency released
1344 their draft guidance document in July. They opened up a 90-
1345 day comment period, and I believe they accepted over 700
1346 pages of comments from over 100 stakeholders in the industry
1347 and the public, et cetera, and we were one of those, meaning
1348 Qualcomm Incorporated. We submitted a document, which I
1349 actually appended to my written statement, so you will find
1350 it at the back of my written statement.

1351 Mrs. {Blackburn.} Okay, then. You and Mr. Thompson,
1352 let me ask you this. Do you think the FDA or Congress should

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1353 set the policy on how we move forward with IMS regulation?

1354 Mr. {Jarrin.} IMS regulation?

1355 Mrs. {Blackburn.} Yes, with the management systems,
1356 health management systems, the mobile apps. Do you think it
1357 should be us or FDA?

1358 Mr. {Jarrin.} I think FDA is squarely within its
1359 jurisdiction right now to move and to act, and that is what
1360 they had begun to do. We took a lot of their initial actions
1361 as a very promising indication to the industry at large that
1362 they were willing to work with all of us.

1363 Mrs. {Blackburn.} Okay. Let me get Mr. Thompson in.

1364 Mr. {Thompson.} I agree with Mr. Jarrin. I think FDA
1365 is taking a fairly measured look at health information
1366 technology and is trying to do in some ways the least that
1367 they can do in the hopes of allowing innovation to flourish
1368 as much as possible, so I am optimistic now. Having said
1369 that, I want to see the document because--

1370 Mrs. {Blackburn.} Yes, kind of back to Dr. Dagi's point
1371 that, you know, if the overreach is there, the money, the VC,
1372 the funding stops.

1373 Mr. {Thompson.} Right. We need to see the document.

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1374 Ms. {Blackburn.} Thank you. Yield back.

1375 Mrs. {Ellmers.} I now turn to Mr. Waxman.

1376 Mr. {Waxman.} Thank you very much, Madam Chair.

1377 First of all, let me say that I agree that innovation is
1378 important, that overregulation can harm public health just as
1379 underregulation can. I think there can be great value in
1380 discussing how to determine the correct balance and how to
1381 achieve it, but when I read the Republican memo for today's
1382 hearing, I got the impression that the only two issues of
1383 interest to my colleagues on the other side of the aisle with
1384 respect to health IT whether the FDA will inhibit innovation
1385 and whether all of our smartphones will be subject to a
1386 device excise tax. I understand Mr. Walden agreed with my
1387 earlier statement that there is a federal interest in
1388 ensuring patient safety, and I very much appreciate that.

1389 I would like to hear from our expert witnesses whether
1390 you think there is a need for any FDA oversight of any mobile
1391 medical apps. In my opening statement, I mentioned the
1392 example of the apps that claim to be able to educate the
1393 consumers as to whether a mole is a sign of a melanoma.
1394 Clearly, if such an app is accurate, it could lower health

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1395 care costs by minimizing unnecessary trips to the doctor for
1396 the nine moles and could save lives by encouraging people to
1397 go to a doctor when they might otherwise have ignored a mole
1398 that could kill them. On the other hand, an app that is
1399 inaccurate can do just the opposite.

1400 So Mr. Chodor, do you think such an app warrants going
1401 through an FDA premarket clearance process just as it would
1402 have to do if it were a conventional standalone medical
1403 device?

1404 Mr. {Chodor.} Yes, we believe that any app that is
1405 going to make clinical decisions should go through a FDA type
1406 of program.

1407 Mr. {Waxman.} Thank you. Mr. Thompson, what do you
1408 think?

1409 Mr. {Thompson.} I agree with that. I think if you look
1410 at the 80 apps, for example, that have already been submitted
1411 to FDA, they represent fairly high-risk technologies that
1412 should be reviewed by FDA.

1413 Mr. {Waxman.} And Mr. Jarrin?

1414 Mr. {Jarrin.} Yes, I would agree with that assessment
1415 as well.

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1416 Mr. {Waxman.} Mr. Spalter, do you agree?

1417 Mr. {Spalter.} I do agree. I think that the important
1418 issue in addition to whether there should be preapproval is,
1419 we also need to keep our eyes and our minds focused on the
1420 costs to application developers who are going through those
1421 approval processes, the time it takes, and the importance of
1422 having a precedential document finally that will set forth
1423 the clear guidance and outline and suggest what the real
1424 balance is between assuring, as we need to, patient privacy
1425 and security at the same time not inhibiting innovation.

1426 Mr. {Waxman.} Good points. Dr. Dagi, do you agree that
1427 there ought to be an FDA premarket clearance for some of
1428 these devices?

1429 Dr. {Dagi.} Absolutely. There is a balance between
1430 innovation and patient safety. Patient safety comes first,
1431 and the balance has to be there as well.

1432 Mr. {Waxman.} And Dr. Ford, do you agree or disagree?

1433 Mr. {Ford.} Sure. There is a balance that has to be
1434 maintained. I think it depends on perhaps what
1435 representations are made by a particular application, things
1436 like that.

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1437 Mr. {Waxman.} To Mr. Thompson, in Mr. Jarrin's
1438 testimony, he stated that 500 new mobile health apps are
1439 being launched every month compared to 400 apps that were
1440 being launched every month just a year ago. Those statistics
1441 indicate to me that the mobile medical app industry is
1442 growing at a healthy rate. We all want to see this pace of
1443 innovation in the mobile medical app market continue and
1444 accelerate. Do you think that the certainty of final
1445 guidance from FDA would help the mobile medical app industry
1446 continue to attract investment?

1447 Mr. {Thompson.} Absolutely. Getting a document out
1448 there in final form will relieve a lot of the uncertainty,
1449 and I think folks who have been sitting on the sidelines will
1450 be encouraged to jump in at that point.

1451 Mr. {Waxman.} Are the members of your coalition
1452 concerned that FDA has plans to aggressively regulate this
1453 industry or do they just want certainty?

1454 Mr. {Thompson.} It is a little bit of both, in all
1455 honesty. For the most part, we want certainty. We always
1456 live in some fear of overregulation but we haven't seen any
1457 evidence of that, so as of right now, we feel pretty good

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1458 about it.

1459 Mr. {Waxman.} Good. Mr. Chodor, you discussed
1460 Happtique's app certification program and the need for an
1461 objective validation process for mobile medical apps. Do you
1462 see Happtique's certification as a substitute for any and all
1463 regulation of mobile medical apps?

1464 Mr. {Chodor.} Absolutely not. It is an add-on.

1465 Mr. {Waxman.} And what types of mobile medical apps
1466 should be subject to FDA oversight?

1467 Mr. {Chodor.} I think anything that is going to make a
1468 clinical decision, anything a doctor is going to use or
1469 patient is going to use that can lead to surgery or a
1470 clinical decision.

1471 Mr. {Waxman.} Do you believe an unfettered market
1472 creates incentives to ensure patient safety, and if not, who
1473 should step in to ensure patient safety?

1474 Mr. {Chodor.} That is a great question. I think it is
1475 a combination. I mean, in that case there is a place for the
1476 government and the federal agencies to participate in that,
1477 and for the public.

1478 Mr. {Waxman.} Of course, if a patient and a doctor

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1479 can't trust the efficacy of a product, that is not going to
1480 do much good.

1481 Mr. {Chodor.} Exactly.

1482 Mr. {Waxman.} Thank you very much. I yield back my
1483 time.

1484 Mrs. {Ellmers.} Thank you. I now turn to Mr. Latta for
1485 his questions.

1486 Mr. {Latta.} Thank you very much, and just following
1487 on. I think that as Chairman Walden said earlier, we want to
1488 make sure that there is a clear line out there for patient
1489 safety, and we also agree that there is the need out there
1490 for FDA to ensure that patients are safe, and we also have to
1491 make sure there is a clear line to make sure that those apps
1492 that are out there that need to be regulated and those that
1493 don't have to be delineated, and I think that is what we are
1494 hearing from our panel today, and I just want to again, as I
1495 had mentioned earlier, thank you all for being here today
1496 because again I think it is an excellent panel and excellent
1497 information that we are receiving here today, and if I can
1498 just start, Mr. Chodor, you know, I would like to go back to
1499 what you said a little bit earlier, you know, saying that

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1500 there is a clear need for the FDA to be reviewing these regs
1501 sooner than later. Would you want to just go into that a
1502 little bit?

1503 Mr. {Chodor.} Well, you know, it has been July 2011
1504 that they came out with their draft guidelines, comment
1505 period came back. The public needs to know, the developers
1506 need to know, hospitals need to know, doctors need to know
1507 what is going to be regulated and what is not going to be
1508 regulated. Right now, we are just sitting in this middle
1509 ground and no one knows, and I think that is the scariest
1510 part because the longer it takes, more apps are going to be
1511 developed, and should they be FDA approved or shouldn't they
1512 be FDA approved, nobody knows.

1513 Mr. {Latta.} Let me go to Dr. Dagi, and thank you very
1514 much for your effort. Many of us know what it is like to be
1515 on planes that are delayed or canceled, so we appreciate you
1516 making the effort to be here today. You know, just following
1517 on to that, when you are looking at the venture capitalist
1518 side, if folks don't have that line out there knowing how
1519 fast these things are going to be approved, what is that
1520 going to do for folks wanting to invest into these apps into

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1521 the future?

1522 Dr. {Dagi.} It is going to increase the risk of
1523 investment and venture capitalists will put their money
1524 elsewhere.

1525 Mr. {Latta.} Okay. And when you say putting their
1526 money elsewhere, does that mean taking that money offshore to
1527 have these apps developed?

1528 Mr. {Dagi.} They might.

1529 Mr. {Latta.} And in your testimony, you were giving
1530 some numbers. How much money are we talking about, do you
1531 think, that these medical device apps would be bringing in
1532 for venture capitalist and they would be investing into in a
1533 year's time?

1534 Dr. {Dagi.} That is a hard number to get a hold of
1535 right now because there are a number of things that may or
1536 may not be medical apps. We don't know whether the
1537 extension, for example, of patient engagement is a
1538 communication or whether it is a medical device. But
1539 probably I am sure we are talking about hundreds of millions
1540 of dollars but I can't give you a specific number at this
1541 point.

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1542 Mr. {Latta.} Well, you know, following up a little bit
1543 when you were just talking about folks wanting to make an
1544 investment in this, what about when they have to look at that
1545 2.3 percent medical device tax and they have to add that in
1546 to the equation? What does that do to an investor?

1547 Dr. {Dagi.} If 2.3 percent is taken off the top, you
1548 have a regressive and repressive tax that is going to tell
1549 the venture capitalist the return that you can get investing
1550 in this area will be curtailed at the very early stage, at
1551 the very vulnerable stage of company development. That is
1552 the fear: the risk increases.

1553 Mr. {Latta.} And Mr. Jarrin, again, thanks for your
1554 testimony today too, and also, I think that Chairman Walden
1555 had brought this up, but it is really looking at, again, on
1556 the FDA side, you know, not getting these things done quickly
1557 and slowing down that development, and we used to talk about
1558 slowing down development, again, as you just have heard from
1559 Dr. Dagi and Mr. Chodor, what does that tell people out there
1560 if they want to get into this or not? I think the chairman
1561 had mentioned a little bit earlier about, you know, does that
1562 mean somebody doesn't get into the mobile medical app side

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1563 and they go and develop, you know, some type of a game or
1564 something like that, what does that mean to the industry?

1565 Mr. {Jarrin.} Well, it is really tough on the industry.
1566 I have got a great example. There is a company out in
1567 California called MedCell, which changed to Vocel, that had
1568 an application called the Pill Phone, and they brought it to
1569 market, and in construction with the FDA, they actually
1570 pushed the FDA and said we are thinking about making this app
1571 and we hope that you can help us make this app, and they
1572 ended up being a regulated app. The CEO of that company
1573 claims that that was very helpful to them because it made
1574 them make a better product. However, the FDA has mentioned
1575 that those apps potentially may not even have to undergo
1576 regulation. So he ended up spending several thousands of
1577 dollars going into the hundreds of thousands of dollars to go
1578 through all of the Good Manufacturing Practices and quality
1579 systems to actually ensure that it would really fall under
1580 the FDA guidelines and regulations, and if in fact, he
1581 wouldn't have had to go through that, then that is a major
1582 capital expense that he incurred technically for nothing, so
1583 we can also argue that it was actually better because his

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1584 product came out better in the long run. So you would have
1585 to weigh both sides, but I think that is very hard on the
1586 industry not knowing whether or not you are or are not going
1587 to be regulated because you have to take that into
1588 consideration.

1589 Mr. {Latta.} Thank you very much, and Madam Chair, I
1590 see my time is expired and I yield back.

1591 Mrs. {Elmers.} Thank you. I now turn to Mr. Lujan for
1592 his questions.

1593 Mr. {Lujan.} Thank you very much, Madam Chair, and to
1594 everyone that is here today, we really appreciate your time
1595 today.

1596 Mr. Chodor, I think the questions have been asked but I
1597 think just for clarification because of the memo that we
1598 received about today's hearing, I think that is why you are
1599 getting a lot of similar questions just to make sure that we
1600 are able to get answers to these questions. Do you think
1601 that some types of mobile medical apps deserve different
1602 levels of scrutiny than others?

1603 Mr. {Chodor.} Yes, I do.

1604 Mr. {Lujan.} And is there anyone on the panel that

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1605 disagrees with that? I don't hear anyone. That is good to
1606 hear.

1607 For example, some apps might not need any premarket
1608 oversight as you have described. For some apps, consumers
1609 and health professionals might expect a version of a
1610 voluntary Good Housekeeping seal that is adequate like your
1611 organization is providing, and some apps might warrant a
1612 little more mandatory federal oversight. Do you think the
1613 FDA's draft guidance recognizes these distinctions?

1614 Mr. {Chodor.} I think they do. We can't wait to see
1615 the final guidelines.

1616 Mr. {Lujan.} Well, and I appreciate the testimony today
1617 because one area where I have seen agreement by the entire
1618 committee today is that we want to push the FDA, we want the
1619 certainty associated with this document to be put into final
1620 form, so that way we are able to move on and work together.

1621 With that being said, Mr. Thompson, you mentioned in
1622 your testimony that there is already 40,000 apps available on
1623 smartphones and tablets under the broad mHealth category, and
1624 we saw them double just last year. Have you seen any
1625 slowdown in mHealth innovation since the passage of the

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1626 Affordable Care Act?

1627 Mr. {Thompson.} I haven't seen any slowdown. I am not
1628 in the best position. I think actually Mr. Jarrin follows
1629 those statistics better than I do, but my impression is that
1630 it is growing quite rapidly.

1631 Mr. {Lujan.} With that being said, Mr. Jarrin, have you
1632 seen a slowdown?

1633 Mr. {Jarrin.} No, no slowdown at all. As a matter of
1634 fact, it is almost like a hockey stick. Two years ago when I
1635 formed our comments to the agency, I believe that the figures
1636 I was using were about 13,000 apps in one of the app stores
1637 and 10,000 in the other, and those were not unique apps.
1638 When you hear the current statistics of 40,000 apps, I think
1639 it is even higher. It might be actually 45,000 apps, but
1640 some of those are the same company, just different types of
1641 the same app in essence, so you can't really count them as
1642 unique. My understanding from MobiHealthNews, which is one
1643 of the sources for the industry right now, is that there are
1644 27,000 unique apps, so in 2 years it has basically doubled,
1645 and that is just unique apps, so I see no slowdown at all. I
1646 think that this is a very dynamic, vibrant space.

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1647 Mr. {Lujan.} I appreciate that, Mr. Jarrin. The memo
1648 that we received today said that the Food and Drug
1649 Administration could potentially classify smartphones and
1650 tablets that run the apps as medical devices. I think that
1651 is one of the reasons that we are here today, and when you
1652 look at the FDCA section 201(h), it states that if a device
1653 addresses the diagnosis of a disease or other conditions or
1654 in the care and mitigation, treatment or prevention of
1655 disease, that it could be subject to one of these
1656 classifications. I just bought these really great pair of
1657 Nikes that have this little chip in them that communicates to
1658 my phone, so do we need to provide clarification that that
1659 shoe is not going to be classified as a medical device?

1660 Mr. {Jarrin.} Are you speaking to me, sir?

1661 Mr. {Lujan.} Yes, Mr. Jarrin.

1662 Mr. {Jarrin.} No, because that is a general health and
1663 fitness type of device.

1664 Mr. {Lujan.} I appreciate that, and that is the point
1665 that I wanted to make today is, you know, when I ride my
1666 mountain bike and I have a Bluetooth connection to it and it
1667 sends some information to my doctor and he says Ben, you have

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1668 gotten a little bit chubby since you have gone to Congress,
1669 you need to start watching what you are eating, you need to
1670 start running a little bit more, and so these other devices
1671 that are communicating to a mobile device, I think what has
1672 been clear today is that there is no evidence even in what
1673 the FDA has put out when we talk about a difference between
1674 component manufacturers and device manufacturers, that there
1675 is a concern there, but we can all agree again that we need
1676 to put the FDA together.

1677 And lastly, Madam Chair, as my time expires, I hope that
1678 there is agreement with the committee and we work with the
1679 chairman and Ranking Member Waxman that we put as much
1680 pressure as we can on the FDA to get this document out, that
1681 I heard a lot of concerns from my Republican colleagues about
1682 the 2.3 percent tax, and I completely hear their opposition
1683 to this. I am hoping that they can join me in voting against
1684 the Paul Ryan budget this week because the Republican budget
1685 released last week relies on the revenue generated by the
1686 medical device excise tax to achieve its revenue targets.
1687 So, look there are some ways to talk about this today and
1688 some ways to show opposition, but when it is included in the

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1689 blueprints associated with the future of what we are looking
1690 at here, there has to be a better way to do this.

1691 The only good thing I can say today, Madam Chair, is
1692 that I think we have seen some clear agreement in this area,
1693 and just one last thing. When we talk about the apps even in
1694 the startup companies and the concerns associated with the
1695 2.3 percent excise tax that was included in the Affordable
1696 Care Act, there is one other thing that startups making
1697 retail mobile applications have an explicit retail exemption
1698 in the law that excludes these types of apps along with
1699 products like contact lenses and hearing aids. That is the
1700 truth. So we as Members of Congress also need to be careful
1701 with how we create uncertainty when we are out saying things
1702 that sometimes mislead the public, and I hope that we can
1703 work together and make sure I can join with some of my
1704 friends and use those new Nike shoes and go for a little jog.
1705 Thanks, Madam Chair.

1706 Mrs. {Elmers.} Thank you, Mr. Lujan, and I would like
1707 to say as far as clarity and factual information, the Ryan
1708 budget does not in fact do that.

1709 I now turn to Mr. Shimkus.

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1710 Mr. {Shimkus.} Yeah, it is a nice attempt. We just
1711 think it is important to balance your budget by 10 years and
1712 start paying down debt, so I guess if balancing the budget in
1713 10 years and not paying down debt is not important to you,
1714 then I guess, you know, you go to your processes.

1715 Mr. {Lujan.} Would the gentleman yield?

1716 Mr. {Shimkus.} No, actually not. I was going to try to
1717 ask for time, but I think I will use mine on this debate.

1718 Mr. Dagi and Mr. Ford, in follow-up to my colleague's
1719 other questions, talk about that chip in the phone. Does it-
1720 -I mean, he is assuming that the whole panel agrees. Where
1721 do you stand on what could happen, Mr. Dagi first and Mr.
1722 Ford, with that example that my colleague just expressed?

1723 Dr. {Dagi.} It depends on the application, sir. If you
1724 have, for example, chips in shoes that can be used for a
1725 runner but can also be used to look at a child with cerebral
1726 palsy and use it to treat them--

1727 Mr. {Shimkus.} My colleague is not paying attention to
1728 your answer, and since I would hope that he would do that, go
1729 ahead.

1730 Mr. {Dagi.} The same chip can have multiple

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1731 applications, and traditionally, the FDA has regulated
1732 applications and clings as well as devices themselves, so the
1733 safety piece of it and the efficacy is one part. The second
1734 part is the application. We would ask for clarity on the way
1735 these are going to be regulated, and we would ask that the
1736 goalpost not be moved in the process of bringing devices to
1737 the market.

1738 Mr. {Shimkus.} Mr. Ford?

1739 Mr. {Ford.} Well, I think it is interesting that we
1740 keep asking the FDA for certainty about things and then we
1741 make certain claims about what they will or will not do. It
1742 has got to be one or the other. We either need certainty or
1743 we don't. The other issue with uncertainty that I think is
1744 important to clarify, resolving the uncertainty is not
1745 helpful in itself. What if we become very certain that they
1746 intend to regulate everything very heavily as class III
1747 devices and tax mobile phones and everything else? I don't
1748 think that would be very helpful for innovation. So
1749 resolving the certainty/uncertainty issue depends on what we
1750 become certain about and what we remain uncertain about. So
1751 resolving uncertainty is not really that helpful if we become

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1752 more certain that the regulation is going to be very heavy-
1753 handed.

1754 Mr. {Shimkus.} And that is a great segue. Mr. Jarrin,
1755 you talked about the hockey stick, all these new apps. How
1756 many of you actually have apps right now? And what is the
1757 approval process to have an app right now?

1758 Mr. {Chodor.} None.

1759 Mr. {Shimkus.} Why do you think we have so many apps?
1760 Now, I have got my iPad here. I have got 21 updates, map
1761 updates. If you had go through--let me ask another question.
1762 How often do you update an app, Mr. Chodor?

1763 Mr. {Chodor.} I mean, all developers do it differently.
1764 Some developers update it three, four, five times a year.
1765 Some developers are only updating once a year.

1766 Mr. {Shimkus.} So if you have to go through the same
1767 regulatory regime on approval of the original app and then
1768 all the updates, doesn't that segue back into the uncertainty
1769 of the risk the raising of capital? That is a problem.
1770 Would you agree?

1771 Mr. {Chodor.} If the app is going to make clinical
1772 decisions, then that is the cost of being in a heavily

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1773 regulated industry called health care where we are dealing
1774 with patients and physicians.

1775 Mr. {Shimkus.} But you are living I a world right now
1776 where you don't have it, right?

1777 Mr. {Chodor.} Well, we--

1778 Mr. {Shimkus.} We are in a new world, a new, brave
1779 world of health care delivery that everyone is going to be
1780 happy with. But health apps developed in the absence of
1781 Obamacare and they are plentiful throughout the system, and
1782 our concern is, as the federal government gets involved, it
1783 creates uncertainty, it raises the cost of capital, it slows
1784 up the delivery process, and it could be very problematic for
1785 delivering the same care that we are all espousing.

1786 Mr. Dagi, you are nodding yes. Do you agree with that?

1787 Dr. {Dagi.} Absolutely. I believe that the medical
1788 application can be seen as a provider extender in some cases,
1789 so we don't have enough primary care physicians, we don't
1790 have enough specialty physicians. This is a way of getting
1791 to the patient.

1792 Mr. {Shimkus.} So we are all saying FDA should publish
1793 final guidance to clear up confusion. However, Mr. Dagi, you

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1794 noted that we should be looking at alternatives to the FDA
1795 framework. I mean, there are some of us that realize
1796 government is big, costly, bureaucratic, slow, the
1797 Telecommunications Subcommittee. The great thing about this
1798 sector is it moves faster than we can regulate, and this is a
1799 concern that we are going to slow it down.

1800 Mr. Dagi, do you believe that the FDA framework is the
1801 best way to balance patient safety and innovation in this
1802 space?

1803 Dr. {Dagi.} They have the credibility and the
1804 experience. They need to take information outside the FDA.
1805 It can't be positivist. It can't be only from the inside.
1806 But with the appropriate inputs, yes.

1807 Mr. {Shimkus.} And you can bring the technology
1808 community in and be tech savvy, and that would be helpful.

1809 Dr. {Dagi.} That is correct.

1810 Mr. {Shimkus.} Thank you, Madam Chairman. I yield back
1811 my time.

1812 Mrs. {Ellmers.} Thank you. I now turn to my colleague,
1813 Mr. Gardner, for his questions.

1814 Mr. {Gardner.} Thank you, Madam Chair, and thank you to

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1815 the witnesses for joining us today at this hearing.

1816 A couple weeks ago I met with a constituent of mine in
1817 Colorado. He was a software developer in his earlier life,
1818 earlier years, and since has focused his attention on
1819 developing applications for a variety of uses, and one of the
1820 things he was talking about was a recent health care scare
1821 that he had. He had a conversation with a doctor in Colorado
1822 where the doctor was showing him some of the new technologies
1823 that he is able to use today when it comes to medical
1824 applications, apps, software apps, things like that, but also
1825 in the near future things that we will be using, and he
1826 described a scenario where you could walk into your bedroom
1827 and you would have a scale and you would get on the scale and
1828 you would check your weight. That scale would have a
1829 Bluetooth connection to it, to the iPad, and it would send
1830 your weight to the iPad, and then you could actually use the
1831 iPad for as little as 100 bucks, I think you said, with a
1832 device that was attached to it where you could check your
1833 blood pressure, your heartbeat, your heart rate, oxygen
1834 levels, and that that would be collected through the iPad as
1835 well. There may be some other things in the room that you

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1836 could have that would also check your health status, and then
1837 that would send it through Bluetooth to the iPad, it would
1838 collect it and then send it directly to the doctor's office.
1839 At what point then are any of those things an app that could
1840 be subject to regulation, subject to a device tax? Would the
1841 scale qualify at that point as a device, Mr. Jarrin?

1842 Mr. {Jarrin.} The scale would qualify as a device if it
1843 is a medical device, if that is the intended use of the
1844 device. There are medical-grade weight scales and there are
1845 non-medical-grade weight scales on the market.

1846 Mr. {Gardner.} So but just if you had just a scale that
1847 was attached to Bluetooth, then that scale would become a
1848 regulated medical device?

1849 Mr. {Jarrin.} Not necessarily. You need the intended
1850 use from the manufacturer.

1851 Mr. {Gardner.} So the intended use would be just you go
1852 buy a scale and the intended use is to check your weight.
1853 That is what a scale is.

1854 Mr. {Jarrin.} Right.

1855 Mr. {Gardner.} That weight then gets sent. Is that a
1856 medical device?

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1857 Mr. {Jarrin.} Not necessarily. It depends again on the
1858 intended use by the manufacturer.

1859 Mr. {Gardner.} So not necessarily but it could be?

1860 Mr. {Jarrin.} Correct. It could be.

1861 Mr. {Gardner.} Okay. So there is no clarity there.

1862 Mr. {Jarrin.} Well, it really--what we would need is
1863 more information about what the manufacturer intends with--

1864 Mr. {Gardner.} Well, it is intended as a scale. It is
1865 intended to check your weight.

1866 Mr. {Jarrin.} But there are some scales that are just
1867 for informational purposes and there are others that are--

1868 Mr. {Gardner.} Well, all scales are for informational
1869 purposes.

1870 Mr. {Jarrin.} Correct, but some make medical claims,
1871 and if that--

1872 Mr. {Gardner.} A medical claim as in, you weigh 150
1873 pounds, which clearly I do not.

1874 Mr. {Jarrin.} But this could be used for medicine.

1875 Mr. {Gardner.} But aren't scales used for medicine?

1876 Mr. {Jarrin.} Not all.

1877 Mr. {Gardner.} Well, why would you check your weight

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1878 then?

1879 Mr. {Jarrin.} For informational purposes. You want to
1880 lose weight--

1881 Mr. {Gardner.} For informational purposes, so it is
1882 like reading, you know, a description of a coloring box, this
1883 is red, this is blue, this is yellow. That has nothing to do
1884 with the color, it just is information?

1885 Mr. {Jarrin.} It is information.

1886 Mr. {Gardner.} That makes no sense to me. A scale is
1887 used to check your weight.

1888 Dr. Dagi, at what point does everything in your room
1889 then, the Bluetooth connection, the iPad, could it check your
1890 oxygen level? Is the scale a medical device subject to a
1891 tax?

1892 Dr. {Dagi.} You are 72 years old. You have just come
1893 out of the hospital with congestive heart failure. If your
1894 weight goes up 6 pounds, you may be about to go back into the
1895 hospital with another cycle of congestive heart failure.
1896 That scale has to be sufficiently accurate and precise to be
1897 able to adjust your medications, and at that point it becomes
1898 a medical device. If you put a penny in a scale at an

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1899 arcade, that is not a medical device.

1900 Mr. {Gardner.} So is there clarity, though, of whether
1901 the iPad at that point that collects the information from the
1902 scale?

1903 Dr. {Dagi.} It depends on whether the iPad has a built-
1904 in algorithm that does something with the information. It is
1905 not only the data, it is converting the data into usable
1906 information and how that information will be used.

1907 Mr. {Gardner.} So I am hearing from several of the
1908 panelists that it depends. It might be, it could be. To me,
1909 that is not clarity. To me, that means that you have an
1910 entire room of iPhones, iPads, BlackBerrys that communicate
1911 with each other but it just depends on whether or not
1912 something is used for its intended purpose.

1913 Dr. Dagi, is there the clarity that we need in this
1914 field to ensure innovation?

1915 Dr. {Dagi.} We do not have the necessary clarity.

1916 Mr. {Gardner.} And Mr. Jarrin, would you agree with
1917 that at that point?

1918 Mr. {Jarrin.} It depends.

1919 Mr. {Gardner.} It depends? ``It depends'' is not

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1920 clarity. If it depends, that doesn't seem to me to give you
1921 the kind of certainty and innovation and funding that we are
1922 seeking.

1923 Mr. {Jarrin.} There is insufficient clarity with low-
1924 risk medical devices or low-risk devices.

1925 Mr. {Gardner.} But is low risk a scale?

1926 Mr. {Jarrin.} Yes, it could be, if it is for
1927 recreational purposes.

1928 Mr. {Gardner.} Mr. Spalter, so is there sufficient
1929 clarity in this realm to know that innovation can continue
1930 unfettered?

1931 Mr. {Spalter.} Clearly not, and we have a group of
1932 experts here that are struggling with this question. Imagine
1933 what it must be like for the members that we represent, the
1934 app developers who are sitting on their laptops in their
1935 living rooms trying to dream up the next innovations. How
1936 are they dealing with this level of uncertainty? What we are
1937 asking for is not necessarily one framework or another. What
1938 we are asking for is let us create that balance, let us find
1939 the line, let us put down on paper where we actually--what we
1940 need to understand, and once we get there, I think the hockey

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1941 stick that we talked about, 40,000 medical apps, will become
1942 100,000, 200,000 medical apps. In fact, I would even say
1943 that if we had that clarity, that the smartphone that is
1944 enabled to test urinalysis that we talked about earlier
1945 today, there would already be three or five new apps that
1946 have been developed just this morning.

1947 Mr. {Gardner.} Madam, if I can just ask one follow-up?
1948 So I mean, the line clearly is in the wrong place at this
1949 point, and we have got to adjust it. Would you agree with
1950 that, Mr. Spalter?

1951 Mr. {Spalter.} I believe that we need clarity, yes.

1952 Mr. {Gardner.} Dr. Dagi?

1953 Dr. {Dagi.} Yes, sir.

1954 Mr. {Gardner.} Thank you. Madam Chair, thank you for
1955 your indulgence.

1956 Mrs. {Ellmers.} Thank you. And I will finish--Mr.
1957 Lujan, did you have additional questions or comments that you
1958 wanted to make? Okay. I will finish up with my questioning.

1959 Mr. Thompson, I have a question for you. In the
1960 wireless world, most wireless devices are replaced in a 2-
1961 year cycle, and mobile operating systems are replaced in as

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1962 little as 1 year by their next version, I mean, having
1963 considered the high rate of technology advancement that is
1964 taking place. In your experiences with the FDA's regulatory
1965 processes, how long does the premarket approval process take
1966 on average for a noninvasive medical device?

1967 Mr. {Thompson.} There is quite a range but the range
1968 could be anywhere from about 90 days at the earliest for the
1969 actual FDA review to up closer to a year and a half would
1970 also be reasonably typical.

1971 Mrs. {Ellmers.} So basically so a year and a half, you
1972 know, so that is time that is going to elapse before some of
1973 these very important medical applications can be put forward.

1974 I would just like to finish by asking all of you to
1975 respond to a couple of questions. Yes or no or unclear, I
1976 would like the response. I think one of the things that this
1977 very important subcommittee hearing has really brought to
1978 light is, one, we all care about patient safety and we want
1979 to practice appropriately. We agree that there is FDA
1980 approval and regulatory processes that need to be in place
1981 for certain levels, especially when we are looking at
1982 something as important as diagnosing a disease or, you know,

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1983 something very important, and Mr. Spalter, you know, I
1984 listened to your testimony and I have personal experience
1985 with diabetes, and I can only think my older brother was
1986 diagnosed 40 years ago, and where we would be today had we
1987 had some of that innovation in place.

1988 So if we are adhering to all of these things, the other
1989 area that I think we all have agreement on, and this is one
1990 where I would like to start to get a yes, no or unclear
1991 answer is, do you all agree that it is still unclear where we
1992 are with what is a medical device, starting with Mr. Jarrin?

1993 Mr. {Jarrin.} Yes.

1994 Mr. {Thompson.} Yes.

1995 Mr. {Chodor.} Yes.

1996 Mr. {Spalter.} Yes.

1997 Dr. {Dagi.} Yes.

1998 Mr. {Ford.} Yes.

1999 Mrs. {Ellmers.} The other question that I have for you
2000 is this. Again, FDA regulation and medical device tax, or
2001 gross tax, these are the two issues that we are really
2002 talking about today. In your opinion, if it is FDA
2003 regulated, should the medical device tax be in place? And

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2004 again, I guess I should preface that by saying, do you
2005 believe that the medical device tax is going to hamper
2006 innovation? And I would like for each of you to answer that
2007 question first.

2008 Mr. {Jarrin.} Unclear.

2009 Mr. {Thompson.} I would say it definitely hampers
2010 innovation.

2011 Mr. {Chodor.} Unclear.

2012 Mr. {Spalter.} It is still unclear.

2013 Dr. {Dagi.} Definitely yes.

2014 Mr. {Ford.} The tax will hamper innovation.

2015 Mrs. {Elmers.} In your opinion then, my last question,
2016 if FDA regulation is in place, and certainly, you know, we
2017 have seen the need for FDA regulation--I mean, you know, I am
2018 a nurse, I get it. We need to make sure we are practicing
2019 safely and best practices are being adhered to. Do you
2020 believe if the FDA regulation is in place that a medical
2021 device tax for such a product should be in place as well?

2022 Mr. {Jarrin.} Unclear.

2023 Mr. {Thompson.} We oppose the tax.

2024 Mr. {Chodor.} Unclear.

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2025 Mr. {Spalter.} Unclear.

2026 Dr. {Dagi.} Separate the tax from the regulation.

2027 Mr. {Ford.} Two completely different questions.

2028 Mrs. {Ellmers.} Thank you very much. I truly

2029 appreciate the testimony that all of you have given here

2030 today. This really opens up that door on this discussion

2031 that we really need to have as to whether or not this medical

2032 device tax is something we need to move forward with, and of

2033 course, all important FDA regulations, so thank you very

2034 much.

2035 This subcommittee hearing is adjourned.

2036 [Whereupon, at 12:24 p.m., the subcommittee was

2037 adjourned.]