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4 ``HEALTH INFORMATION TECHNOLOGIES: ADMINISTRATION

5 PERSPECTIVES ON INNOVATION AND REGULATION''

6 THURSDAY, MARCH 21, 2013

7 House of Representatives,

8 Subcommittee on Oversight and Investigations

9 Committee on Energy and Commerce

10 Washington, D.C.

11 The subcommittee met, pursuant to call, at 9:08 a.m., in  
12 Room 2322 of the Rayburn House Office Building, Hon. Tim  
13 Murphy [Chairman of the Subcommittee] presiding.

14 Present: Representatives Murphy, Burgess, Blackburn,  
15 Harper, Olson, Griffith, Johnson, Long, Ellmers, Barton,  
16 DeGette, Butterfield, Tonko, and Waxman (ex officio).

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17 Staff present: Mike Bloomquist, General Counsel; Matt  
18 Bravo, Professional Staff Member; Karen Christian, Chief  
19 Counsel, Oversight; Andy Duberstein, Deputy Press Secretary;  
20 Julie Goon, Health Policy Advisor; Debbie Hancock, Press  
21 Secretary; Brittany Havens, Staff Assistant; Sean Hayes,  
22 Counsel, O&I; Robert Horne, Professional Staff Member,  
23 Health; Peter Kielty, Deputy General Counsel; Katie Novaria,  
24 Legislative Clerk; John O'Shea, Professional Staff Member,  
25 Health; David Redl, Counsel, Telecom; Alan Slobodin, Deputy  
26 Chief Counsel, Oversight; Jean Woodrow, Director, Information  
27 Technology; Tiffany Benjamin, Democratic Senior Counsel;  
28 Brian Cohen, Democratic Staff Director, Oversight &  
29 Investigations, Senior Policy Advisor; Eric Flamm, FDA  
30 Detailee; Elizabeth Letter, Democratic Assistant Press  
31 Secretary; Stephen Salsbury, Democratic Special Assistant;  
32 Rachel Sher, Democratic Senior Counsel; and Matt Siegler,  
33 Democratic Counsel.

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|  
34           Mr. {Murphy.} All right. Good morning, everyone, and  
35 welcome to our hearing today on ``Health Information  
36 Technologies: Administrative Perspectives on Innovation and  
37 Regulation.'' Thank you for being here. Today, we convene  
38 the Subcommittee on Oversight and Investigations to discuss  
39 development and innovation and these technologies,  
40 particularly mobile medical applications or ``apps,'' and how  
41 federal regulations may impact this growing industry.

42           We are joined by two witnesses from the Administration,  
43 Dr. Farzad Mostashari, who is the head of the Office of the  
44 National Coordinator with HHS; and Christy Foreman, who is  
45 the director of the Office of Device Evaluation in the Center  
46 for Devices and Radiological Health at the FDA. Both of  
47 these agencies have been leading the government's response to  
48 the rapid changes that new technologies are making to our  
49 Nation's healthcare system.

50           On March 4, this committee sent a letter to the FDA on  
51 its approach to regulating the rapidly growing market  
52 applications used on smartphones and tablets. With this  
53 explosive growth, the use of those apps to monitor health

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54 information is growing, as well as increasing in accuracy and  
55 technological sophistication. News reports indicate that  
56 there are as many as 40,000 medical applications on the  
57 market for smartphones and tablets.

58 We are here today to discuss the discretion FDA has in  
59 regulating these apps as devices under the Food, Drug, and  
60 Cosmetic Act, and over the last few days, we have heard a  
61 number of examples of medical apps and concerns from apps  
62 companies about whether these apps are devices. For example,  
63 where does an app that transmits photos of potential skin  
64 cancer or the healing of surgical scars cross the line to FDA  
65 scrutiny? If an app that turns a smartphone into an  
66 ultrasound can be regulated, what about apps that let you  
67 review images from ultrasound or x-rays?

68 You know, there has been incredible advances in all  
69 these things and we expect to see more in not only areas of  
70 dermatology in the use of photos, endocrinology with  
71 monitoring blood glucose levels, x-rays with radiology and  
72 orthopedics, heart monitors with cardiology, mental status  
73 tests with neurology. The list goes on and on.

74 In 2011 the FDA issued Draft Guidance on how the Agency

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75 planned to regulate mobile medical applications. The FDA has  
76 not yet issued Final Guidance. To our witnesses from the  
77 FDA, over the last 2 days we have heard from a variety of  
78 witnesses and members of both sides of the aisle, and the  
79 message was clear: we need Final Guidance. The developers of  
80 these apps and the healthcare industry need certainty.

81 That certainty is also needed because of the tax on  
82 medical devices put in place by the new healthcare law. As  
83 we have heard this week, a tax on medical devices can make  
84 capital needed to develop these apps and new breakthrough  
85 technologies more scarce. This can slow innovation. And we  
86 are caught in its cycle of the snake eating its own tail  
87 whereby we raise taxes on medical devices, thus increasing  
88 the costs, and then use those taxes to subsidize increased  
89 costs and offer tax incentives to cover R&D. It doesn't  
90 quite make sense but we want to make sure we are not slowing  
91 innovation.

92 So this isn't about scaring people into thinking this  
93 tax will apply to their iPhones, Blackberries, or iPads, but  
94 this tax could absolutely halt the development of new apps to  
95 run on those devices. Everyone here recognizes the need to

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96 balance patient safety and innovation. I hope that today's  
97 hearing will provide some certainty that regard.

98 We will also hear from Dr. Mostashari on the efforts  
99 that have been made by the Department of Health and Human  
100 Services to encourage the utilization of health information  
101 technology, and particularly, the incentive payments that  
102 have been made to providers to adapt to new healthcare  
103 technologies. Recently, HHS announced that for this year  
104 they hope to have 50 percent of physicians' offices using  
105 electronic health records with 80 percent of eligible  
106 hospitals receiving incentive payments by the end of this  
107 year.

108 While the movement to increased use of electronic health  
109 records may seem like an obvious choice as doctors and  
110 hospital employees become more comfortable with new  
111 technologies, as a supporter of health IT, I am concerned  
112 that the promised benefits of electronic medical records have  
113 yet to arrive. I have personally heard from physicians in my  
114 district who have struggled to adapt or received unclear  
115 Guidance from the Agency. Of particular concern are  
116 complaints that systems in place aren't able to share

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117 information with other systems. I hope our witnesses today  
118 will be able to address these concerns over interoperability.

119 I am encouraged by the work this committee has done this  
120 week. We have had a great dialogue on these issues and today  
121 I hope we will be able to hear the Administration's view on  
122 its approach to innovation and regulation of healthcare  
123 technologies.

124 I also want to apologize ahead of time. I have another  
125 hearing that I have to testify, and I will be leaving in a  
126 little bit, but it will be taken over by the capable hands of  
127 the vice chairman, Dr. Mike Burgess.

128 And now, I would like to recognize Ms. DeGette for her  
129 opening statement.

130 [The prepared statement of Mr. Murphy follows:]

131 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

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132 Ms. {DeGette.} Thank you very much, Mr. Chairman.

133 Mobile medical apps and electronic health records are  
134 developing at a rapid pace and they have the capacity to  
135 transform the patient-doctor relationship, improve healthcare  
136 quality, and also to save billions of dollars. And I am  
137 looking forward to hearing from the FDA and HHS about the  
138 efforts to integrate these new technologies into the  
139 healthcare sector.

140 Dr. Mostashari, I want to welcome you, the national  
141 coordinator for Health Information Technology.

142 The 2009 stimulus bill contained billions of dollars to  
143 help incentivize doctors and hospitals to implement  
144 meaningful use of electronic medical records. That  
145 investment has already made a big difference. Since 2009,  
146 the use of electronic health records by physicians has  
147 doubled from 20 to 40 percent in the hospital adoption of  
148 electronic health records has more than tripled. More than  
149 230,000 healthcare providers have qualified for payments for  
150 implementing the use of electronic health records.  
151 Ultimately, the adoption of these records will reduce medical

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152 errors, save money, and most importantly, improve the quality  
153 of care.

154 Earlier this week, the Premier Healthcare Alliance  
155 reported that 333 hospitals in their network had, since 2008,  
156 save \$9.1 billion and avoided 92,000 deaths by implementing a  
157 set of patient-centered quality improvement reforms that was  
158 made possible in part by enhanced data-sharing and use of  
159 health information technology. But the transition to  
160 electronic health records is not without challenges, and Dr.  
161 Mostashari, I am glad you are here to address questions about  
162 the Agency's roadmap to help us fully implement health IT.

163 Ms. Foreman, I also want to welcome you to talk about  
164 the FDA's role in regulating and improving mobile medical  
165 apps.

166 Mr. Chairman, I have got to admit the discussion of  
167 FDA's role in regulating medical apps seems a little  
168 redundant. This is the third hearing that is focused on  
169 these issues. As we heard during the first two hearings, the  
170 other subcommittee heard from 11 different nongovernment  
171 witnesses about how the Administration is balancing the need  
172 to promote innovation in this field against the need to

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173 ensure patient safety. Those witnesses thankfully already  
174 debunked some of the biggest myths that we have heard from  
175 the outside about the FDA's role. Thank goodness the myth of  
176 the iPhone tax has now been put to rest.

177         We also learned from the witnesses that smartphones and  
178 tablets are exempt from the Affordable Care Act medical  
179 device tax. We learned that the FDA is not currently and  
180 does not intend in the future to regulate smartphones or  
181 tablets as part of its regulation of mobile medical apps. We  
182 also learned that the FDA does not intend to regulate calorie  
183 counters or pedometers or other kinds of similar apps as  
184 medical devices. But we also learned about how the Agency  
185 has a role in ensuring that other medical devices like  
186 monitoring blood glucose or providing other vital medical  
187 information are accurate and work the way they are supposed  
188 to do, which is exactly what the FDA is therefore.

189         But the Committee also heard from some industry  
190 witnesses expressing concerns about the FDA's regulatory  
191 efforts and worrying that they could overreach and limit  
192 innovation. These concerns are not new and they are not  
193 specific to mobile medical apps. FDA, and frankly this

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194 committee, has to constantly address this balance, whether  
195 the Agency is regulating food, drugs, traditional medical  
196 devices, or these apps. That is part of what we have to do.

197 The FDA addressed all of these concerns in a letter that  
198 was sent to the Committee yesterday and, Mr. Chairman, I  
199 would like to ask that the letter be made part of the hearing  
200 record. The letter makes it abundantly clear that the FDA  
201 will not tax your iPhone and it provides new information that  
202 shows for the mobile medical apps FDA has reviewed, those  
203 reviews are moving quickly, taking an average of only 67  
204 days. So to me that sounds pretty much like an agency that  
205 is trying to foster innovation while at the same time  
206 ensuring that patients are safe.

207 And so, Mr. Chairman, I don't think that the debate over  
208 how to balance patient safety and innovation will end any  
209 time soon, but I am hopeful that at least we can have a  
210 common understanding of the facts with regard to electronic  
211 health records and mobile medical apps, and we can continue  
212 in our joint effort with the agencies to make sure we balance  
213 innovation and safety.

214 And with that, Mr. Chairman, I yield back and thank you.

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

216 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

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|  
217           Mr. {Murphy.} Thank you. And we do have a copy of this  
218 letter for the record, but I thank the ranking member for  
219 bringing that up again.

220           I now yield to Dr. Burgess for 5 minutes for an opening  
221 statement.

222           Dr. {Burgess.} I thank the chairman. And certainly we  
223 have heard from a number of qualified and distinguished  
224 scientists and specialists in medical technology and the  
225 communications industries for the past two hearings, and  
226 today, we are going to hear the perspectives of the agencies  
227 that wrote the proposed regulations guiding these industries.

228           The emergence of mobile medical technology does hold  
229 great promise not only for lowering the care cost, but most  
230 importantly, for improving health outcomes. The increasing  
231 availability of these technologies has revolutionized how  
232 providers interact with patients. We are at a point now  
233 where the number of providers using these devices has  
234 increased, almost doubled, from a year ago such that nearly  
235 2/3 of providers are using some type of device. The rapid  
236 proliferation of these new technologies also raises

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237 legitimate concerns about patient safety, but we also want to  
238 encourage important advancements that can improve patients'  
239 quality of life. And it is not just the overregulation by  
240 the government but it is the uncertainty of pending  
241 regulation that also drives some of this discussion.

242         The FDA struggles to maintain their current regulatory  
243 charge, but we need to be assured that they have the  
244 experience, that they have the expertise to handle the  
245 additional responsibilities of an emerging market.

246         Ms. Foreman, I would like to thank you and your agency  
247 for the rapid response to the letter earlier this week. I  
248 hope that sets a new benchmark in the Administration. We are  
249 accustomed to waiting years for a response, and this was  
250 indeed refreshing that it was only a few weeks in turnaround.  
251 And certainly, we look forward to similar quick turnaround  
252 for the final regulations of the Draft Guidance, which was  
253 issued in July 2011.

254         And Dr. Mostashari, I have enjoyed visiting with you in  
255 the past, and I thank you for being with us as well.

256         As a provider, I have direct experience using health  
257 information technology and seeing the benefits as well as

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258 some of the downfalls that it brings to both patients and  
259 providers. Artificial barriers do nothing for care  
260 coordination, for patient safety, or for provider  
261 communication. As a physician, my primary concern is the  
262 health and safety of the patient. Inaction is not an option  
263 on this issue. However, we must do so in a way that  
264 encourages the development of innovative technologies, and we  
265 certainly do not want to push them outside of our borders.

266 I will now yield the balance of the opening statement  
267 time to the gentlelady from Tennessee, Mrs. Blackburn.

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

269 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

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|  
270 Mrs. {Blackburn.} And I thank the gentleman for  
271 yielding. And thank you, Mr. Chairman, for the hearing. And  
272 to our witnesses, Ms. Foreman, Dr. Mostashari, we thank you  
273 for being here with us.

274 The hearings that we have done this week I think are  
275 essential. I don't think they are redundant. I do think  
276 they are essential to getting our arms around an issue that  
277 we are going to have to deal with on mobile medical apps.  
278 And I would say that one of the things that has come forward  
279 through the testimony we have received is that a 40-year-old  
280 FDA statute is not nimble enough to address the needs that  
281 are in front of us with this new innovation sector.

282 I do think that ONC has a unique perspective on these  
283 HIT issues, and along with input from the FDA and from  
284 stakeholders that Congress can find a path forward on what a  
285 framework would look like. One of the things we have heard  
286 from the innovators is the uncertainty that is there within  
287 FDA. This big gray area of whether you will or will not be  
288 regulated, that is stifling innovation. And as we heard in  
289 the hearing on Tuesday, it also does not do anything to

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290 provide certainty to investors who are going to be there. So  
291 that is of concern to us.

292 Now, Dr. Burgess mentioned yesterday that these are the  
293 tools of today's doctors and future doctors, and 15 percent  
294 of these apps that are out there, the 97,000 apps, the mobile  
295 medical apps, 15 percent are used by physicians. This is a  
296 way for us to achieve efficiency. It is a way for us to  
297 expand access, and what we want to be certain is that our  
298 innovators know with certainty what their classification  
299 would be, how they would be dealt with as an industry.

300 So we thank you all for the testimony and for being here  
301 and we look forward to concluding our series and finding a  
302 way forward on the issue.

303 And I yield back.

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

305 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

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306 Mr. {Murphy.} Thank you.

307 I now recognize the ranking member of the full committee  
308 for an opening statement, 5 minutes, Mr. Waxman.

309 Mr. {Waxman.} Mr. Chairman, we are here today for the  
310 third day in a row to discuss electronic health records and  
311 FDA's regulation of mobile medical apps, and I am surprised  
312 at the amount of time and attention given to this issue.

313 I have attended the last 2 days of hearings, and from  
314 what I have heard, the members on your side of the aisle seek  
315 to answer two basic questions: question one, whether the FDA  
316 is regulating mobile medical apps with too heavy a hand; is  
317 the Agency impeding innovation and harming this market by  
318 regulating too aggressively or approving mobile medical apps  
319 too slowly?

320 This is not a new responsibility for FDA. For over 100  
321 years the Agency has been balancing patient and consumer  
322 safety with the need for innovation. In the case of mobile  
323 medical apps, the answers that we heard in the first 2 days  
324 of hearings indicate little by way of concern. The witnesses  
325 told us that they understood the role of FDA and the need for

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326 agency regulation and were unable to point out any legitimate  
327 examples of apps that FDA was improperly regulating under its  
328 Draft Guidance. Although they had some anxiety about it,  
329 they had nothing to point to.

330 Question two is whether FDA will impose a new tax, the  
331 Affordable Care Act medical device tax, on your cell phone.  
332 The answer to this question is as plain as day. The answer  
333 is no. The Affordable Care Act itself contains a clear  
334 retail exemption. Even if a cell phone was designated to be  
335 a medical device, the Act says that any device that is  
336 ``generally purchased by the general public at retail for  
337 individual use'' is not subject to the tax. That exemption  
338 would apply to any cell phone you can buy at a retail store.  
339 And FDA has been clear that the Agency is not currently  
340 regulating and does not intend in the future to regulate  
341 smartphones or tablets as part of its regulation of mobile  
342 medical apps. The IRS has provided similar indications.

343 Mr. Chairman, this issue is a non-issue. We did not  
344 need to spend 1 day of hearings on this, let alone 3. This  
345 committee could have used this time more wisely. I have  
346 asked you to hold hearings on the abuse of tax and regulatory

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347 loopholes by the tobacco industry and their efforts to  
348 undermine the Tobacco Control Act. Ranking Member DeGette  
349 and I have asked for hearings on the impacts of sequestration  
350 on the agencies of our committee's jurisdiction. We have  
351 asked for hearings on the risks associated with antibiotic-  
352 resistant bacteria, a very serious and growing public health  
353 threat. We have asked for you to hold hearings on Lifeline,  
354 the Universal Service Fund's low income phone program. These  
355 hearings could examine the expenditure of billions of dollars  
356 of consumer funds.

357         In the last 2 years, I have sent over 20 letters asking  
358 for hearings on the impacts of climate change. And we have  
359 not held a hearing on a single one of these important issues.  
360 Mr. Chairman, I hope you can understand our concern. I don't  
361 mean to discount the importance of mobile medical apps and  
362 the electronic health records. This is an industry that,  
363 thanks to the investment we made in the 2009 Obama stimulus  
364 bill, is growing, is creating jobs, and has the potential to  
365 dramatically improve healthcare quality and save billions of  
366 dollars in healthcare costs.

367         But there are too many pressing issues before us for

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368 this committee and this Congress to get bogged down for 3  
369 days in what amounts to an inaccurate talking point about FDA  
370 overregulation and the nonexistent iPhone tax. I hope that  
371 in the future this subcommittee can use its time more wisely.  
372 I must say, Mr. Chairman, for this particular subcommittee, I  
373 thought that the first hearings we have held under your  
374 leadership have been very worthwhile and that we can go back  
375 to doing things that are constructive and not just talking  
376 points for political purposes, which is all these 3 days have  
377 been about.

378 I yield back the balance of my time.

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

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

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|  
381           Mr. {Murphy.} Thank you very much, Mr. Waxman. I would  
382 now like to recognize Christy Foreman. She is currently the  
383 director of the Office of Device Evaluation for the Center  
384 for Devices and Radiological Health for the FDA. Before  
385 being named to the director position, she served as the  
386 deputy director for Science and Regulatory Policy in the  
387 Office of Device Evaluation.

388           I would also like to introduce Farzad Mostashari. He  
389 currently serves as national coordinator for Health  
390 Information Technology within the Office of the National  
391 Coordinator for Health Information Technology at the U.S.  
392 Department of Health and Human Services. Farzad joined ONC  
393 in July of 2009.

394           You are aware that the Committee is holding an  
395 investigative hearing, and when doing so, has had the  
396 practice of taking testimony under oath. Do you have any  
397 objections to testifying under oath?

398           Both witnesses have said they do not.

399           The chair then advises you that under the rules of the  
400 House and the rules of the Committee, you are entitled to be

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401 advised by counsel. Do you desire to be advised by counsel  
402 during your testimony today?

403 Both witnesses have said no.

404 In that case, if you please rise and raise your right  
405 hand, I will swear you in.

406 [Witnesses sworn]

407 Mr. {Murphy.} And if someone could work on the volume,  
408 I would appreciate that, too.

409 You are now under oath and subject to the penalties set  
410 forth in Title XVIII, Section 1001 of the United States Code.  
411 You may now give a 5-minute summary of your written  
412 statements. Ms. Foreman, if you would like to begin.

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|  
413 ^TESTIMONY OF CHRISTY FOREMAN, DIRECTOR, OFFICE OF DEVICE  
414 EVALUATION, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, FOOD  
415 AND DRUG ADMINISTRATION; AND FARZAD MOSTASHARI, NATIONAL  
416 COORDINATOR, HEALTH INFORMATION TECHNOLOGY, U.S. DEPARTMENT  
417 OF HEALTH AND HUMAN SERVICES

|  
418 ^TESTIMONY OF CHRISTY FOREMAN

419 } Ms. {Foreman.} Mr. Chairman, Ranking Member DeGette,  
420 and members of the subcommittee, I am Christy Foreman,  
421 Director of the Office of Device Evaluation in the Center for  
422 Devices and Radiological Health, or CDRH, at the Food and  
423 Drug Administration. Thank you for the opportunity to  
424 testify today. I am pleased to be here to discuss issues  
425 related to health IT and to talk specifically about the  
426 actions FDA is taking to foster innovation in the field of  
427 mobile medical applications, also referred to as mobile  
428 medical apps.

429 The widespread adoption and use of mobile technologies  
430 is opening new and innovative ways to improve health and

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431 healthcare delivery. Mobile apps, which are software  
432 programs that run on smartphones and other mobile devices,  
433 can help consumers and patients manage their own health and  
434 wellness, promote healthy living, and gain access to useful  
435 information when and where they need it.

436 FDA believes it is important to adopt a balanced  
437 approach to mobile medical apps that supports continued  
438 innovation while assuring appropriate patient protections.  
439 We also recognize that mobile health application developers  
440 need a clear, predictable, and reasonable understanding of  
441 the Agency's expectations.

442 Now, while many mobile apps carry minimal risk, others  
443 can pose significant risk to patients if they don't operate  
444 correctly. In some cases, those risks are identical to the  
445 risks associated with an already marketed medical device.  
446 For example, a mobile app that affects the programming of a  
447 drug infusion pump or a CT scanner could lead to a drug or  
448 radiation overdose. And an inaccurate or malfunctioning  
449 mobile medical app that diagnosis skin cancer could delay  
450 life-saving diagnosis and treatment.

451 In July 2011, FDA issued a Draft Guidance announcing our

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452 intention to exercise enforcement discretion for most mobile  
453 apps. The Guidance also clarifies that the focus of our  
454 oversight will be a small subset of mobile apps, which we  
455 refer to as mobile medical apps. These are apps that meet  
456 the definition of a device in the Federal Food, Drugs, and  
457 Cosmetic Act and that are either intended to be used as an  
458 accessory to a regulated medical device or transform a mobile  
459 platform into a regulated medical device.

460 Just as importantly as what our policy proposes is what  
461 our policy does not propose. It would not regulate the sale  
462 or general consumer use of smartphones or tablets. It would  
463 not consider entities that exclusively distribute mobile  
464 medical apps such as the iTunes App Store or the Android  
465 Market to be medical device manufacturers. It would not  
466 consider mobile platform manufacturers to be medical device  
467 manufacturers just because their mobile platform could be  
468 used to run a mobile medical app regulated by FDA. It would  
469 not require mobile medical app developers to seek agency  
470 reevaluation for minor iterative product changes. And it  
471 would not apply to mobile apps that perform the functionality  
472 of an electronic health record, EHR system, or personal

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473 health record system.

474 We have received more than 130 written comments on our  
475 Draft Guidance. The commenters have been overwhelmingly  
476 supportive of our narrow, tailored, risk-based approach,  
477 which we continue to receive many inquiries from industry  
478 stakeholders who are eager to see this Guidance finalized.  
479 Some commenters have sought additional clarity on the types  
480 of mobile apps that would fall within the scope of  
481 enforcement discretion. Our Final Guidance will provide that  
482 additional clarity and examples.

483 Pursuant to Section 618 of FDASIA, the FDA, ONC, and  
484 Federal Communications Commission have established a FDASIA  
485 workgroup which will provide expert input from a wide range  
486 of stakeholders to provide recommendations on an appropriate  
487 risk-based regulatory framework pertaining to health  
488 information technology, including mobile medical apps.

489 It is important to note that FDA has been regulating  
490 medical device software for decades and medical device  
491 software on mobile platforms for more than 10 years. We have  
492 reviewed approximately 100 mobile medical apps, including  
493 remote blood pressure, heart rhythm, and patient monitors;

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494 and smartphone-based ultrasound and glucose meters.

495 We recognize the importance of using a balanced,  
496 transparent approach that fosters the development of  
497 innovative mobile medical apps while ensuring appropriate  
498 patient protections. We intend to strike the right balance  
499 by providing a risk-based, focused approach to the oversight  
500 of a small subset of mobile medical apps that present a  
501 serious potential risk to patients if they do not work as  
502 intended. We believe that focusing the Agency's oversight  
503 will encourage the development of new products while also  
504 providing appropriate patient protections.

505 Thank you for the opportunity to testify today about  
506 issues related to health IT, including mobile medical apps,  
507 and about the actions FDA is taking to foster innovation.

508 Mr. Chairman, I commend the Subcommittee's efforts and  
509 am pleased to answer any questions the Subcommittee may have.

510 [The prepared statement of Ms. Foreman follows:]

511 \*\*\*\*\* INSERT 1 \*\*\*\*\*

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|  
512 Dr. {Burgess.} [Presiding] The chair thanks the  
513 witness. I recognize Dr. Mostashari, 5 minutes for your  
514 opening statement, sir.

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|  
515 ^TESTIMONY OF FARZAD MOSTASHARI

516 } Dr. {Mostashari.} Dr. Burgess, Ranking Member DeGette,  
517 distinguished subcommittee members, thank you for the  
518 opportunity to appear today on behalf of the Department of  
519 Health and Human Services. My name is Dr. Farzad Mostashari.  
520 I am the national coordinator for Health Information  
521 Technology.

522 In 2009, HITECH was enacted as part of the American  
523 Recovery and Reinvestment Act. HITECH provided the resources  
524 and infrastructure needed to stimulate the rapid, nationwide  
525 adoption and use of health IT, especially electronic health  
526 records, or EHRs. HITECH is working. The CNS Medicare and  
527 Medicaid EHR Incentive Program, the ONC-led Certification  
528 Program for EHRs, as well as the hands-on technical  
529 assistance provided by 62 regional extension centers, or  
530 RECs, across the country are critical in facilitating  
531 unprecedented progress in EHR development, adoption, and use.

532 There are now over 1,700 unique products produced by  
533 nearly 1,000 EHR developers and certified by 1 of 5 ONC-

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534 accredited private sector certification bodies. Adoption of  
535 EHRs has doubled among providers and more than tripled in  
536 hospitals. Electronic prescribing has increased sevenfold.  
537 RECs have signed up more than 130,000 primary care providers  
538 in over 30,000 practices. As of February 2013, more than  
539 230,000 providers, nearly 43 percent of the Nation's eligible  
540 professionals, and over 75 percent of eligible hospitals have  
541 earned payments for meeting the initial requirements of EHR  
542 Incentive Program.

543         Recognizing the need to strike a balance between the  
544 urgency of modernizing our healthcare system and the pace of  
545 change that can be safely absorbed, CMS and ONC have  
546 developed the Incentive Program in stages. Each stage is  
547 designed to add increased advanced concepts. Published in  
548 July 2010, the Stage 1 final rules focused on functionality  
549 that support the electronic capture of data and its use to  
550 improve patient care, enhance care coordination in population  
551 health management, and increase patient and family  
552 engagement. The final rules for Stage 2 were published in  
553 September 2012 and represent an important next step with a  
554 focus on increasing standards-based health information

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555 exchange between providers and with patients.

556 Even as we work to bring data and data tools to doctors  
557 and hospitals, we have also been encouraged by the pace of  
558 progress in the domain of consumer e-health tools.

559 Increasingly, people are literally taking their health into  
560 their own hands. Mobile phones can be an incredible tool for  
561 empowering consumers to take control of their health, their  
562 care, their healthcare finances. And as we all know, more  
563 engaged consumers get better outcomes.

564 ONC strategy in consumer e-health is to work with  
565 partners to increase patients' ability to access their own  
566 health data, to increase the use of this data for actionable  
567 apps and services, and to shift attitudes around patient  
568 empowerment. However, we recognize there are risks as well  
569 as benefits to any technology. We must carefully balance the  
570 need for the widest possible innovation with protection of  
571 patient privacy, security, and safety.

572 Over the past 4 years, we have worked with FDA and other  
573 departmental agencies on a risk-based approach to health IT  
574 that promotes innovation and avoids regulatory duplication.  
575 ONC advised FDA on the Draft Guidance for mobile medical

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576 apps. Where it concerns EHR technologies, FDA has advised us  
577 on a health IT patient safety action and surveillance plan,  
578 the draft of which was released on December 21, 2012. The  
579 draft plan prescribes actions that all stakeholders can take  
580 within their existing authorities and resources, including  
581 safety requirements related to user-centered design quality  
582 management systems and easier reporting of adverse events in  
583 ONC regulations, use of ONC-authorized testing and  
584 certification bodies to collect complaints and conduct  
585 surveillance, working with developers to establish a code of  
586 conduct, working with AHRQ and patient safety organizations  
587 to improve aggregation and analysis of reported events and  
588 working with CMS to train surveyors and use health IT to  
589 assist investigations. ONC has received public comments on  
590 the draft plan, and those comments have been generally  
591 favorable.

592         On February 20, ONC, FDA, and FCC announced the  
593 formation of the Food and Drug Administration's Safety  
594 Innovation Act Work Group under ONC's Health IT Policy  
595 Committee to provide expertise for the development of a  
596 congressionally mandated report on an appropriate risk-based

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597 regulatory framework pertaining to health IT broadly,  
598 including mobile medical applications that will further  
599 promote innovation, protect patient safety, and avoid  
600 regulatory duplication. We are now in the process of  
601 reviewing nominations.

602         New technologies, including health IT and mobile  
603 applications, offer great promise to improve the quality of  
604 care and bring down healthcare costs. This doesn't happen  
605 overnight. To truly transform delivery, healthcare providers  
606 must also redesigned workflows and reengineer care. Payments  
607 must promote value over volume and care that is better  
608 coordinated and safe. Implementation of any program of this  
609 scale and complexity will inevitably include challenges, but  
610 by working within an open and transparent process and in  
611 partnership with our public and private sector stakeholders,  
612 we can build on this strong start in bringing better care to  
613 all Americans.

614         Thank you.

615         [The prepared statement of Dr. Mostashari follows:]

616 \*\*\*\*\* INSERT 2 \*\*\*\*\*

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617           Dr. {Burgess.} I thank the gentleman for his testimony.

618           Before we start members' questioning, I do want to  
619 stress the importance of the members' questions and the  
620 importance of getting direct answers from all of you all.  
621 The importance of this questioning is reflected in the fact  
622 that the Committee recently changed rules to limit member  
623 opening statements to provide more time for testimony and  
624 questioning. In order to make the question-and-answer period  
625 as productive as possible, I ask that you answer the  
626 questions in as a director manner as possible. Some members  
627 will ask yes-or-no questions and I ask that you limit  
628 yourself to a yes-or-no answer. I thank you in advance for  
629 your understanding.

630           I will now yield myself 5 minutes for the purposes of  
631 questions.

632           Ms. {DeGette.} That is not part of the rules.

633           Mr. {Butterfield.} Will the chairman allow a question  
634 at this point? Is that part of our committee rules?

635           Dr. {Burgess.} Stop the clock.

636           Mr. {Butterfield.} Yes.

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637 Dr. {Burgess.} Yes, the committee rules as adopted and  
638 the Committee was to limit the opening statements.

639 Mr. {Butterfield.} Dr. Burgess--

640 Ms. {DeGette.} Yes, but not the whole rest of the stuff  
641 you said.

642 Mr. {Butterfield.} Dr. Burgess, I have been in this  
643 Congress for 8-1/2 years--not as long as you have--but I have  
644 never, ever, ever heard of a rule such as that.

645 Ms. {DeGette.} It is not a rule.

646 Mr. {Butterfield.} Thank you.

647 Dr. {Burgess.} Well, let me direct it as a courtesy  
648 then to the members of the committee that we keep our answers  
649 direct and to the questions at hand.

650 I yield myself 5 minutes for questions.

651 Now, we are here today of course to discuss the issue of  
652 the guidance that was produced in July of 2011. Ms. Foreman,  
653 the FDA proposed its mobile medical apps policy would not  
654 regulate the sale of the general consumer or the use of  
655 smartphones or tablets. And certainly, today, we thank you  
656 for the certainty. Will the Final Guidance definitively say  
657 that the sale or general consumer use of smartphones or

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658 tablets will not be regulated by the Food and Drug  
659 Administration?

660 Ms. {Foreman.} No, it is not the Agency's intent to  
661 change that position in the Final Guidance.

662 Dr. {Burgess.} But, as everything, there is that  
663 possibility. And that is where the uncertainty comes from.  
664 And really, one of the things that the last 2 days and today  
665 are all about is trying to provide some certainty for the  
666 people who work into this space and are making significant  
667 investments of dollars and time, and they are doing so  
668 because they think they have ideas that are ultimately going  
669 to help people. And we would like to provide them that  
670 certainty. I think that is one of the reasons these  
671 committee hearings have been so important.

672 Some of the uncertainty we have heard this week relates  
673 to the fact that the Guidance issued in July of 2011 is a  
674 draft. When can we look for the final draft, the Final  
675 Guidance? When can that be released?

676 Ms. {Foreman.} We have prioritized that Guidance for  
677 publication this year. It should be coming soon with the  
678 intent of providing clarity to the--

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679 Dr. {Burgess.} Is your microphone working?

680 Ms. {Foreman.} It is on.

681 Dr. {Burgess.} Okay. Pull it a little closer then.

682 Ms. {Foreman.} We intend to finalize that Guidance this  
683 year. It is a priority for the Agency. It should be coming  
684 out in the final months. And the point of the Final Guidance  
685 will be to seek to clarify the questions received during the  
686 comment period and provide additional examples to clarify the  
687 Agency's policy.

688 Dr. {Burgess.} Did you say it will be coming out in the  
689 final month of this year?

690 Ms. {Foreman.} No, it will be coming out in the coming  
691 months.

692 Dr. {Burgess.} In the coming months. And when you say  
693 this year, you are talking about the calendar year and not  
694 the fiscal year?

695 Ms. {Foreman.} It should be out before the end of the  
696 fiscal year, yes.

697 Dr. {Burgess.} Okay. The fiscal year. Well, then  
698 let's make a note of that.

699 Some of the statements made by the FDA either in the

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700 Guidance or were made by you today, is the Guidance going to  
701 be binding on the Food and Drug Administration? Are there  
702 situations where the Food and Drug Administration has  
703 deviated from its Guidance when exercising its enforcement  
704 discretion?

705 Ms. {Foreman.} So Guidance is not binding. Guidance  
706 represents agency thinking. It is not a regulation. It is  
707 not statute. It is a lower level that represents agency  
708 thinking to provide clarity both to staff and to industry.

709 Dr. {Burgess.} And again, I do want to just for the  
710 record thank you for your rapid response to that letter.  
711 Again, I do hope that sets a new standard for the  
712 Administration in replying to letters from this committee.  
713 Historically, it can take some time to get questions  
714 answered, but these are important questions. These are  
715 questions not asked in a partisan manner in any way, shape,  
716 or form, and really trying to advance the science of the  
717 knowledge.

718 Dr. Mostashari, I will tell you, again, I do get to  
719 travel to a lot of places in the country. I talked to a lot  
720 of provider groups. And I will just say there is some

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721 concern. You know, the FDA always looks to whether things  
722 are safe and effective, well, with the exception of tobacco,  
723 but always looks to whether things are safe and effective  
724 under its regulatory jurisdiction. I can't recall if we ever  
725 saw the randomized clinical trials for electronic health  
726 records. Are those trials in existence? Were they done? Do  
727 we have that data?

728 Dr. {Mostashari.} Dr. Burgess, thank you for your  
729 question. There are many, many studies that have looked at  
730 whether when you try to improve quality, whether having  
731 information helps. And it is not something that perhaps is  
732 well-suited to a randomized trial at the policy level, but  
733 the overwhelming evidence--and we have commissioned a study  
734 of--that looks at every published study on this--and while  
735 some of the negative studies, the ones that are  
736 counterintuitive, get a lot of press, the preponderance of  
737 the evidence is absolutely that when implemented  
738 appropriately, health IT is going to improve quality, safety,  
739 and efficiency.

740 Dr. {Burgess.} And yet, I just noticed from your  
741 testimony--I mean it was the end of last year, December of

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742 2012, when your safety guidelines were published. Our  
743 stimulus bill was passed 4 years ago. The implementation  
744 began June of 2011 as I recall, and December of 2012 is when  
745 you were providing the safety guidelines. And you have  
746 stipulated such things as privacy and patient protections.

747 Dr. {Mostashari.} We have been--you know, our belief is  
748 that--and I think the evidence is that the best thing we can  
749 do for safety in general is to get off of paper. And the  
750 evidence around computerized order entry, for example,  
751 reducing medication errors by 48 percent, is clear. And we  
752 have seen an increase in e-prescribing that gets away from my  
753 handwriting and perhaps yours, which is a good thing in terms  
754 of improving the safety of prescribing.

755 We just heard from the Premier System just this week  
756 about how they have saved \$9 billion and 91,000 lives by  
757 implementing data-driven processes to improve care that can't  
758 be done in a paper-based world. So we believe that really  
759 getting healthcare into the data age is critical for  
760 improving safety.

761 Now, as I mentioned, any technology--

762 Dr. {Burgess.} Sir, I am actually going to stop you

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763 because my time has expired. In the interest of getting  
764 everyone heard, I will yield to the ranking member of the  
765 subcommittee.

766 Ms. {DeGette.} Thank you, Mr. Chairman.

767 I just have a few questions. Over the last 2 days of  
768 hearings before today there was a lot of testimony and claims  
769 that app developers face a threat from the FDA and that the  
770 Agency is planning to regulate mobile phones on a wide range  
771 of apps and then impose a medical device tax on phones. In  
772 the chairman's opening statement, I think he implied that he  
773 understands that the Agency is not planning to put the  
774 medical device tax on phones, but I just want to clarify  
775 exactly what the Agency is planning to do, Ms. Foreman. So I  
776 want to ask you a couple questions.

777 Is it within the Agency's jurisdiction to regulate  
778 mobile medical apps?

779 Ms. {Foreman.} Yes, it is.

780 Ms. {DeGette.} If you can pull that microphone even  
781 closer, I think you are a very soft-spoken person. Can you  
782 give us some examples of the types of apps that the FDA is  
783 trying to regulate?

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784 Ms. {Foreman.} So the apps that we are trying to  
785 regulate and that we have been regulating for a decade are  
786 similar to what is regulated through other medical device  
787 technology, a central monitoring station for a nurse that  
788 transmits patient data, heart rate, SpO2, other critical  
789 parameters for a patient that need to be monitored. We have  
790 ultrasound technology that there is an app and a transducer  
791 that can plug into a smartphone to allow ultrasounds to take  
792 place. Those are the types of technology that we are  
793 regulating.

794 Ms. {DeGette.} And why are you trying to regulate those  
795 types of technology, Ms. Foreman?

796 Ms. {Foreman.} So those types of technology pose  
797 patient risk. If the device does not perform as intended,  
798 there is a potential for patient risk. Additionally, it is  
799 the same as other medical devices we regulate. We regulate  
800 based on intended use, not based on platform. So just  
801 because a device moves to a mobile platform, it would not be  
802 the Agency's intention that that would make it deregulated.

803 Ms. {DeGette.} So you are not looking at how the app is  
804 used; you are looking at what the purpose is, right?

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805 Ms. {Foreman.} Exactly.

806 Ms. {DeGette.} And this is an ability that the Agency  
807 has had for some years; it is just not new under the  
808 Affordable Care Act or under the stimulus, correct?

809 Ms. {Foreman.} That is correct. Our first clearance of  
810 a mobile app product goes back to 1997.

811 Ms. {DeGette.} 1997, okay. And can you tell me what  
812 types of apps the Agency will not be regulating and why?

813 Ms. {Foreman.} So there are apps that do not meet the  
814 definition of a medical device. The Agency would not  
815 regulate those. That would be, for example, a device that--  
816 an app that takes an electronic version of a printed  
817 textbook. We have said that is not a medical device.

818 Ms. {DeGette.} Okay.

819 Ms. {Foreman.} There are devices that--it meets the  
820 definition of a device, but the risk is low. The Agency  
821 would rather focus our regulatory priorities on the higher-  
822 risk products. So devices for maintaining a healthy  
823 lifestyle that help with--

824 Ms. {DeGette.} Pedometers--

825 Ms. {Foreman.} Exactly. We would not put regulatory

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826 oversight priorities into those products.

827 Ms. {DeGette.} Okay. Now, in a different subcommittee  
828 the other day, members of the industry also agreed with what  
829 you are saying. Qualcomm's representative testified at that  
830 hearing ``the FDA is squarely within its jurisdiction and we  
831 took a lot of their initial actions as a very promising  
832 indication to the industry at large that they were willing to  
833 work with all of us.'' So Ms. Foreman, I want to ask you,  
834 what are you doing to make sure that the Agency doesn't  
835 overreach when regulating these devices and using the  
836 standards that you have set forth?

837 Ms. {Foreman.} So, as I mentioned, for us to regulate  
838 the product, it must first meet the definition of a medical  
839 device. That is what gives the Agency its authority. But  
840 for all of the products that meet the definition of a medical  
841 device, we have actually narrowed our focus to a small subset  
842 of those. So we are actually refining our regulatory  
843 approach rather than overreaching.

844 Ms. {DeGette.} Okay. So that is good that you are  
845 narrowing it down, looking at things that affect patient  
846 safety and so on, but we are still hearing concerns about the

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847 impact of uncertainty on the mobile medical device market.

848 Can you tell me what the Agency is doing to eliminate this

849 uncertainty for investors and developers?

850 Ms. {Foreman.} So we believe finalizing the mobile  
851 medical apps Guidance is the first step in eliminating that  
852 uncertainty. That Guidance will provide clear, transparent,  
853 and predictable messaging regarding mobile medical apps.

854 Ms. {DeGette.} And that is the Guidance that you told  
855 Mr. Burgess that you are planning to issue by the end of the  
856 fiscal year, right?

857 Ms. {Foreman.} Correct.

858 Ms. {DeGette.} Now, also, we have heard concerns about  
859 the effects of FDA-induced delays on the mobile medical  
860 device market. Now, how do you respond to those?

861 Ms. {Foreman.} So we looked at our performance over the  
862 last 3 years, which we believe gives a contemporary  
863 performance. It--on average, it takes the FDA 67 days to  
864 review a mobile medical app. That is well within our  
865 statutory time frame of 90 days for the 510(k) process. All  
866 mobile apps we have seen thus far have been in the 510(k)  
867 process on--

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868 Ms. {DeGette.} And you are going to continue that--

869 Ms. {Foreman.} For the most part, yes.

870 Ms. {DeGette.} Thank you. Mr. Chairman, I had  
871 referenced the letter from the FDA in my opening statement  
872 and asked for inclusion in the record, and the chairman said  
873 he had received it but I don't believe he agreed to my  
874 unanimous consent request to put it into the record, so I  
875 would renew that request.

876 Dr. {Burgess.} I also received it and I accept your  
877 unanimous consent request. So ordered.

878 [The information follows:]

879 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

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|  
880 Ms. {DeGette.} Thank you so much.

881 Dr. {Burgess.} The chair recognizes Mr. Johnson from  
882 Ohio, 5 minutes, for the purposes of questions, sir.

883 Mr. {Johnson.} Thanks to our panelists for coming  
884 today.

885 The Meaningful Use Program has made good progress in  
886 automating the current system. The first stage was to  
887 encourage adoption of current technology and gain automation  
888 efficiencies. Of course, Stage 2 addressed connectivity and  
889 sharing of information, and Stage 3, the final stage, is  
890 where providers and patients have accurate, real-time  
891 information in the systems and devices that provide care  
892 anywhere.

893 As an IT professional myself for nearly 30 years,  
894 architecture and a roadmap of where you are going is vitally  
895 important because, as they say, if you don't know where you  
896 are going, any road will get you there. And you can pump  
897 millions, billions into these projects. And in today's  
898 environment, our healthcare providers simply don't have  
899 millions and billions to pump into something that is not

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900 working for them.

901           So what is the gap between today's technology and the  
902 architecture of tomorrow to achieve an integrated,  
903 coordinated care system? How are we making sure that the  
904 data that is being collected, that people can use? You know,  
905 I call it decisional information. How are we making sure  
906 that we are connecting the dots?

907           Dr. {Mostashari.} That is a terrific question and you  
908 are absolutely right that it is the use of data not just the  
909 data itself that improves care. And as we found in other IT  
910 endeavors, it--particularly--IT becomes particularly  
911 important when you redesign the processes to take advantage  
912 of the information technology instead of merely digitizing  
913 the paper-based or former processes.

914           Mr. {Johnson.} And I would certainly agree with you.  
915 You know, over my 30 years in IT, one of the cardinal lessons  
916 is just because something can be automated doesn't mean that  
917 it should be automated. It is an issue of business process  
918 reengineering, and if you don't do that, you don't have a  
919 complete solution or certainly you don't have a solution that  
920 is connected.

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921           So who is developing the architecture that tells our  
922 healthcare providers in our system how this is all going to  
923 fit together?

924           Dr. {Mostashari.} We have developed that roadmap that  
925 you speak of, and it is an incremental roadmap, as you  
926 mentioned, through the stages. And it begins with making  
927 sure that we have data because until you have data, you  
928 really can't see what you are doing. You can't have  
929 accountable care if you can't count. And that is where  
930 paper-based systems are today. So in Stage 1, the idea is  
931 let's collect the information in a structured way because--  
932 yes.

933           Mr. {Johnson.} Well, that goes back to what I said  
934 earlier, and I think this is a discussion between two IT  
935 professionals here that everybody else may get bored with.  
936 That goes back to the ``if you don't know where you are  
937 going, any road will get you there.'' I don't think you know  
938 what data you need until you have an architecture and you  
939 know what the end stage looks like. You know, in the many,  
940 many software and technology programs that I managed  
941 throughout my 30-year career, if you don't start with an idea

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942 of what the end state looks like, then you waste a lot of  
943 money; you waste a lot of time.

944 Dr. {Mostashari.} That is right.

945 Mr. {Johnson.} So I am not sure data collection up  
946 front without knowing what data you want to collect makes a  
947 whole lot of sense.

948 Dr. {Mostashari.} Let me clarify my response.

949 Mr. {Johnson.} Sure. Because we start with data. Data  
950 doesn't become information until it is relevant and until it  
951 can be used. And data just for the sake of data, as you  
952 know, is--

953 Dr. {Mostashari.} That is right.

954 Mr. {Johnson.} So go ahead. I am sorry.

955 Dr. {Mostashari.} Sorry about that. So we start with--  
956 in the framework, we actually start with the end in mind. So  
957 we said what is it about the use of technology that can--we  
958 can expect to improve safety, improve the quality of care,  
959 patient engagement, public health. And then we work  
960 backwards to say, okay, if we want to reduce deaths--  
961 unnecessary deaths, those are associated with better decision  
962 support at the point of care, it is associated with quality

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963 measurement, and being able to make a list of patients by  
964 certain criteria, okay, and taking that a step back, you need  
965 to be able to have a list of medications for patients. That  
966 is pretty clear. We need to have a list of their problems  
967 and diagnoses. You need to know their allergies. You need  
968 to know their laboratory values. You need to know their  
969 blood pressure and smoking status. And it was those data  
970 elements recognizing that as the system evolves, there would  
971 need to be flexibility and the ability to extend that  
972 framework and add in the next iteration devices, for example.

973 Mr. {Johnson.} Like I said, people are probably going  
974 to get bored. You and I can--

975 Dr. {Mostashari.} We would--

976 Mr. {Johnson.} But how many physicians have been  
977 involved in the development of this roadmap and the kind of  
978 data that we need to--

979 Dr. {Mostashari.} We have one of the, I think, hardest-  
980 working and most respected Federal Advisory Committees in  
981 government. We--it--there--it is--there are certain  
982 statutory representations on that. The house majority and  
983 minority leaders appoint members to the Policy Committee.

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984 The Senate minority, majority leaders, the Comptroller

985 General--

986 Mr. {Johnson.} My time is expired.

987 Dr. {Mostashari.} Sorry.

988 Mr. {Johnson.} The chairman is making that known, so I  
989 thank you for your answers. I would love to talk to you more  
990 sometime.

991 Dr. {Burgess.} And the gentleman may request the answer  
992 in writing, and I hope that he will.

993 The chair recognizes--

994 Dr. {Mostashari.} Will do.

995 Dr. {Burgess.} --now Mr. Waxman, the ranking member of  
996 the full committee.

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

998 Ms. Foreman, we have heard a lot of allegations over the  
999 last few days that FDA is intending to regulate everything  
1000 and anything digital or online that has any relation to  
1001 healthcare. But the facts seem to be very different. I know  
1002 you have attempted in your testimony, as well as in the 2011  
1003 Draft Guidance, to allay concerns about the scope of what FDA  
1004 intends to regulate. But I would like for the record to go

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1005 over some of the examples we heard in testimony yesterday or  
1006 the day before. Is FDA currently proposing or does it intend  
1007 in the future to regulate ordinary smartphones and tablets?

1008 Ms. {Foreman.} No, it does not.

1009 Mr. {Waxman.} What about mobile platforms in general  
1010 such as the iPhone, Blackberry, Android phones, tablet  
1011 computers, or other computers that are typically used as  
1012 smartphones or personal digital assistants?

1013 Ms. {Foreman.} No.

1014 Mr. {Waxman.} What about the entire mobile network?

1015 Ms. {Foreman.} No.

1016 Mr. {Waxman.} Each new mobile device released on the  
1017 market?

1018 Ms. {Foreman.} No.

1019 Mr. {Waxman.} All health IT?

1020 Ms. {Foreman.} No.

1021 Mr. {Waxman.} An iPad application to help track the  
1022 number of steps walked per day?

1023 Ms. {Foreman.} No.

1024 Mr. {Waxman.} An iPad application that reminds one that  
1025 it is time to refill a prescription?

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1026 Ms. {Foreman.} No.

1027 Mr. {Waxman.} Software that enables a physician to  
1028 search a medical textbook?

1029 Ms. {Foreman.} No.

1030 Mr. {Waxman.} Apps to allow parents to access online  
1031 services such as personal health records to document  
1032 procedures that a baby has undergone and drugs their baby was  
1033 given?

1034 Ms. {Foreman.} No.

1035 Mr. {Waxman.} I don't think you can be any clearer.  
1036 FDA has established limits on what it can and cannot regulate  
1037 in the mobile device market, and I appreciate you walking  
1038 through these limits.

1039 While I know that IRS, not FDA, implements the tax code,  
1040 I would like to ask you a bit about the recent claims that  
1041 mobile platforms will be taxed under the Medical Device Act.  
1042 Under the new medical device tax, will smartphones and iPads  
1043 now be taxed as medical devices?

1044 Ms. {Foreman.} So the FDA is a public health agency,  
1045 not a tax agent agency.

1046 Mr. {Waxman.} I understand.

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1047 Ms. {Foreman.} The questions would probably be best  
1048 answered by IRS or the Treasury, but my understanding is no.

1049 Mr. {Waxman.} These type of products are exempt from  
1050 the medical device tax, isn't that correct? Can you explain  
1051 a little bit about this exemption?

1052 Ms. {Foreman.} So, as I said, we are public health  
1053 agency--

1054 Mr. {Waxman.} Yes.

1055 Ms. {Foreman.} --not a tax agent agency, but they would  
1056 not be regulated as medical devices, therefore, not subject  
1057 to the medical device tax.

1058 Mr. {Waxman.} Okay. As I understand it, they will be  
1059 exempt because FDA will not define them as a medical device,  
1060 and even if you did define them as a medical device, they  
1061 won't be tax because they will qualify for the retail  
1062 exemption. The law says that items sold to consumers by way  
1063 of retail cannot be taxed. Isn't that your understanding as  
1064 well?

1065 Ms. {Foreman.} That is my understanding.

1066 Mr. {Waxman.} Although we don't rely on you for tax  
1067 information.

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1068 Ms. {Foreman.} You really should not.

1069 Mr. {Waxman.} But we are interested in this issue  
1070 because it has been brought up so many times, and this  
1071 committee is not a committee that has jurisdiction over tax.

1072 I thank you very much. It is clear that fears that  
1073 iPhones and other smartphones are going to be regulated by  
1074 FDA and taxed as medical devices are unfounded and we can put  
1075 this myth to rest.

1076 Okay. Well, Mr. Chairman, my staff informs me the next  
1077 question is not for me to pursue and I have asked the  
1078 questions that I think are important and I think they are  
1079 good way to end the third day of hearings to allay a lot of  
1080 the fears that have been raised in the other two. And so  
1081 unless anybody wants my minute, I will yield it back.

1082 Dr. {Burgess.} And the chair thanks the ranking member.  
1083 It is forever in his debt.

1084 Now yields for 5 minutes to Ms. Ellmers from North  
1085 Carolina.

1086 Mrs. {Ellmers.} Thank you, Mr. Chairman.

1087 Thank you. Thank you. And Dr. Mostashari, good to see  
1088 you again. We have worked together many times on this issue

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1089 and there again thank you for coming. Thank both of you for  
1090 coming to testify today.

1091 You know, one of the things--and I know we have  
1092 discussed this in the past--is really the cost to physicians  
1093 who are small business owners, and as important as we all  
1094 know health information technology is, the cost being passed  
1095 on to them, you know, there are estimations of 15,000 to  
1096 \$70,000 for the cost of implementing IT. And also, there is  
1097 the issue of the physician really being taken away from the  
1098 patient at the bedside to implement the information. And  
1099 there is of course that learning curve that everyone has to  
1100 go under.

1101 Now, one of the points that is being made is how this is  
1102 helping eliminate errors and actually thereby improving  
1103 healthcare. However, when limited time is given to the  
1104 patient directly, hands-on, and eye-to-eye contact with that  
1105 patient, don't you think that subsequently it could actually  
1106 have a bearing on the ultimate outcome of the patient, maybe  
1107 something being missed, possibly tests being over-ordered as  
1108 a result of not an adequate time with the patient?

1109 Dr. {Mostashari.} Overall, the--we actually have data

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1110 from the National Center for Health Statistics where  
1111 providers report that EHRs have, in their estimation,  
1112 produced clinical benefit for their patients. It is 79  
1113 percent. And if you look at those who are using the modern  
1114 systems and who have been using it for more than 2 years--and  
1115 this is important because it takes time--

1116 Mrs. {Ellmers.} Um-hum. Um-hum. Sure. Sure.

1117 Dr. {Mostashari.} --to get used to the systems, that  
1118 rises to 92 percent. Now, providers believe that in their  
1119 practice the electronic health records are providing clinical  
1120 benefit to their patients.

1121 Mrs. {Ellmers.} Okay. Now, that leads me to my next  
1122 question because a lot of the software is incompatible with  
1123 other facilities, so software that one physician may be using  
1124 may not be the same software another physician or the  
1125 physician in the hospital not using the same. So getting  
1126 back to again considering errors, considering the possibility  
1127 of information not being exchanged adequately, but also  
1128 considering cost, which of course ultimately gets passed on  
1129 to the patient, and we are always looking for good quality of  
1130 care, what is going to happen when we are trying to integrate

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1131 all those systems? Is this cost then going to be passed on  
1132 to the physician again and, you know, having to bear the  
1133 brunt of that expense?

1134 Dr. {Mostashari.} Making sure that the patient  
1135 information is available when and where it is needed is one  
1136 of our top priorities. And we could have, as some countries  
1137 have done, have said we are going to solve that problem by  
1138 the government is going to buy the EHR system for the whole  
1139 country. That is not the way we do things--

1140 Mrs. {Ellmers.} Um-hum. Um-hum.

1141 Dr. {Mostashari.} --right? We said the people who are  
1142 best suited to make those purchasing decisions are the  
1143 hospitals and doctors who have to live with the systems. But  
1144 in order to make sure that they can talk with each other,  
1145 then we need to have some standards. We need to have a  
1146 certification program and to evolve that certification  
1147 program and to create consensus, industry consensus--

1148 Mrs. {Ellmers.} Um-hum.

1149 Dr. {Mostashari.} --private sector consensus around how  
1150 we can have one doctor choosing one system, the other  
1151 choosing a different system that meets their needs but having

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1152 those systems--

1153 Mrs. {Ellmers.} Be able to communicate.

1154 Dr. {Mostashari.} --be able to talk to each other.

1155 That is the approach we have taken, and the certification  
1156 criteria for 2014 put a big step up in those requirements.

1157 Mrs. {Ellmers.} Okay. Thank you, Dr. Mostashari.

1158 Ms. Foreman, I do have a couple questions. I know we  
1159 continuously are talking about, one, the FDA regulation  
1160 issue, which is very important, but also the tax on the  
1161 medical devices. Has the FDA looked at this as an issue that  
1162 it might actually be stifling some of the innovation moving  
1163 forward with having the tax on medical devices?

1164 Ms. {Foreman.} So, as I said, we are public health  
1165 agency. Our decisions are governed by public health. But  
1166 to--our decision-making was based on balancing innovation and  
1167 public health.

1168 Mrs. {Ellmers.} Um-hum. Um-hum.

1169 Ms. {Foreman.} We identified a large subset of devices  
1170 that could be under enforcement discretion without our  
1171 regulatory oversight.

1172 Mrs. {Ellmers.} Um-hum. Um-hum.

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1173 Ms. {Foreman.} As it happens, those devices would not  
1174 be--it may not be subject to the device tax.

1175 Mrs. {Ellmers.} Okay.

1176 Ms. {Foreman.} As was mentioned, there is a retail  
1177 exemption as well--

1178 Mrs. {Ellmers.} Right.

1179 Ms. {Foreman.} --products available at the retail--even  
1180 if it is declared to be a medical device--is exempt from the  
1181 tax, but FDA does--is a public health organization, not a tax  
1182 agent agency.

1183 Mrs. {Ellmers.} Thank you. Thank you. My time is  
1184 expired. Thank you both.

1185 Dr. {Burgess.} The chair recognizes the gentleman from  
1186 North Carolina 5 minutes for purposes of questions, sir.

1187 Mr. {Butterfield.} I thank you, Mr. Chairman.

1188 And I thank both of you for your testimony here today.

1189 Over the course of the last 2 days of hearings, and  
1190 actually in Ms. Foreman's testimony here today, we have  
1191 learned that FDA has proposed regulating only a very small  
1192 subset of mobile applications. FDA's Draft Guidance states  
1193 that the Agency will only look at those mobile apps that are

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1194 essentially acting as a medical device or as part of one.  
1195 The Guidance also explicitly exempts many of the apps that my  
1196 colleagues on the other side have been trying to scare people  
1197 into thinking FDA was going to take over, things like  
1198 electronic PDRs and electronic health records. That seems  
1199 like a very reasonable approach to me.

1200 But I want to learn more about exactly what kind of  
1201 regulatory burden we are talking about even with this small  
1202 subset of applications that will be regulated as devices. I  
1203 know that an FDA-regulated medical device may fall into one  
1204 of three tiers. We have heard about that. Class 1 devices  
1205 are the least risky devices while Class 3 devices are the  
1206 most risky.

1207 And so let me start with Ms. Foreman. Ms. Foreman, can  
1208 you briefly elaborate on these three levels of device  
1209 oversight and explain what responsibilities a device  
1210 manufacturer has under each of these levels?

1211 Ms. {Foreman.} Certainly. I will start at the bottom  
1212 and work up. So if the device is a Class 1 device, which  
1213 this small subset could have devices that meet the Class 1  
1214 definition of a medical device, they are not subject to

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1215 agency premarket review. They are subject to meeting  
1216 registration and listing requirements, as well as the quality  
1217 system regulation, making sure that they have manufactured  
1218 the devices properly.

1219         Moving up to Class 2 devices, they have to meet those  
1220 same criteria--registration, listing, quality system--but  
1221 they also need what is called a 510(k) or a premarket  
1222 notification. That application would allow the Agency to  
1223 review and clear the device as equivalent to another device  
1224 on the market. There is a user fee associated with that. It  
1225 is just under \$5,000. However, if it is a small business, it  
1226 is half of that. If they make significant modifications to  
1227 the device, they would need a new 510(k), but as I mentioned,  
1228 we planned many of those iterative changes to not require new  
1229 submissions of 510(k)s.

1230         If we move up to the next level, Class 3, that requires  
1231 a premarket approval application. To date, we have not found  
1232 a mobile app that would fit under that bucket. I am not  
1233 saying that in the future it wouldn't be possible, but we  
1234 have not seen that yet.

1235         Mr. {Butterfield.} So essentially, what you are saying

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1236 is that a Class 1 or 2 device doesn't have to do all that  
1237 much in terms of premarket clearance, while Class 3, if there  
1238 is one, sounds like it may be subject to more stringent  
1239 requirements if one evolves--

1240 Ms. {Foreman.} Correct.

1241 Mr. {Butterfield.} --is that correct?

1242 Ms. {Foreman.} Correct.

1243 Mr. {Butterfield.} Okay. Now, which level of  
1244 regulatory oversight will most of these medical applications  
1245 fall under?

1246 Ms. {Foreman.} Class 1 or Class 2.

1247 Mr. {Butterfield.} Class 1 or Class 2. And you don't  
1248 know of any Class 3 existing at this moment?

1249 Ms. {Foreman.} I do not.

1250 Mr. {Butterfield.} All right. Now Ms. Foreman, there  
1251 were also some assertions yesterday that FDA lacked the  
1252 expertise to regulate mobile applications. Your testimony  
1253 states that you have regulated medical device software for  
1254 decades and mobile apps for more than 10 years. Can you  
1255 elaborate on FDA's experience regulating in this area?

1256 Ms. {Foreman.} Absolutely. This is not new for the

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1257 FDA. We have been regulating software and mobile apps for  
1258 some time. When we do our review, we actually bring together  
1259 two different sets of expertise. There is the software  
1260 expertise that we have software engineers who will review the  
1261 software information to make sure that it was developed  
1262 properly. That is coupled with a clinical review because the  
1263 app is intended for a medical application. So for example,  
1264 if you take an app to view a radiology image on a smartphone,  
1265 the software reviewer can make sure that all of the technical  
1266 specifications happen properly on the smartphone. But what  
1267 we will bring the clinical reviewer in to look at is--so if  
1268 we view an image on a smartphone, can we actually detect  
1269 cancer with the same level of sensitivity and specificity  
1270 that we would on the large view station? So you can zoom the  
1271 image, you can pan, you can look at it that way, but is there  
1272 a difference between looking at the whole image versus pieces  
1273 of the image to make sure that patient safety is not  
1274 compromised? Because you don't want somebody to have  
1275 undergone radiation for a diagnostic purpose and then that  
1276 purpose--there is a false negative or a false positive.

1277 Mr. {Butterfield.} Can you finally address how you plan

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1278 to keep up with the world in which so many apps are already  
1279 on the market and so many new ones are coming out every day?  
1280 How are you going to keep up with all this stuff?

1281 Ms. {Foreman.} So as we mentioned, part of keeping up  
1282 with it is prioritizing our focus, so we are prioritizing our  
1283 focus on the small subs that we get about 20 a year. Right  
1284 now, we are getting less than 20 a year. That is actually in  
1285 our 510(k) inventory. That is about .5 percent of the  
1286 medical device applications that we review. And keeping up  
1287 with technology is something that we are always faced with,  
1288 so that is why we have--we break on competent staff and we  
1289 make sure we try and provide training opportunities for those  
1290 staff so that they can continue to stay abreast of the latest  
1291 technology.

1292 Mr. {Butterfield.} Thank you. My time is expired.

1293 Dr. {Burgess.} The gentleman's time is expired.

1294 I am advised that votes have the called. We will try to  
1295 go over and get through as many of the panel as we can.

1296 I recognize the gentleman from Missouri 5 minutes for  
1297 questions.

1298 Mr. {Long.} Thank you, Mr. Chairman. And thank you all

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1299 for being here today.

1300 Director Foreman, I have a question for you. As far as  
1301 current FDA Risk Evaluation and Mitigation Strategy, REMS for  
1302 short, their Guidance requires, doesn't it, that medication  
1303 guides upon first dispensing of the medication and then for  
1304 every subsequent refill you have to have the medication  
1305 guides printed out. Is that correct?

1306 Ms. {Foreman.} So I am going to apologize because REMS  
1307 is a provision implemented by CDER, or Center for Drug  
1308 Evaluation and Research. So that is really outside of my  
1309 area of expertise in the Center for Devices and Radiological  
1310 Health.

1311 Mr. {Long.} Okay. Who should I go to to answer that  
1312 question? Who should I--

1313 Ms. {Foreman.} CDER is headed by Dr. Janet Woodcock.

1314 Mr. {Long.} Okay. Okay. Because that was my intent  
1315 was to ask if on a refill prescription if that could be able  
1316 to be handled through a mobile device as opposed to trying to  
1317 mail a stack of how to retake your medicine every time that  
1318 it is prescribed. So with that--and I know we are short on  
1319 time--Mr. Chairman, I yield back.

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1320 Dr. {Burgess.} The gentleman yields back.

1321 The gentleman from New York is recognized for 5 minutes  
1322 for questions.

1323 Mr. {Tonko.} Thank you, Mr. Chair.

1324 Dr. Mostashari, there is a broad consensus that the  
1325 increased use of electronic health records and health  
1326 information technology ultimately leads to better patient  
1327 care and a bending of that cost curve and savings, but there  
1328 is also a concern that the adoption of these EHRs also  
1329 provide an increased opportunity for fraud by exaggerating  
1330 the intensity of care or severity of patients' conditions on  
1331 their Medicare claims. We have, I guess, labeled this as up-  
1332 coding and it is often facilitated by software programs that  
1333 prompt billing for additional services that were not provided  
1334 and maybe only tangentially related to the care received.  
1335 Many of our health IT vendors are developing these systems to  
1336 promote their products as a way to increase the bottom line.  
1337 So my question is can you discuss what your office is  
1338 doing to develop guidance and technological standards in  
1339 electronic health records software that will help to prevent  
1340 this type of fraud?

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1341 Dr. {Mostashari.} Yes, thank you for the question. I  
1342 want to make one thing very clear, which is that if there is  
1343 documentation of care that did not occur, that is fraud. And  
1344 CMS and the Attorney General and the Secretary of Health have  
1345 made it very clear that we will not tolerate fraud. And the  
1346 electronic health records provide increased tools also on our  
1347 side to be able to better investigate and prosecute fraud  
1348 should it occur. There are always those who will attempt to  
1349 defraud the system and I think this Administration in  
1350 particular has been very successful and has had record  
1351 prosecutions and recoveries under that.

1352 But I think your question gets to also issues where it  
1353 is not explicit fraud, and those are more complicated  
1354 situations. I think some of the analysis has been done  
1355 looked at patterns of coding intensity over the past decade.  
1356 Before the first meaningful use payment check ever went out,  
1357 for a decade there has been this creep towards higher  
1358 intensity codes. CMS--this is not a new issue for CMS and  
1359 they have ways of dealing with shifts in these patterns. But  
1360 the electronic health records that were formally  
1361 predominantly used for documentation and billing purposes

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1362 before meaningful use, that may have been part of the  
1363 business case for them. I think that our challenge is  
1364 twofold. First, to make sure that we get the broadest  
1365 possible input on ways that we can mitigate any possibility  
1366 of the records systems themselves inducing inadvertent  
1367 violations.

1368 The second is to make sure that the systems meet the  
1369 needs of the future, which is, as I think there is broad  
1370 consensus, means moving away from paying fee-for-service  
1371 based on documentation and more towards outcomes and value.

1372 Mr. {Tonko.} Thank you. And what lessons can be drawn  
1373 from the implementation of EHRs nationwide from the VA's long  
1374 successful track record with VISTA, their Veterans Health  
1375 Information Systems and Technology Architecture program,  
1376 specifically in terms of interoperability and usability of  
1377 records?

1378 Dr. {Mostashari.} It is interesting, following on your  
1379 previous question, one of the groups that had the most  
1380 experience with the perils of copy-and-paste was the VA,  
1381 which, even though there was no billing incentive, it was  
1382 convenient to carry forward notes from before, and it

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1383 resulted in not--it is not a billing issue. It is a clinical  
1384 documentation issue where it wasn't easy to understand. If  
1385 you practiced at the VA, sometimes you saw notes that were  
1386 copied forward and forward and forward, and it wasn't good  
1387 for clinical care. You couldn't understand what was really  
1388 going on with the patient in this visit. And the VA has done  
1389 a lot working with clinical leadership to say how can we  
1390 improve the quality of the clinical documentation and the  
1391 usability of the systems?

1392         The VA--there is very strong evidence that they have  
1393 saved billions of dollars by implementing IT and by  
1394 continually improving the systems that they have. And if  
1395 there is one lesson I would take from the VA it is that, that  
1396 no system is perfect the day it is implemented. And it  
1397 becomes improved over time through the polishing of that  
1398 stone to the application of clinical judgment, improved  
1399 usability, improved interoperability, and that is what we are  
1400 engaged with here. This is not a, you know, one-and-done  
1401 process. This is going to be a continual process of  
1402 refinement, optimization, improvement, and redesign.

1403         Mr. {Tonko.} Thank you, Dr. Mostashari and Ms. Foreman,

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1404 for appearing before us.

1405 And Mr. Chair, with that, I yield back.

1406 Dr. {Burgess.} The gentleman's time is expired.

1407 The chair now recognizes Mr. Griffith for 5 minutes for  
1408 questions, sir.

1409 Mr. {Griffith.} Thank you.

1410 And I apologize to the witnesses in advance. I have to  
1411 move fairly quickly so I am cutting through a lot of the  
1412 explanation because I think you all know where we are heading  
1413 with the questions as we get to it. But if you need further,  
1414 let me know.

1415 Ms. Foreman, your testimony notes that questions about  
1416 medical device tax should be directed to the IRS, but  
1417 clearly, they are going to need help in figuring out what is  
1418 a medical device at what you are regulating as a medical  
1419 device if it is the purpose of it and not the platform. And  
1420 so I would ask, have you had any discussions with the IRS  
1421 about this tax, if they have asked for your input on that?

1422 Ms. {Foreman.} We provided technical input to the IRS  
1423 on the interpretations of our laws. The way it was  
1424 implemented is that if a medical device lists, it would be

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1425 subject to the tax.

1426 Mr. {Griffith.} And can you provide us with a copy of  
1427 what you gave the IRS so we can take a look at that to the  
1428 committee? Not today, but subsequently?

1429 Ms. {Foreman.} I can look into that.

1430 Mr. {Griffith.} Okay. Thank you. And has the FDA done  
1431 any analysis on the impact of the tax either in dollar  
1432 figures or the number of manufacturers it will have an impact  
1433 on?

1434 Ms. {Foreman.} FDA is a public health agency. We are  
1435 not involved in the taxation. We receive no direct benefits.

1436 Mr. {Griffith.} In regard to the questions, the list of  
1437 examples that Mr. Waxman listed out, while the FDA does not  
1438 currently have any plans, do you believe that the FDA could  
1439 if it so chose to do so regulate those examples down the road  
1440 if it had a change of heart?

1441 Ms. {Foreman.} So if the device meets the definition of  
1442 a device as defined in the Food, Drug, and Cosmetic Act, we  
1443 could. We have no intent to. The only thing that would  
1444 change our mind is if there was a strong safety signal that  
1445 we became aware of a device that we were not regulating

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1446 appropriately under enforcement discretion. By not  
1447 regulating it, that would cause us to reconsider our  
1448 position. But absent strong safety signals, no, we would not  
1449 change our mind.

1450 Mr. {Griffith.} All right. And then the practical  
1451 question that I would have is if somebody is currently  
1452 developing an app of a medical nature, how does anybody know  
1453 if they are supposed to be contacting the FDA? And, you  
1454 know, I am just an old country lawyer and I got on my tablet  
1455 here--it is an Android--and found an article yesterday and  
1456 there was lots of; I just chose this one because it sounded  
1457 interesting--that the iPhone is now a handy tool for  
1458 detecting and diagnosing parasites, and the article says  
1459 ``using little more than an iPhone, strips of double-sided  
1460 tape, a cheap ball lens, and a battery-powered flashlight, a  
1461 workable model was assembled to determine whether or not a  
1462 child had parasites.'' Are you all regulating that or not?

1463 Ms. {Foreman.} To my knowledge, we have not regulated  
1464 that. It has not come before us. A diagnostic device,  
1465 though, would meet the definition. That would--

1466 Mr. {Griffith.} So if the Canadians, the Bostonians,

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1467 and the Swiss who worked this up to help in other countries  
1468 decided that it might be helpful in rural parts of the United  
1469 States, they would have to come to you first, and instead of  
1470 costing \$8, it would cost what? Hundreds of thousands?

1471 Ms. {Foreman.} We are not involved in the pricing of  
1472 medical devices.

1473 Mr. {Griffith.} No, no, no, I am not talking about with  
1474 the price is. I am talking about how much it costs to get it  
1475 approved.

1476 Ms. {Foreman.} So, as I say, a 510(k) fee is just under  
1477 \$5,000. If it is a small business, it would be half of that.

1478 Mr. {Griffith.} Okay.

1479 Ms. {Foreman.} So 2,500.

1480 Mr. {Griffith.} But you would want all kinds of tests  
1481 and studies, not the fact that they have been out in the  
1482 field and made it work with double-sided tape, am I not  
1483 correct?

1484 Ms. {Foreman.} I am not inherently opposed to double-  
1485 sided tape but--

1486 Mr. {Griffith.} I understand. I think I have made my  
1487 point, and I yield back my time, Mr. Chairman.

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1488 Dr. {Burgess.} I thank the chair. The chair yields to  
1489 the gentleman from Texas, Mr. Barton, for questions.

1490 Mr. {Barton.} Mr. Chairman, I appreciate the time. I  
1491 want to yield it to you to use as you so decide.

1492 Dr. {Burgess.} Well, I thank the chairman emeritus.

1493 Dr. Mostashari, I just have to ask you here as we  
1494 conclude today, I hear a lot of stuff about interoperability.  
1495 I mean you are the head. Why don't you just fix that? Why  
1496 don't you just make that happen?

1497 Dr. {Mostashari.} We are using every lever at our  
1498 disposal to increase the sharing of information, and that  
1499 includes not just the data standards and getting industry  
1500 together to help us. We don't want to be the ones to say,  
1501 you know, we will choose the standards. We really want to  
1502 work with industry to get consensus and to accelerate this.

1503 Dr. {Burgess.} But, you know, in the interest of time,  
1504 we do hear about this a lot. Even anecdotally, hospital  
1505 systems in the same city that have the same operating system  
1506 aren't talking to each other. It seems like you could make  
1507 that happen.

1508 Dr. {Mostashari.} We--the 2014 certification criteria,

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1509 Dr. Burgess, I--we--I would be happy to go into great detail  
1510 with you, but they are a big step forward, and I believe that  
1511 hospitals and doctors around the country will see a palpable  
1512 difference once those certification criteria are in place.

1513 Dr. {Burgess.} Well, I want to thank both of our  
1514 witnesses for being here today and for bearing with us. I  
1515 apologize about votes cutting the hearing short. Dr.  
1516 Mostashari, I look forward to having you back at either the  
1517 Health Subcommittee or this subcommittee and the future. You  
1518 are a fascinating witness. We have learned a lot this  
1519 morning from both of you, and I appreciate your time.

1520 I want to thank the members for their devotion to the  
1521 hearing today.

1522 The committee rules provide that members have 10 days to  
1523 submit additional questions for the record to the witnesses.  
1524 I also failed to ask for unanimous consent that all members'  
1525 statements that wish to be entered in the record be entered.

1526 Hearing no objection, so ordered.

1527 [The information follows:]

1528 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

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1529 Dr. {Burgess.} The hearing stands adjourned.

1530 [Whereupon, at 10:25 a.m., the subcommittee was

1531 adjourned.]