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4 HEARING ON THE VIEWS OF THE DEPARTMENT OF HEALTH AND HUMAN
5 SERVICES ON REGULATORY REFORM: AN UPDATE
6 MONDAY, JUNE 13, 2011
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 2:08 p.m., in
12 Room 2322 of the Rayburn House Office Building, Hon. Cliff
13 Stearns [Chairman of the Subcommittee] presiding.

14 Members present: Representatives Stearns, Bilbray,
15 Scalise, and Waxman (ex officio).

16 Staff present: Allison Busbee, Legislative Clerk; Todd
17 Harrison, Chief Counsel, Oversight and Investigations; Sean
18 Hayes, Counsel, Oversight and Investigations; Debbie Keller,

19 Press Secretary; Alan Slobodin, Deputy Chief Counsel,
20 Oversight; Sam Spector, Counsel, Oversight; John Stone,
21 Associate Counsel; Kristin Amerling, Minority Chief Counsel
22 and Staff Director for Oversight; Brian Cohen, Minority
23 Senior Policy Advisor and Staff Director for Investigation;
24 Karen Lightfoot, Minority Communications Director and Senior
25 Policy Advisor; Bruce Wolpe, Minority Senior Advisor; Anne
26 Tindall, Minority Counsel; Stacia Cardella, Minority Counsel;
27 and Ali Neubauer, Minority Investigator.

|
28 Mr. {Stearns.} Good morning, everybody, and the
29 Subcommittee on Oversight and Investigations is convened. I
30 will start with my opening statement.

31 We have convened this hearing of the subcommittee to
32 examine how the Department of Health and Human Services is
33 implementing President Obama's executive order, which was
34 announced on January 18, entitled ``Improving Regulation and
35 Regulatory Review.'' Regulatory reform has been a priority
36 of this subcommittee in the 112th Congress and will remain so
37 as long as Americans suffer from prolonged high unemployment
38 and sluggish economic growth.

39 A 2/10 study commissioned by President Obama's Small
40 Business Administration places the total annual compliance
41 cost of federal regulations at \$1.75 trillion, a number that
42 trumps the record federal budget deficit. Cass Sunstein, the
43 head of the office of Information and Regulatory Affairs, a
44 primary overseer of the administration's reform efforts,
45 disagreed with this study in his testimony before this
46 subcommittee on June 3. This seemed to be a theme of the
47 administration. If a study or report comes out that they
48 disagree with, it is denounced as inaccurate or labeled an
49 outlier, even if the administration actually commissioned the
50 study themselves. Case in point is a White House response to

51 a recently released study by the McKinsey Group, indicating a
52 radical restructuring of employer-sponsored health benefits,
53 following the passage of the President's health care plan.

54 Overall, 30 percent of the employers surveyed said that
55 they will definitely or probably stop offering health care
56 coverage in the years after 2014, due to the overwhelming
57 burden and expense of Obamacare, and an incredible 50 percent
58 of employers with a high awareness of the laws say they will
59 stop offering coverage.

60 White House Deputy Chief of Staff Nancy-Ann DeParle
61 shrugged off the report saying it misses some key points and
62 doesn't provide the complete picture. This study, however,
63 is not an outlier. Two other reports have been released by
64 reputable independent experts within the last month. Each
65 one concludes that the Obamacare has made coverage more
66 expensive and that many individuals who like their current
67 plan will simply be dropped from it.

68 In fact, according to the administration's own estimate
69 cited in the interim final rule implementing the
70 grandfathered health plans, its regulations will force half
71 of all employers and as many as 80 percent of small
72 businesses to give up their coverage in the next 2 years as
73 this graph clearly shows.

74 President Obama's executive order requires agencies,

75 when promulgating rules, to consider costs and benefits to
76 ensure that the benefits justify the costs and to select the
77 least burdensome alternatives. It requires increased public
78 participation. It directs agencies to take steps to
79 harmonize, simplify, and coordinate rules. And finally, it
80 directs agencies to consider flexible approaches that reduce
81 burdens and maintains freedom of choice for the public.

82 I do not see how the regulations that will force as many
83 as 80 percent of small businesses to drop their employees'
84 health coverage can possibly pass any of these tests and
85 criteria that the President outlined. Quite frankly, it
86 seems like Obamacare itself has received a waiver from this
87 executive order itself.

88 In addition to prospective requirement agencies are
89 supposed to adhere to while promulgating regulations, the
90 executive order directs agencies to conduct ongoing,
91 retrospective analyses to identify rules that should be
92 streamlined, reduced, improved, or eliminated.

93 HHS arguably touches more aspects of America's daily
94 lives than any other agency. FDA in itself regulates more
95 than 25 percent of the U.S. economy. We need to ensure that
96 the regulations it has on the books as well as the ones it
97 currently drafting promote public health as well as private
98 sector innovation and job creation. After all, the health

99 and well being of our citizens is inherently tied to the
100 health and well being of our economy. The number and size of
101 the regulations that have been expedited through the review
102 process at HHS and ORIA is matched only by the number and
103 sizes of the rules still in the queue. Among these is the
104 establishment of an essential benefits package, which will
105 increase premiums and further put people's coverage at risk.

106 Hopefully our witnesses today--our witness today will
107 share with us what HHS has learned from the process used to
108 promulgate such rules and regulation as a grandfathered
109 health plans rule. HHS will hopefully do better, while
110 reviewing the essential benefits package and other large
111 rules coming down the pike.

112 An unprecedented amount of authority has been delegated
113 to HHS and other agencies in the administration. The
114 principles President Obama affirms in his executive order are
115 important. We agree. I am just concerned they are being
116 ignored when it comes to the actual implementation of large
117 scale government program such as the President's health care
118 plan.

119 I would like to welcome our witness, Sherry Glied, who
120 is the assistant secretary for planning and evaluation at the
121 Health and Human Services Department. And with that, I
122 recognize the ranking member of Energy and Commerce, the

123 distinguished Henry Waxman from California.

124 [The prepared statement of Mr. Stearns follows:]

125 ***** COMMITTEE INSERT *****

|
126 Mr. {Waxman.} Thank you, Mr. Chairman. The subject of
127 regulatory reform deserves review, and Congress has a
128 legitimate interest in making sure that the administration is
129 living up to its promises with regard to making the
130 regulatory process simple and more transparent. But as we
131 investigate regulatory reform, we need to make sure we
132 consider both the costs and the benefits of regulations.

133 This is the third hearing in this committee on
134 regulatory reform this year. In these hearings, the
135 administration's opponents have relentlessly focused on the
136 negative with no regard for why we need regulations or for
137 the good that they do. Regulations aren't pulled out of thin
138 air for no reason. They exist to implement laws Congress
139 enacted to help protect taxpayers' funds, improve public
140 health and safety, keep our air and water clean, and keep
141 consumers safe.

142 Today's hearing is a good illustration. Some of the
143 administration's recent health regulations will do enormous
144 good for American families. New food safety regulations
145 promulgated by FDA will reduce salmonella contamination and
146 prevent as many as 79,000 illnesses each year. New tobacco
147 control regulations promulgated by FDA will protect children
148 and adolescents from the dangers of addiction to cigarettes

149 and smokeless tobacco.

150 New regulations issued by CMS under the Affordable Care
151 Act will end the insurance industry's worst abuses. They
152 will prevent health insurers from rescinding policies when
153 beneficiaries get sick, end discrimination against children
154 with preexisting conditions, prohibit the imposition of
155 lifetime caps on coverage and require all health plans to put
156 more of consumers premium dollars into actual care and less
157 into insurance company profits.

158 Another set of CMS regulations also authorized by the
159 Affordable Care Act will cut Medicare and Medicaid fraud and
160 safe taxpayers millions of dollars. No one wants unnecessary
161 or duplicative regulations, but at the same time, no one
162 should want to eliminate regulations that save taxpayers
163 money and protect the health and welfare of America's
164 families.

165 That is why we must look at both the costs and benefits
166 of regulations. When we focus solely on costs, as often
167 seems to happen in this committee, we lose sight of the
168 critical benefits these regulations provide.

169 Before I yield back my time, I want to note that Ranking
170 Member Diana DeGette regrets being unable to attend this
171 hearing. Today is a return day. We don't have votes until
172 6:30, and unfortunately the ranking member of the

173 subcommittee was not consulted about the hearing that was
174 going to be called today before 6:30. In the last Congress,
175 we engaged in a lot of these consultations. I think they are
176 useful for everybody involved, and I would urge the majority
177 to be sure to consult with the minority so that the minority
178 ranking members of the subcommittee can change their
179 schedules or can be accommodated in some possible way.

180 I have completed my opening statement. I want to
181 welcome Ms. Glied to be here. We are looking forward to your
182 testimony. I think what HHS is doing by way of regulations
183 is very important, very worthwhile, and while any regulation
184 may have some downsides, we have to realize that many of them
185 have very, very important upside for the American people.
186 Thank you, Mr. Chairman.

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

188 ***** COMMITTEE INSERT *****

|
189 Mr. {Stearns.} I thank the gentleman from California.
190 I would point out that we gave 1 week's notice according to
191 the rules for this hearing, but I also want to again
192 reiterate we welcome Sherry Glied. She again is the
193 assistant secretary for planning and evaluation at the U.S.
194 Department of Health and Human Services.

195 And, madam, as you know, the testimony that you are
196 about to give is subject to Title 18, Section 1001 of the
197 United States Code.

198 When holding an investigative hearing, this committee
199 has a practice of taking testimony under oath. Do you have
200 any objection to testifying under oath?

201 Ms. {Glied.} No, sir.

202 Mr. {Stearns.} The chair then advises you that under
203 the rules of the House and the rules of the committee, you
204 are entitled to be advised by counsel. Do you desire to be
205 advised by counsel during your testimony today?

206 Ms. {Glied.} No, sir.

207 [Witness sworn.]

208 Mr. {Stearns.} You may now give your 5-minute opening
209 statement. Thank you.

|
210 ^TESTIMONY OF SHERRY GLIED, ASSISTANT SECRETARY FOR PLANNING
211 AND EVALUATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

212 } Ms. {Glied.} Mr. Chairman, Congressman Waxman, other
213 members of the subcommittee, my name is Sherry Glied, and I
214 am the Assistant Secretary for Planning and Evaluation in the
215 U.S. Department of Health and Human Services. I am grateful
216 to have the opportunity to appear before you today to discuss
217 issues relating to regulation and to Executive Order 13563,
218 Improving Regulation and Regulatory Review.

219 I will focus in particular on the retrospective review
220 of the existing rules. The President's order laid the
221 foundations for a regulatory system that is designed to
222 protect public health and welfare while also promoting
223 economic growth, innovation, competitiveness, and job
224 creation. On May 18 and in compliance with the executive
225 order, HHS released our preliminary plan. HHS's systematic
226 review of regulations will focus on eliminating rules that
227 are no longer necessary and strengthening or modernizing
228 rules where appropriate.

229 For example, the Centers for Medicare and Medicaid
230 services is working to address conflicting requirements
231 between Medicaid and Medicare that potentially create

232 barriers to high quality, seamless, and cost-effective care
233 for dual eligible beneficiaries.

234 The Administration for Children and Families is also
235 encouraging State's child support programs to use cost-
236 effective technologies like electronic signature and document
237 storage. And the Food and Drug Administration is going
238 paperless with its adverse events reporting requirements for
239 medical devices.

240 HHS's retrospective review plan has 4 goals: to increase
241 transparency, to increase opportunities for public
242 participation, to set retrospective review priorities, and to
243 strengthen analysis of regulatory options. This
244 administration believes that retrospective regulatory review
245 must be accompanied by efforts to make more information
246 available to all interested parties and that regulations and
247 the regulatory process should be as clear as possible.

248 HHS will increase transparency in its regulatory process
249 by making available to the extent feasible and permitted by
250 law information that is useful for businesses, States, local
251 and travel government, and the public. It is essential that
252 people be able to understand the basis of a proposed
253 regulatory activity including the science or evidence base
254 for a regulation.

255 Public participation is a very important part of our

256 retrospective review plan. We are currently soliciting
257 public comment on the HHS preliminary plan on the
258 www.hhs.gov/open website through June 30. Suggestions are
259 welcome, and HHS will carefully review all comments before
260 finalizing our plans. HHS also intends to increase the
261 breadth and quality of public participation in its role-
262 making and retrospective review activities.

263 All HHS agencies already reach out to obtain public
264 input and advice on regulation subject to review and
265 modification. For example, twice a year, FDA sends letters
266 to State and local elected officials and to small businesses,
267 highlighting upcoming regulations and seeking suggestions o
268 FDA's regulatory activities.

269 FDA also recently established a new web page
270 specifically devoted to its regulatory review activities.
271 CMS conducts monthly open-door forums and provider outreach
272 activities. Feedback from these activities allows CMS to
273 identify and change obsolete regulatory requirements and to
274 reduce regulatory burden.

275 Moving forward, HHS is establishing a public
276 participation task force within the department to explore way
277 to increase interactivity in the public comment process
278 including the use of podcasts, webinars, video teleconference
279 sessions, wickeys, YouTube, and other social media.

280 HHS has also actively encouraged public participation as
281 we implement the Affordable Care Act. For example, we
282 solicited public comment even before putting out rules around
283 medical loss ratios, grandfathered health plans, and rate
284 review. Similarly, CMS held public forums on wellness and
285 exchanges to provide opportunities for public input by
286 effected stakeholders.

287 The last cornerstone of our plan is to strengthen the
288 use of regulatory analysis such as cost/benefit analysis.
289 The secretary has asked me to establish an agency-wide
290 analytics team to share information, make the quality of
291 analysis more consistent across the department, and ensure
292 the integration of such analysis into regulatory decision
293 making to improve the quality of the regulations we
294 promulgate.

295 We have also redoubled our longstanding commitment to
296 making regulatory review an integral part of our operations
297 and culture.

298 As our work continues in the months and years to come,
299 we will rely on the four key principles I have just
300 highlighted: increasing transparency, improving public
301 participation, being clear about our priorities, and ensuring
302 that analysis guides our efforts. Our department's mission
303 is to protect the health and safety of all Americans. The

304 plan we will be discussing today does that while promoting
305 economic growth, job creation and innovation.

306 I look forward to working with you in this endeavor and
307 am happy to answer any questions.

308 [The prepared statement of Ms. Glied follows:]

309 ***** INSERT 1 *****

|
310 Mr. {Stearns.} Dr. Glied, thank you very much. I will
311 start the questions here. What we have in the Oversight and
312 Investigation Subcommittee is a little different. We try to
313 get succinct answers because we are more of an investigative
314 body rather than a legislative body. So if you possibly can,
315 just keep your comments short. Just by background, I
316 understand you are an economics professor at Columbia. Is
317 that correct?

318 Ms. {Glied.} Yes, sir.

319 Mr. {Stearns.} Did your background include any health-
320 related things at being an academic professor at Columbia?

321 Ms. {Glied.} Yes, sir.

322 Mr. {Stearns.} Did you--is this your first job working
323 in the administration?

324 Ms. {Glied.} No, sir.

325 Mr. {Stearns.} What other administrations did you work
326 for?

327 Ms. {Glied.} I worked for the first Bush Administration
328 back in 1992 and for the Clinton Administration in 1993 at
329 the Council of Economic Advisors.

330 Mr. {Stearns.} And was that dealing with health too?

331 Ms. {Glied.} Yes, sir.

332 Mr. {Stearns.} So when you walked into this job, you

333 didn't feel like you were walking into a brand new storybook?

334 Ms. {Glied.} No, sir.

335 Mr. {Stearns.} Okay, how does Health and Human Service
336 identify which rules that are already on the books will be
337 reviewed?

338 Ms. {Glied.} We have laid out, after process of public
339 comment, a set of principles that are going to guide which
340 rules we want to look at. And we have also opened our plan
341 up to the public for further comment so they can also suggest
342 rules they would like us to look at. But the main principles
343 that guide our decisions are situations where circumstances
344 have changed since the rule was originally promulgated, where
345 new technologies or innovations have come along that should
346 lead us to change how we do something, or there has been a
347 failure to realize public health benefits that were
348 anticipated on passing a rule.

349 So for example, HRSA, the Human Resources and Services
350 Administration, has rules that were promulgated back in the
351 1970s defining health professional shortage areas. That is a
352 real priority for us to go after because it has been a long
353 time since we have looked at those rules.

354 Mr. {Stearns.} You indicated there might be public
355 comment to or--

356 Ms. {Glied.} Yes, sir.

357 Mr. {Stearns.} --the public can submit to you rules
358 that they think are outdated too.

359 Ms. {Glied.} That is correct. The website is open for
360 comment through June 30.

361 Mr. {Stearns.} Once a rule is identified for review,
362 possibly reform or elimination if it goes back to 1970, what
363 is the next step, and how long does the process take?

364 Ms. {Glied.} I think that we will see that as we go
365 through each rule. Each rule will go through a careful
366 analysis including redoing the regulatory impact, trying to
367 assess what the impact of that rule is, and what potential
368 for modification or rescission of that rule might be
369 appropriate.

370 Mr. {Stearns.} So is it possible that you could
371 interpret through your office a way to enforce a rule in a
372 totally different manner?

373 Ms. {Glied.} We have to abide by the statutory
374 authority under which the rule was promulgated, but we could
375 look at that rule and come up with better ways of doing it.

376 Mr. {Stearns.} But you are saying you could also decide
377 not to enforce it.

378 Ms. {Glied.} Only if that would be consistent with the
379 statutory authority under which the rule was promulgated.

380 Mr. {Stearns.} Well, if it is on the books and it is

381 statutory authority, how could you suddenly decide not to
382 enforce it?

383 Ms. {Glied.} We would have to enforce it. We might
384 come up with a different way to enforce it, a different way
385 to implement the authority.

386 Mr. {Stearns.} So you would come up with a new
387 interpretation?

388 Ms. {Glied.} Correct.

389 Mr. {Stearns.} Would this go to public comment?

390 Ms. {Glied.} All of our laws do go to public comment,
391 yes.

392 Mr. {Stearns.} And how long is that public comment?

393 Ms. {Glied.} There is a standard process where we might
394 put out a notice of proposed rulemaking and seek public
395 comment on that. I don't remember exactly how long it is. A
396 couple of months, I think.

397 Mr. {Stearns.} Have you identified any rules already?
398 I mean how many rules have you identified today?

399 Ms. {Glied.} The first part of this process was for the
400 various agencies within HHS to identify rules that they
401 thought were important. We have identified many rules. I
402 would say dozens of rules already that we are looking at. In
403 a separate and parallel effort, CMS has looked at its own
404 ways of doing business and has identified 80 practices

405 including rules that it is going after. So there is a large
406 number that we are investigating.

407 Mr. {Stearns.} So you are saying at this date you have
408 identified, in your office, 12 rules?

409 Ms. {Glied.} No.

410 Mr. {Stearns.} You said dozens.

411 Ms. {Glied.} More than dozens. More than a dozen.

412 Mr. {Stearns.} More than? So would you 48 or 24?

413 Ms. {Glied.} I don't have the exact number before me,
414 and we are waiting for public comment to get more rules in.
415 So we anticipate that we will get quite a few.

416 Mr. {Stearns.} Anybody on your staff that could tell
417 you how many rules you have identified so far? Just
418 approximately.

419 Ms. {Glied.} Probably--

420 Mr. {Stearns.} Are we talking about 10?

421 Ms. {Glied.} --20, 25 so far.

422 Mr. {Stearns.} Twenty? Twenty-five, okay.

423 Ms. {Glied.} I am not--I don't want to be, you know--

424 Mr. {Stearns.} No, I am not going to hold you to it.
425 It is just a round figure.

426 Ms. {Glied.} And we are waiting for public comment to
427 get many more.

428 Mr. {Stearns.} Of any of those 25, have you decided not

429 to enforce any of those 25?

430 Ms. {Glied.} We haven't--no, we have not decided not to
431 enforce any of them. We are looking at ways to revise them.
432 For example, to recalculate how we would determine to help
433 professional shortage area or to change the way we use
434 symbols and device labeling at FDA.

435 Mr. {Stearns.} And so the criteria--I would like to
436 understand how you decided to select those roughly 20 rules.
437 How did you single those out? Was it age on the books or
438 based upon implementation not working, or is it based upon
439 not clear? What--

440 Ms. {Glied.} We laid out five, a series of criteria
441 including that there were new technologies, that there had
442 been changes--

443 Mr. {Stearns.} Which you mentioned earlier.

444 Ms. {Glied.} Right, the ones that I had mentioned
445 earlier.

446 Mr. {Stearns.} Those are the criteria you mentioned
447 earlier.

448 Ms. {Glied.} So we looked at them. We asked all of the
449 agencies to look at the rules on their own books to see ones
450 that made the most sense to modify where they had
451 opportunities to modify those rules and see that it looked
452 like it was important. And now we have opened it up for

453 public comment so that other people can also tell us where
454 they think we should be looking.

455 Mr. {Stearns.} It seems to me that, you know, the
456 executive branch issued this executive order to look at these
457 rules, but as I recollect, it is already on the books that
458 HHS should be doing this on a regular fashion. Isn't that
459 true?

460 Ms. {Glied.} That is true. There are several
461 authorities under which we already look at rules, the
462 Regulatory Flexibility Act.

463 Mr. {Stearns.} So would it be fair to say that the
464 executive order really wasn't necessary because the
465 legislation is already on the books to do exactly what you
466 are doing, and it wasn't necessary for the executive order to
467 be issued?

468 Ms. {Glied.} We have routinely within the department
469 looked over our rules, and we--even before the executive
470 order came forward, we had rules that we were working on.
471 But the executive order does tell us to prioritize this
472 activity, and that is what we have done.

473 Mr. {Stearns.} In your plan, it says ``the priority
474 will be to identify regulations that agencies can easily
475 modify, streamline, or rescind to address regulatory burdens
476 or inefficiency.'' You feel this is strong enough?

477 Ms. {Glied.} I think those make sense as a criteria for
478 us to look at, yes.

479 Mr. {Stearns.} And you are saying one of your criteria
480 is to take and prioritize regulations that are easiest to
481 fix. Wouldn't also you determine what is the most impact?

482 Ms. {Glied.} Of course, you want to look at both--

483 Mr. {Stearns.} I mean I would think that that would be
484 the criteria rather than easiest to fix because you might be
485 putting a parentheses somewhere, and that is easiest to fix.
486 But it really is a meaningless regulation. Whereas you might
487 have a whole set within that 20 that has huge impact, that
488 would impact constituents.

489 Ms. {Glied.} As you know, Chairman Stearns, we want to
490 weigh the costs and benefits of everything we do, including
491 which regulations to pick. The ones that are--

492 Mr. {Stearns.} Do you actually weigh the cost benefits?

493 Ms. {Glied.} Yes.

494 Mr. {Stearns.} Do you do an economic analysis?

495 Ms. {Glied.} We do. For any regulation we put forward,
496 we do an economic--

497 Mr. {Stearns.} Even if it is easiest to fix?

498 Ms. {Glied.} Well, if it is easiest to fix, the cost of
499 repairing it are very small, and that has to be taken into
500 account. So we take into account both what can be done

501 easily and what is most important to do, and both of those
502 things need to be weighed.

503 Mr. {Stearns.} Now, I am sure this is pretty easy of
504 the stand for you. Aren't the most burdensome regulations
505 the ones that are most complex? Is that a fair statement?

506 Ms. {Glied.} Not necessarily, Chairman. Sometimes
507 there could be very burdensome regulations that are very
508 simple.

509 Mr. {Stearns.} Let me give you an example. Under the
510 President's health care plan, this is a regulation that those
511 covering medical loss ratios--and I have talked to insurance
512 companies about this--accountable care organizations and
513 grandfathered health plans, these are pretty complex rules.
514 Wouldn't you agree?

515 Ms. {Glied.} Some of them are complex, yes.

516 Mr. {Stearns.} Okay, yet your plan says that that
517 complexity on important rules would make it not a priority
518 for your review. That is what we understand. That because
519 of the complexity of it, you have not done a review. Yet
520 everywhere I go, people are talking about medical loss ratio,
521 how complicated it is and the impact it is going to have. It
522 seems like that one would be one you would look at together
523 with, as I mentioned, the grandfathered health plans, what
524 that means in accountable care organizations.

525 Ms. {Glied.} So, Chairman, you have spoken about three
526 of our very important regulations under the Affordable Care
527 Act, which promulgate regulations to really put forward a
528 change in the U.S. health care system that I think is very
529 important. Those regulations have only very recently been
530 passed. So we are not going to look at them not because of
531 their lack of complexity, but because there has been no
532 change in circumstances. There have been no new technologies
533 or innovations. There is really not much that has changed
534 since we promulgated those rules that would lead it to make
535 sense from a--to look at them again within this short period
536 of time.

537 Mr. {Stearns.} We both agree that you would look at
538 burdensome regulations if they had a huge economic impact. I
539 think you said you would.

540 Ms. {Glied.} We have just completed doing the economic
541 impact analysis of those regulations. So we have already
542 weighed their benefits and costs and shown that their
543 benefits considerably exceed their costs.

544 Mr. {Stearns.} Well, if I identified--let us take
545 medical loss ratio--as having huge economic impact, is it
546 safe to say that you are going to look at that regulation in
547 detail and allow public to comment on it in the very near
548 future?

549 Ms. {Glied.} Chairman, that regulation was actually
550 developed after an extensive period of public comment, and we
551 had assessed the cost and benefits. We estimate that the
552 cost of that regulation for insurers are on the order of
553 \$100,000 per insurer for insurance to set up the plan and
554 \$25,000 per insurer to continue maintaining the plan over
555 time. And then it is going to generate \$3 billion in
556 benefits to American consumers over the period from 2011 to
557 2013. That is a great benefit/cost ratio.

558 Mr. {Stearns.} Now those analyses that you did are
559 within your department made those projections, right?

560 Ms. {Glied.} That is correct.

561 Mr. {Stearns.} That was not done by an outside
562 accounting firm or an outside economic group? It was done by
563 your people, right?

564 Ms. {Glied.} As with all regulatory impact analyses,
565 those are conducted within the agency and reviewed by OIRA.

566 Mr. {Stearns.} Have you actually sat down with the
567 people that have been impacted, insurance companies? Do they
568 agree? Because I heard--I have not heard any of them think
569 that it is just going to cost \$100,000 plus the very small
570 figures that you--none of them have told me that. So I don't
571 know where you get your figures.

572 Ms. {Glied.} Chairman Stearns, the rules for the

573 medical loss ratio were actually developed by the National
574 Association of Insurance Commissioners, which is an
575 organization of all the state insurance commissioners from
576 around the country. They are the ones who developed these
577 rules, and we worked on the regulatory impact analysis in
578 conjunction with those rules that that had developed.

579 Mr. {Stearns.} Well, as you know, between the cup and
580 the lip, if you develop a regulation based upon someone else,
581 there could be some nuisances of parse language. Because the
582 insurance companies are not coming back, at least to this
583 member, and feeling the costs are so diminutive that you
584 pointed out. Let me go to another series of questions here.
585 I think I have the opportunity to speak a little longer. I
586 assume that there is no one on the Democrat side, and I am
587 sure they would want me to use my time as wisely as I could
588 so that I will continue. Dr. Glied, if you don't mind, we
589 will--I will be glad to--if another member shows up, I would
590 be glad to--I am told Mr. Waxman might come back. I hope he
591 will. He had very good questions to offer you too.

592 Dr. Glied, you have released your preliminary plan for
593 retrospective review of existing rules. Is that correct?

594 Ms. {Glied.} Yes, sir.

595 Mr. {Stearns.} This is a retrospective plan though. Is
596 that correct?

597 Ms. {Glied.} This particular part of the plan is
598 retrospective, yes

599 Mr. {Stearns.} Because it only looks backwards.

600 Ms. {Glied.} Many of the principles in the plan are
601 also encapsulated in existing HHS practices, so the President
602 actually specifically called for retrospective review. But
603 we actually have implemented those principles both going
604 prospectively and looking the regulations we are about to
605 promulgate and concurrently, the regulations that we are
606 working on right now as well as retrospectively, sir

607 Mr. {Stearns.} That is a pretty good answer. You have
608 it both ways there. Of the 20 regulations, how many of those
609 are retrospective and how many...

610 Ms. {Glied.} But those are retrospective. That is part
611 of our retrospective review plan, but we are engaging...

612 Mr. {Stearns.} Do you have any prospectively?

613 Ms. {Glied.} So prospectively, we are working on many
614 regulations right now, and we have already implemented those
615 efforts by, for example, increasing the transparency with
616 which we put forward those regulations, by putting them up on
617 our websites in a much more easy to access way, and by
618 getting public comment even before we start the rulemaking
619 process

620 Mr. {Stearns.} It is interesting with the passage of

621 the President's health care plan, there is so much regulation
622 that involves moving prospectively forward. And so yet you
623 are talking at this point of retrospective. So I guess the
624 question is how would your office address prospectively all
625 of the regulations from the President's health care? Because
626 as this is presented and enforced every year, there is going
627 to be much complexity and much angst.

628 As you saw the graph I showed, small, medium, and large
629 businesses, particularly small businesses have decided,
630 almost 80 percent in the next 2 years, they are going to give
631 up their health care plan, and they are going to go to the
632 government option. So you see the angst is out there. So I
633 guess the question is how does your plan address these
634 prospective regulations that are all part of the President's
635 new health care plan?

636 Ms. {Glied.} Sir, the Affordable Care Act offers great
637 new opportunities for small businesses. As you know, they
638 are already eligible for tax credits, and they will be able
639 to buy insurance on much better terms. We can really level
640 the playing field once those exchanges get going.

641 As we develop those plans to get the exchanges going to
642 move into 2014, we are soliciting a lot of public comment,
643 both in advance of rulemaking and as part of the rulemaking
644 process, including a lot of public comment from small

645 businesses, from providers, from insurers, from all effected
646 groups.

647 Mr. {Stearns.} Dr. Glied, I think that what you can
648 hear from me is, based upon the graph I showed you and the
649 angst that is out there, that retrospective is fine, but
650 there is a huge burdensome number of regulations that are
651 being implemented as we move forward. And I just--I think on
652 this side of the aisle, we would certainly like to feel that
653 you are using your general principles that you mentioned in
654 your opening statement are being applied to the rules from--
655 for the President's health care.

656 So that in addition to looking at rules that are
657 obsolete, not effective, burdensome, complex, that same thing
658 applies in probably a larger sense based upon what we see and
659 the statistics and based upon that graph, that we would urge
660 you to also concentrate and focus your energy on the
661 President's health care plan moving forward.

662 With that, my time is expired, and we recognize the
663 gentleman from California, Mr. Waxman.

664 Mr. {Waxman.} Thank you, Mr. Chairman. Dr. Glied,
665 regulations have two sides to them. There are downsides
666 because we are requiring some industry to have to do
667 something often or regulations mean we are regulating certain
668 activities. But there is an upside to it, and sometimes we

669 don't hear about the upside, especially in this committee.
670 For instance, there are estimated 19.4 million children
671 living in this country with preexisting conditions. Until
672 last year, it was perfectly legal for insurance companies to
673 discriminate against these children, issuing rides that
674 excluded coverage for critical medical problems or refusing
675 to cover these children at all.

676 And when the Republicans said they wanted to repeal the
677 ACA and then replace it, I would have thought they were
678 saying they were going to replace some of these very same
679 provisions. Otherwise, what are they doing to help children
680 and families, Americans that can't get insurance because they
681 are being discriminated against?

682 Is it true that extending coverage to children with
683 preexisting conditions provides benefits to the children,
684 their families, to the country as a whole?

685 Ms. {Glied.} Yes, sir, it certainly does, and I think
686 it also improves the efficiency of our economy because my
687 providing coverage to children with preexisting conditions,
688 we make it easier for their parents to choose the right job
689 for themselves and to really seek employment opportunities
690 that might not otherwise be available to them.

691 Mr. {Waxman.} Now, HHS has also issued regulations to
692 end the lifetime caps on coverage, prevent insurance

693 companies from using decades-old paperwork errors to justify
694 canceling someone's insurance as soon as they get sick.
695 These practices also have costs. They may cut into the
696 insurance industry's bottom line. But, Dr. Glied, in issuing
697 regulations that ban the practices, did HHS determine that
698 such bans would have significant benefits?

699 Ms. {Glied.} They certainly did. We certainly did. In
700 fact, the estimates that those consumer protections and the
701 patient bill of rights would increase insurance premiums by
702 4/100ths of 1 percent--between 4/100ths of 1 percent and
703 2/10ths of 1 percent, a tiny increase in costs. And in
704 exchange for that, all Americans would get reliable valuable
705 coverage. And about 25,000 people who already exhausted the
706 lifetime limits in their coverage would actually have
707 meaningful insurance for the first time.

708 Mr. {Waxman.} We hear a lot about burdens on industry
709 from our Republican colleagues, but I think a conversation
710 about HHS regulations, their focus is exclusively on costs
711 borne by the insurance industry is dangerously misleading.
712 To understand the real impact of regulations, we have to
713 consider the health benefits and cost savings offered to
714 consumers as well. And I assume that HHS considered the full
715 range of both costs and benefits in issuing these
716 regulations?

717 Ms. {Glied.} Yes, sir, we did.

718 Mr. {Waxman.} Many of my colleagues on the other side
719 of the aisle have raised concerns that these regulations,
720 under the affordable care act, were not subject to
721 retrospective review that HHS conducted. In the executive
722 order issued in January, President Obama cited a number of
723 principles of regulatory review. The President required
724 regulations to be proposed or adopted only when benefits
725 justified costs. He asked for regulations to be tailored to
726 impose the least burden on society. Then he called for
727 regulations to be adopted through a process that involves
728 public participation.

729 Dr. Glied, I would like to ask you some questions about
730 regulations issued under the Affordable Care Act and the
731 manner in which they were promulgated. Did the department
732 issue regulations under the ACA only when it found the
733 benefits of a rule outweighing the costs?

734 Ms. {Glied.} Yes, sir, we did.

735 Mr. {Waxman.} Can you provide some examples of
736 regulations issued under the Affordable Care Act where the
737 benefits outweigh the costs?

738 Ms. {Glied.} Well, for example, the regulation that
739 requires that insurers allow young adults up to age 26 to
740 remain on their parents' insurance coverage is estimated to

741 increase premiums by about 1 percent for families and to
742 cover over a million young adults, up to a million young
743 adults. And that will improve the earnings of those young
744 adults, reduce uncompensated care, improve job mobility
745 within the American economy, so the benefits are enormous.

746 Mr. {Waxman.} In his executive order, President Obama
747 emphasized the importance of public participation in the
748 rulemaking process. He wrote ``regulations shall be based to
749 the extent feasible and consistent with the law on the open
750 exchange of information and perspectives among state, local,
751 and tribal officials, experts in relevant disciplines,
752 effected stake holders in the private sector, and the public
753 as a whole.'' Dr. Glied, can you explain how HHS
754 incorporated public participation into the ruling making
755 process under the Affordable Care Act?

756 Ms. {Glied.} Yes, sir. As you know, the rulemaking
757 process has periods of public comment built into it, but we
758 went well beyond those required periods of public comment and
759 actually solicited public comment even in advance of
760 beginning our rule making around the medical loss ratios,
761 rate review exchanges, and so on. We held open forums around
762 external review and co-ops. We have been very proactive in
763 getting out there and asking stakeholders to give us their
764 views.

765 Mr. {Waxman.} Well, I know that the Republicans have a
766 fervent opposition to the whole law, but I hope that that
767 doesn't cloud their ability to thoughtfully examine the
768 administration's steps to apply executive order principles to
769 the health reform regulatory process. I know that they would
770 want those principles applied to all regulations, which is
771 what the President intended in opposition to a certain law.
772 It is the law. Shouldn't affect their appreciation that the
773 department in your case of HHS has tried to keep within the
774 President's executive order in following the regulatory
775 procedures that would weigh the benefits and the costs and do
776 what is best after full participation of all the parties in
777 establishing those regulations.

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

779 Mr. {Stearns.} I thank the gentleman. We recognize the
780 gentleman from Louisiana, Mr. Scalise, for 5 minutes.

781 Mr. {Scalise.} Thank you, Mr. Chairman. If I could, I
782 would like to ask a little bit about the waivers that have
783 been issued for Obamacare. We had a hearing on the issue in
784 general. A lot of unanswered questions regarding the number
785 of entities, both businesses and labor unions that have
786 requested and received waivers. A lot of unanswered
787 questions about who has requested and been denied waivers.
788 So first if you can give me kind of the broad brush of the

789 administration's policy on this. How long have waivers been
790 granted? And can you further expand on who has not been
791 granted waivers and why?

792 Ms. {Glied.} So the criteria that we use for providing
793 waivers around the annual limits within the Affordable Care
794 Act, and those waivers are waivers that allow farms in the
795 short run as a bridge to when we provide people with much
796 better coverage in 2014, to continue to have plans that have
797 annual limits in them.

798 So the waivers allow plans to maintain those annual
799 limits just until 2014. We have--the criteria that have been
800 established to grant waivers are up on the HHS website and
801 are available, as is the complete list of all of the entities
802 that have been granted waivers. And, sir, fewer than 10
803 percent--sorry, fewer than 2 percent of the health insurance
804 market has been--is in plans that have been associated with
805 waivers. So the waiver--

806 Mr. {Scalise.} How many--if roughly 1,400 entities have
807 been granted waivers, those are the most updated numbers I
808 have. I don't know if you have more updated numbers. I
809 think 1,372 entities, employers, unions, other entities have
810 been granted waivers. What numbers do you have?

811 Ms. {Glied.} Those are the numbers. I am not familiar
812 with other numbers, sir.

813 Mr. {Scalise.} Okay, so you would say that that is a
814 fair number to use?

815 Ms. {Glied.} I believe so.

816 Mr. {Scalise.} And that is who have been granted. Do
817 you know how many have been denied, who have requested a
818 waiver but have not been granted it?

819 Ms. {Glied.} I believe the list of entities that
820 requested waivers and were denied them was actually given to
821 this committee. So you actually have those.

822 Mr. {Scalise.} Okay, and I will pull those if they are
823 here. When you talk about fewer than 2 percent, have--I
824 guess that is of all the companies that provide health care
825 for their employees, fewer than 2 percent of the companies
826 have been granted a waiver?

827 Ms. {Glied.} Less than 2 percent of the market is
828 affected by these waivers, yes.

829 Mr. {Scalise.} Yeah, and when you say affected, this
830 gets, I guess, into the bigger question. You know when I
831 talk to small business owners, and this last week we had a
832 district work period. And again I was meeting with small
833 businesses throughout my district, and I hear this from other
834 colleagues of mine. Small businesses I talk to, they don't
835 even know that there is the ability to go get a waiver. Many
836 of these companies you talk to are struggling right now with

837 how they are going to comply with Obamacare. One thing they
838 do know is that it is going to be very difficult for them to
839 comply, and they still don't know what all the rules and
840 regulations are because there are still many rules and regs
841 still yet to come out.

842 But what they do know from what they have already seen
843 and what they have calculated, it is going to be very
844 difficult for them to comply. And when I ask them about this
845 waiver process and talk to them about the nearly 1,400
846 entities, many of whom were ironically entities that were
847 asking for the bill to be passed. I mean you get groups like
848 AARP, a lot of these organized union groups who were up here
849 at the Capitol saying we need this law. It is going to be so
850 great. And then they went and kind of got this secret deal
851 with the White House to get a waiver.

852 A lot of these small businesses that didn't want
853 Obamacare in the first place don't even know you can go get a
854 waiver. So, you know, was this kind of some secret memo that
855 was leaked? I mean why is it that our small businesses, who
856 are on the front lines of creating jobs in America, who many
857 of whom can't go and create new jobs because of this law and
858 other regulations like it, they don't even know that this
859 process is out there.

860 When I tell them about it, they say look, I would love

861 to get the waiver. And of course, you know, they are not
862 even aware of it. I direct them, you know, to go apply. I
863 would love everybody to be able to get a waiver from the
864 entire law, meaning repeal of the law. But, you know, can
865 you tell me what process you all use to promote it? Because
866 it seems like a lot of the administration's friends know
867 about it and got the waiver, and a lot of small businesses
868 across America don't even know it exists.

869 Ms. {Glied.} The waiver process is--the information of
870 the waiver process is publically available on our websites.
871 And I think insurers particularly are very well aware of it.
872 They are the ones who are selling the policies to small
873 businesses that have the annual limits, if they have annual
874 limits in them. Remember that the waiver is only applicable
875 to 1 piece of the Affordable Care Act.

876 Mr. {Scalise.} Right, I mean it is an important piece
877 of it though, and it is a piece that many employers seem to
878 have a problem with compliance on. In many cases, it is
879 going to be yet another determining factor on whether or not
880 these employers can continue to provide health care to their
881 employees, and their employees like the health care plan.

882 Ms. {Glied.} So it is providing--the annual limit
883 regulation means that the health insurance that people buy
884 actually has real value to them if they get sick. And the

885 annual limit waiver process is simply a bridge to allow
886 people to keep that coverage only until 2014 when we will
887 have a much better insurance system available, particularly
888 to small businesses.

889 Mr. {Scalise.} Well, they are already paying higher
890 premiums, but hopefully we don't have Obamacare on the books
891 anymore, but it just seems like there was a favoritism that
892 was shown because, like I said, ironically a lot of the
893 companies and entities that have received the waivers were
894 many of the same that were working with the administration to
895 pass the law, and many of the people, our small businesses,
896 our job creators across the country who didn't want this in
897 the first place, don't even know it exists.

898 So, you know, again it just seems like a real peculiar
899 situation that seems like some of the biggest proponents of
900 the law and the favorites of the administration are the ones
901 who know about it and got the waivers. People who don't want
902 it don't even know it existed. I yield back.

903 Mr. {Stearns.} I thank the gentleman. I will continue
904 with my questions. Mr. Waxman made some points in his
905 opening statement. I thought I would follow up, Dr. Glied.
906 He referred to the ban on preexisting exclusions for
907 children. Are you aware that since passage of the
908 President's health care plan, many insurers have opted not to

909 offer child-only policies? So because of what the regulation
910 says, they are getting around it by offering no child
911 policies. Did you know that?

912 Ms. {Glied.} I think it is horrifying, Chairman
913 Stearns, that any insurer would choose to deny providing
914 coverage to children who are sick, and I think it is one of
915 the reasons that we needed the Affordable Care Act in the
916 first place. Beginning in 2014, these practices will not be
917 possible, and insurers will be providing insurance to all
918 Americans.

919 In the meantime, the administration has taken serious
920 steps to make sure that children who have been denied
921 coverage because of insurance company practices can get it
922 within every state.

923 Mr. {Stearns.} So how would, for example, in the State
924 of Florida, if the insurance company did not provide it, how
925 would a person get it for their child?

926 Ms. {Glied.} Chairman, I will have to get back to you
927 about the details in Florida. Different arrangements have
928 been made in different States.

929 Mr. {Stearns.} Let us take your State of New York. How
930 would you do it in New York?

931 Ms. {Glied.} There is not a problem in New York because
932 we have community rating and guaranteed issue already.

933 Mr. {Stearns.} So a person would just apply?

934 Ms. {Glied.} Yes, there is no problem in New York.

935 Mr. {Stearns.} This whole question--we wrote a letter
936 to Mr. Waxman, in all deference to him, last year, asking for
937 a hearing on this. We never heard back. So he is making a
938 point about this, but I just want to make it clear that we
939 are on record of asking for a hearing on this.

940 He also mentioned that the ban on annual limits. This
941 obviously could lead to increases in the premiums or loss of
942 coverage. Don't you agree?

943 Ms. {Glied.} Mr. Chairman, the basic economics of
944 insurance that says insurance is most important and most
945 valuable to people when it protects them against catastrophic
946 losses, that is very high losses. Insurance that includes
947 annual limits doesn't meet that basic economic test for
948 value. It is really critical that we get rid of those lousy
949 policies.

950 Mr. {Stearns.} Mr. Scalise mentioned the waivers.
951 These waivers are only good for one year, right?

952 Ms. {Glied.} Correct.

953 Mr. {Stearns.} So these 1,400 people that got waivers,
954 McDonald's, Waffle House, seven States, they are all going to
955 have to come back in a year, right? Would you be giving them
956 waivers again?

957 Ms. {Glied.} I believe that the annual limit waiver
958 process is under discussion right now. I am not aware of
959 where it is going.

960 Mr. {Stearns.} But isn't the reason why you have these
961 annual limits--this is why you have annual limit waivers. Is
962 that correct?

963 Ms. {Glied.} The reason we have annual limit waivers is
964 that we need to get from here to 2014. These provide a
965 bridge until people can be assured of better, more valuable
966 insurance coverage.

967 Mr. {Stearns.} When you passed legislation and you
968 suddenly give out 1,400 waivers, what does that--wouldn't
969 that tell you something about the angst, the feeling of the
970 people who are asking for those waivers, they can't comply?
971 Don't you think that that shows that perhaps--and as Mr.
972 Scalise said, I don't think anybody in my congressional
973 district knows they could get a waiver either. So if you
974 really put the word out, I think you would find thousands of
975 people asking for waivers.

976 Ms. {Glied.} That would be very disappointing, Chairman
977 Stearns, because it would suggest that the magnitude of the
978 problem of really lousy insurance policies in the United
979 States is much greater than we had anticipated.

980 Mr. {Stearns.} That is funny. I would interpret it

981 different. That is your--my interpretation is people do not
982 want the President's health care plan, and they can't comply
983 with the existing strategies and objectives that are outlined
984 in your legislation, and they want out. Because if they
985 thought it was going to be something they could comply with,
986 they wouldn't ask for a waiver. And in fact, the graph that
987 we showed you clearly shows the most--that small businesses,
988 80 percent, and going to get out and just say forget it. We
989 are not going to be bothered. We will just pay a fee and
990 just let all our employees go into the government plan. So
991 that is my opinion.

992 Anyway, let me ask you another question. The key to
993 this whole health care debate is what is the essential
994 benefits package. That, I think, people have been asking me.
995 What is the essential benefit package? And everybody is
996 talking generalities. But what is the administration going
997 to require, and what is the rule? Are you familiar with the
998 rule yourself?

999 Ms. {Glied.} Yes, sir.

1000 Mr. {Stearns.} And when will it be released? What
1001 date?

1002 Ms. {Glied.} Sir, we are waiting for the Institute of
1003 Medicine, which was commissioned to do a duty to provide us
1004 with principles for determining the essential benefits

1005 package. And that report from the Institute of Medicine,
1006 which is this expert group, is not expected until late
1007 September. Beginning then, we will be working on developing
1008 the notice of proposed rulemaking that will include the
1009 principles around that.

1010 Mr. {Stearns.} Within the legislation, they had sort of
1011 outlined what the essential benefits package. So here we are
1012 sometime after the passage, and yet you are saying that the
1013 essential rule will be released in September of this year.
1014 Is that fair to say?

1015 Ms. {Glied.} The Institute of Medicine--so the
1016 President's plan says that all Americans should be guaranteed
1017 a package that includes 10 critical categories of benefits--

1018 Mr. {Stearns.} Right.

1019 Ms. {Glied.} --and that is similar to that offered to a
1020 typical--by a typical employer today. So that is a very
1021 basic standard of benefits that all Americans should be
1022 entitled to.

1023 Mr. {Stearns.} So it has to be 10? It couldn't be 11?

1024 Ms. {Glied.} There are 10 categories--

1025 Mr. {Stearns.} 10 categories.

1026 Ms. {Glied.} --that have passed.

1027 Mr. {Stearns.} But there could be more categories, or
1028 is 10 the--

1029 Ms. {Glied.} It says that there are at least 10
1030 categories that are laid out--

1031 Mr. {Stearns.} At least, okay.

1032 Ms. {Glied.} --in the legislation.

1033 Mr. {Stearns.} Okay.

1034 Ms. {Glied.} Those are things like hospital benefits,
1035 pharmaceutical benefits, things like that.

1036 Mr. {Stearns.} Right.

1037 Ms. {Glied.} Those are the categories. We have asked
1038 the Institute of Medicine, which is an august body of
1039 experts, to help us in defining a process for developing
1040 those benefits.

1041 Mr. {Stearns.} All right.

1042 Ms. {Glied.} They have been meeting for 6 or 8 months--

1043 Mr. {Stearns.} No, I understand.

1044 Ms. {Glied.} --and have had a lot of public--

1045 Mr. {Stearns.} It is--

1046 Ms. {Glied.} It is a very challenging project.

1047 Mr. {Stearns.} --challenging.

1048 Ms. {Glied.} But we are trying to get to get as much
1049 information as possible.

1050 Mr. {Stearns.} And not everybody is going to be in
1051 agreement on these 10 essential benefits. I understand that,
1052 but I would just like to pin down a date. Can I say by 15

1053 September this rule will be released?

1054 Ms. {Glied.} No, sir, we are waiting for the--

1055 Mr. {Stearns.} How about 15 of September next year?

1056 Ms. {Glied.} The Institute of Medicine is coming back
1057 in--

1058 Mr. {Stearns.} Well--

1059 Ms. {Glied.} Wait, the--pardon me. The Institute of
1060 Medicine is coming back in September. Then we will go into
1061 the rulemaking process. We are likely to put out a notice of
1062 proposed rulemaking. Then, of course, you would want us to
1063 wait for public comment on that before we finalize the rule.

1064 Mr. {Stearns.} And public comment would be 60 days?

1065 Ms. {Glied.} It will be--I don't know how long it will
1066 be. I believe that there is a minimum, and I confess. I
1067 apologize. I don't know what that minimum is. It can go
1068 longer than that.

1069 Mr. {Stearns.} No, I understand, but let us just try to
1070 come up with a timeline. You are saying the report, this
1071 analysis, this study will be done by September.

1072 Ms. {Glied.} At some point in September.

1073 Mr. {Stearns.} And then after September, they will
1074 issue a rule within 30 days, 60 days?

1075 Ms. {Glied.} I don't exactly know. I am not privy to
1076 what exactly the timeline is.

1077 Mr. {Stearns.} Get a rule for--

1078 Ms. {Glied.} We are working on that rule.

1079 Mr. {Stearns.} --before next year?

1080 Ms. {Glied.} We are working on the development of that
1081 rule, and there was be a notice of proposed rulemaking that
1082 will go out and that will lay out that and other elements.

1083 Mr. {Stearns.} So when you sit in a meeting and you
1084 talk about the most important aspect about the President's
1085 health care bill, what the essential benefits package is, no
1086 one ever says there is a drop dead date when we have to get
1087 this done? No one ever says that in the meeting? No one
1088 ever says we should get this done by X time? They just say
1089 we will just do it when we do it? Generally in planning of
1090 something of that magnitude, there is generally a timeline.
1091 You and I both know, and I think you would respect the fact,
1092 in your position, you would come up with a date. Let us
1093 shoot for this date, but you are telling me there is no date.
1094 There is no one that has asked the question what is the drop
1095 date, and you are just sort of winging along month after
1096 month?

1097 Ms. {Glied.} We know that we need to give this
1098 information to States and exchanges so that they can lay out--
1099 -

1100 Mr. {Stearns.} What date do you have to give it by?

1101 Ms. {Glied.} The exchanges need to be up and--

1102 Mr. {Stearns.} Anyone on staff could tell us what date
1103 you expect to give it to the States?

1104 Ms. {Glied.} I don't think that there is a date that
1105 has been written down. We are trying to figure out when we
1106 can do this, and there are a lot of issues that are pending
1107 right now.

1108 Mr. {Stearns.} It is a little puzzling, don't you
1109 think?

1110 Ms. {Glied.} The key here, I think, sir, is that the
1111 basic structure of the plan is very much defined in the
1112 legislation itself which calls for it to mimic a typical
1113 employer plan. So there isn't that much leeway here. We are
1114 trying to lay down the specifics of this and many other
1115 provisions in the law through regulation, and this is one of
1116 them.

1117 Mr. {Stearns.} You are building a ship, and you got 10
1118 aspects, categories of the ship that have to be built, and
1119 they have to be coordinated and everybody agrees upon it.
1120 But I will tell you, there is a date when that ship expects
1121 to be done, when that ship is complete and everybody knows
1122 it. So you are telling me here that the essential benefits
1123 package, no one in your office, no one in any meeting has
1124 ever said to you when there is going to be a date when we can

1125 provide, one, for the public comment, two, hopefully for the
1126 States to comply. You can't have it--

1127 Ms. {Glied.} Sir, I believe--

1128 Mr. {Stearns.} --2014.

1129 Ms. {Glied.} I am aware that the noticed of proposed
1130 rulemaking which will include the essential health benefits
1131 is supposed to come out this fall. I don't have an exact
1132 date when in the fall.

1133 Mr. {Stearns.} Okay, I mean you are not going to go
1134 through a trap door if--

1135 Ms. {Glied.} No, I don't know exactly what date it is
1136 in the fall. It is--

1137 Mr. {Stearns.} Because this trap door doesn't exist.
1138 All you have to do in your best estimation--

1139 Ms. {Glied.} It will be in the fall though.

1140 Mr. {Stearns.} --as the crowning chief here is to give
1141 us a little date.

1142 Ms. {Glied.} Fall, the fall. When in the fall? I
1143 don't know.

1144 Mr. {Stearns.} Okay, the leaves turn in October.

1145 Ms. {Glied.} The leaves turn in October. It is likely
1146 to be in October.

1147 Mr. {Stearns.} Okay.

1148 Ms. {Glied.} It could be in November, sir. There you

1149 go.

1150 Mr. {Stearns.} So we are going to say in October is
1151 when the rule will be released. Now, if you come back--

1152 Ms. {Glied.} It may be November. I don't want to be
1153 held to October, sir. I don't know.

1154 Mr. {Stearns.} Now, if I was a businessman and I felt
1155 that I wanted to work with you--

1156 Ms. {Glied.} Yes, sir.

1157 Mr. {Stearns.} --this uncertainty that you are creating
1158 by sort of double taking on this date provides me a feeling
1159 that I better not do anything until I start to see this
1160 essential rule. So you are an economics professor. You and
1161 I both know that uncertainty in the marketplace is not a good
1162 thing. Isn't that correct?

1163 Ms. {Glied.} That is correct, sir.

1164 Mr. {Stearns.} So you are creating uncertainty by
1165 giving us such a nebulous span here of you are not sure of a
1166 critical aspect for the rule to be released on the essential
1167 benefit package. So I would just suspect that if I went back
1168 to your people, you could say look, why don't we give the
1169 Oversight and Investigation Committee the best guess of what
1170 we can do because that would be better certainty than you are
1171 giving me today.

1172 Ms. {Glied.} I will be very happy to go back and see if

1173 we have a date that we would be able to give to the Oversight
1174 Committee.

1175 Mr. {Stearns.} Now, during this process here, are you
1176 going to meet with stakeholders?

1177 Ms. {Glied.} Yes, sir. We actually have an extensive
1178 plan for public comment. That is one of the reasons we want
1179 to get the NPRN out.

1180 Mr. {Stearns.} What individuals in the administration
1181 has HHS discussed this rule with, if any?

1182 Ms. {Glied.} Within the administration?

1183 Mr. {Stearns.} Yeah, in other words, I assume these 10
1184 categories, that you are talking to other people within HHS
1185 about these. I mean who is this cadre that we are talking
1186 with?

1187 Ms. {Glied.} Well, the 10 categories, of course, are
1188 laid out in the legislation itself as is required...

1189 Mr. {Stearns.} I know the categories are, but how about
1190 the people?

1191 Ms. {Glied.} And we have already done work. We have
1192 released, for example, a report from the Department of Labor
1193 looking at what typical employer plans include.

1194 Mr. {Stearns.} I am not being too clear on the
1195 question. When the FCC came up with the broadband plan, they
1196 went out and brought all these stakeholders in to help them

1197 write it. We didn't like some of it, and then they paid them
1198 money. And they also had staff, but you are not doing that.

1199 Ms. {Glied.} No--

1200 Mr. {Stearns.} You are not bringing in stakeholders to
1201 help you write the essential benefits package. You all are
1202 doing it in house.

1203 Ms. {Glied.} No, sir. That is actually one of the
1204 reasons we went to the IOM. The IOM is actually already
1205 engaged in a long period of public engagement.

1206 Mr. {Stearns.} Who is the IOM?

1207 Ms. {Glied.} The Institute of Medicine.

1208 Mr. {Stearns.} Okay.

1209 Ms. {Glied.} They actually held two large public
1210 meetings back in January and April. They are--

1211 Mr. {Stearns.} Will they be writing the rule?

1212 Ms. {Glied.} --eventually going to be--they will be
1213 providing us with this process. We will then be working on
1214 the rule. We will be engaging stakeholders. We are actually
1215 developing a plan for actively engaging all types of
1216 stakeholders. Then we will release an NPRM and get even more
1217 stakeholder comment.

1218 Mr. {Stearns.} Okay.

1219 Ms. {Glied.} This is actually anticipated to be a very
1220 public process, but we have to wait for the IOM report since

1221 we did commission it.

1222 Mr. {Stearns.} Okay, my time is expired. The gentleman
1223 from California, Mr. Bilbray, is recognized for 5 minutes.

1224 Mr. {Bilbray.} Thank you. Look, Doctor, I would like
1225 to try to do something very unique in the Oversight hearing
1226 process. I would like to work with you to come to a
1227 consensus of a strategy we should go to. Rather than talking
1228 about stakeholders to, you know, someone to the left means
1229 political activist stakeholder. Somebody to the political
1230 right means business community. Let us talk FDA, and let us
1231 talk about real stakeholders, patients, people who are ill--

1232 Ms. {Glied.} Yes, sir.

1233 Mr. {Bilbray.} --people who are dying, people who are
1234 waiting patiently for something to save their lives. Let us
1235 take a look at something that I think all of us can agree was
1236 a bipartisan effort that probably did--was more of a medical
1237 movement or success than anything we have seen probably since
1238 polio, and that is in the '90s. We not only put massive
1239 amounts of research out there, but we changed our FDA
1240 oversight and regulatory guidance for AIDS. We did things to
1241 fight the AIDS epidemic that we basically hadn't done in the
1242 past, at least the near past, and we haven't done since as
1243 far as I know.

1244 And sadly, I think what happened was we were so

1245 successful that we walked away from that success and said
1246 okay, we have really done a great breakthrough here and pat
1247 ourselves on the back. But we left it at that. And this is
1248 what my challenge would be to you. What is the possibility
1249 of Democrats and Republicans getting together, taking a look
1250 at what we did in the '90s to put AIDS in that situation,
1251 move it from acute to a chronic, basically make it a livable,
1252 survivable process?

1253 What is the possibility of us going back and saying damn
1254 it, we had a successful formula here? Why don't we go back
1255 and take a look at that? And one of the most important
1256 successful formulas was not one of you got to have a
1257 bureaucracy that is totally insulated from the private sector
1258 so they are not polluted by capitalism. Or we have to have
1259 somebody who has some reality and connection to the industry
1260 so they know the physical movements.

1261 And let me tell you something as somebody who comes from
1262 local government, a former mayor and county chairman,
1263 building inspectors are required to have had private sector
1264 involvement. And that is one of the most successful local
1265 government aspect. But that aside, I think the one place we
1266 should be able to agree is that we should be looking at
1267 implementing the stakeholders' place at the table with all of
1268 these FDA reviews, not just on AIDS.

1269 And what is the possibility, do you think, of the
1270 administration working with us at modifying the FDA process
1271 at least--maybe it is some targeted issues. Maybe we talk
1272 about cancer. Maybe we talk about diabetes, but changing the
1273 oversight process to allow patients, not advocates, patients
1274 at the table like we did with AIDS. What is the possibility
1275 of us resurrecting that model and applying it as being the
1276 happy medium, some place the Democrats and Republicans can
1277 agree on?

1278 Ms. {Glied.} That sounds like a very interesting idea,
1279 and I am actually not very familiar with the FDA is doing now
1280 to enhance patient engagement around medical innovation. I
1281 know that they have--they are working very hard to try and
1282 improve the speed and innovation process on several different
1283 fronts. But I am not actually sure how much patient
1284 engagement has played a part in that.

1285 Mr. {Bilbray.} Okay, let me just tell you--

1286 Ms. {Glied.} I will get back to you on that.

1287 Mr. {Bilbray.} Doctor, if there is any place that I
1288 think the administration really is very vulnerable, and I
1289 praise the administration on--secretary of energy. I praise
1290 him what I think has been--you know, praise him about the
1291 team he put together for national defense. But if you look
1292 at the timelines since this administration has taken over--

1293 and granted it might be a timeline that started a little bit
1294 before this administration.

1295 Patients are watching the clock slow down. They are
1296 watching it so much to where we end up with what happened
1297 this week where you had the First Lady, rightfully so, point
1298 out that obesity is a major crisis here. And at the same
1299 time, the FDA telling a drug company that may have a major
1300 breakthrough in obesity, we are going to require you to go
1301 60,000 test site number, and they are just basically saying
1302 forget it. They are packing up and going to Europe.

1303 At the same time that our system is doubling in certain
1304 applications, Europe is reducing their numbers with no more
1305 adverse impact. So if I can say frankly to you, I think we
1306 are in crisis at the FDA, and I am trying, rather than just
1307 screaming bloody murder about patients waiting, you know, on
1308 a death list, while the bureaucrats are fiddling. Why don't
1309 we take a look at, okay, let us go back and maybe we can both
1310 work together and learn from the past and move it forward.

1311 Ms. {Glied.} You know, the FDA has to balance patient
1312 protection and trying to take care of patients in need, and I
1313 understand that you know that too. Let me get back to you on
1314 some ideas that we have.

1315 Mr. {Bilbray.} Okay, my biggest point is this. As
1316 somebody that has worked 35 years in bureaucracy, I don't

1317 care if it is FDA, I don't care if it is a planning director,
1318 I don't care if it is somebody putting up stop signs. It is
1319 much easier to say stop than it is to say go. There is risk
1320 at go. The fact is the bureaucrat doing the oversight isn't
1321 at risk when he says stop. The patient who is dying of
1322 cancer, who is dying of AIDS, they are at risk, and they
1323 should be able to sit at the table and be able to look the
1324 bureaucrat in the eye, like they did on AIDS.

1325 Ms. {Glied.} Let me get back to you on what is
1326 happening on the FDA because I am just not very familiar with
1327 that, sir.

1328 Mr. {Bilbray.} Okay, then I will ask that we look at
1329 this and bring in some balance, and I think that we have to
1330 understand there isn't balance now. As long as you have
1331 somebody who is coming out of the government structure and
1332 has no personal vested interest in the outcome, you are going
1333 to have it.

1334 Now, some people say business there would have too much
1335 financial vested interest, but I think we should both agree
1336 that patients have the right type of vested interest. And so
1337 they will encourage and, let me say, force the process to be
1338 more responsive without it opening itself up to being abused
1339 by the private sector. And I hope they will leave that as an
1340 open invitation.

1341 Ms. {Glied.} Okay.

1342 Mr. {Bilbray.} Thank you. I yield back, Mr. Chairman.

1343 Mr. {Stearns.} The gentleman yields back. The
1344 gentleman from Louisiana, Mr. Scalise, is recognized for 5
1345 minutes.

1346 Mr. {Scalise.} All right. Thank you, Mr. Chairman.
1347 When Mr. Stearns was asking you kind of a follow-up about the
1348 waiver, you had made a comment that when he said, you know,
1349 all of these 1,300, almost 1,400 people have received a
1350 waiver from the component that would take effect in 2014, you
1351 had said that that shows that there is a lot of lousy plans
1352 out there. I am not sure if you are familiar. They are not
1353 asking for a waiver from their plan. They are asking for a
1354 waiver from Obamacare. So can you explain what you meant by
1355 that comment?

1356 Ms. {Glied.} Yes, sir.

1357 Mr. {Scalise.} It is an odd comment to make.

1358 Ms. {Glied.} They are asking for a waiver from the
1359 requirement in the Affordable Care Act that says that plans
1360 may not limit the amount that an insurance plan will pay out
1361 to a person who is very ill. So right now, there are plans
1362 before the Affordable Care Act came out, that would say this
1363 plan covers you unless you have more than \$5,000 in medical
1364 expenses. Now, after \$5,000, hey, buddy, you are on your

1365 own. Which actually means hey, the rest of us, we get to pay
1366 your bills because you are not going to be able to do it.

1367 Mr. {Scalise.} So--

1368 Ms. {Glied.} The Affordable Care Act--

1369 Mr. {Scalise.} You know, I guess what you are saying is
1370 that you have defined that yourself as that is a lousy plan.
1371 Is that what you are saying?

1372 Ms. {Glied.} Basic economic theory--

1373 Mr. {Scalise.} You referred to it as a lousy plan.

1374 Ms. {Glied.} --as well as, I think, U.S. taxpayers
1375 ought to see that as a lousy plan because we are going to pay
1376 your cost for you if you have any.

1377 Mr. {Scalise.} So if a family has that plan and they
1378 like that plan, you are sitting here in your ivory tower
1379 saying that is a lousy plan. We need to fix it. We need to
1380 go and change the rules in a way that your employer might
1381 drop your coverage all together. Because that is what these
1382 employers are saying.

1383 The employers aren't saying, you know, I want to try to
1384 figure out how to add cost to health care in a way that they
1385 can't afford, they might go bankrupt. They have decided I
1386 can either provide health care to my employees or not provide
1387 it. And if I can provide a plan that gives their family
1388 something that their family likes, you are sitting here

1389 saying that is a lousy plan. We are going to change the law
1390 in a way that now you can't afford the plan anymore.

1391 The companies have told you. This isn't me suggesting
1392 it. You granted them the waiver because they said they can't
1393 afford it. They are going to have to dump all their
1394 employees off of that health care plan that you just called
1395 lousy. They liked the plan. 80 percent of the employees
1396 like those plans, and you are calling them lousy saying no.
1397 But if you get a waiver, you can keep doing it. But if you
1398 don't get the waiver, your employer is going to dump the plan
1399 because they can't afford to do it anymore. So now you don't
1400 have any insurance and you are off fending for yourself out
1401 there because you decided in some ivory tower that their plan
1402 that they liked was lousy.

1403 Now, you don't understand how a lot of people have
1404 trouble with that concept that somebody in Washington is now
1405 going to determine that their plan that they like is no
1406 longer valid, and if they get a waiver, they can keep getting
1407 it. But if they don't get a waiver from you, their employer
1408 said they can't provide it anymore. They are going to have
1409 to stop providing health coverage to their employees all
1410 together. And now that plan that they liked is no longer
1411 available for them.

1412 Ms. {Glied.} That, sir, is why we need to move to 2014

1413 when everybody will have much better, more affordable
1414 coverage available to them. And the reason for the waivers
1415 is just to keep those plans, which we recognize are better
1416 than nothing, in existence until we can provide people with
1417 much better coverage that is comprehensive and that protects
1418 them against catastrophic expenses beginning in 2014.

1419 Mr. {Scalise.} There is a big flaw with that theory,
1420 and I am glad you acknowledge now that maybe it is a good
1421 plan because you were calling it a lousy plan earlier. That
1422 employee likes the plan. You might think it is lousy. That
1423 is not your decision. It shouldn't be your decision. I mean
1424 under Obamacare, I guess it is your decision. You can take
1425 it away from them. But the President said--I mean he pledged
1426 it time and time again before, during, and after this debate
1427 that if you like what you have, you can keep it.

1428 And frankly that is a tenet that ought to be established
1429 in the law, and it is not. Because if you like what you
1430 have, you are going to lose it in many cases, and there was a
1431 study done by McKenzie and Company. I don't know if you had
1432 looked at it, but a very well-respected firm who did an in-
1433 depth study, the only one I have seen out there that really
1434 goes into detail about employers who do provide health care.
1435 It said 30 percent of employers would drop their coverage
1436 when all the costly requirements of Obamacare become law.

1437 Now, I don't know if you have disputed the McKenzie
1438 study, but it is out there. It has a lot of factual basis
1439 behind it. They talked to real people. They talked to
1440 employers who provide health care, to employees who like the
1441 care, and so when the President says if you like what you
1442 have, you can keep it. According to this study, over 30
1443 percent of those companies said they are not going to be able
1444 to keep providing it. So the employees lose the care they
1445 like. That breaks the President's pledge.

1446 Now I would like to see what your response is to the
1447 McKenzie study. Maybe it was flawed in how they asked the
1448 question. Maybe you think it is going to be a lot rosier
1449 when all those lousy plans are dumped, as you categorize
1450 them.

1451 Ms. {Glied.} Sir, we have actually seen many studies.
1452 The McKenzie study is only the most recent in a very long
1453 series of studies. Virtually all of them have not found
1454 anything like that result. They found very small changes in
1455 employer offering including previous surveys of employers.
1456 So the McKenzie study--

1457 Mr. {Scalise.} Would you dispute the findings of the
1458 McKenzie study?

1459 Ms. {Glied.} Wait a second. And moreover, we have one
1460 real world example of what happens when you do something very

1461 much like the Affordable Care Act, which is what happened in
1462 Massachusetts. And what happened in Massachusetts is that
1463 the number of employers offering coverage increased
1464 substantially and significantly even as the rest of the
1465 country--

1466 Mr. {Scalise.} Well, we have heard all kind of problems
1467 with Massachusetts, but regardless of that--

1468 Ms. {Glied.} Well, certainly whatever--

1469 Mr. {Scalise.} --this isn't Massachusetts. This is the
1470 United States, and you have 1,400 companies that your office
1471 has said they need a waiver. Otherwise, they are going to
1472 have to drop the plan. I mean if 1,400 entities, you know,
1473 unions and all kind of other groups that were supporting this
1474 law said we can't provide the health care anymore unless we
1475 get the waiver.

1476 Well, what happens at 2014 when they can't get the
1477 waiver anymore? What happens to the countless others who
1478 have asked for the waiver and couldn't even get it, now 30
1479 percent of them according to study. But even if you don't go
1480 by this study, 1,400 according to your own numbers of who you
1481 gave waivers to said they couldn't provide health care to
1482 their employees anymore. They were going to have to dump
1483 them if they didn't get the waiver from the component of the
1484 law.

1485 Ms. {Glied.} Beginning in 2014, everyone is going to be
1486 insured much better, more comprehensive, and affordable
1487 coverage. Right now, fewer than 2 percent--

1488 Mr. {Scalise.} I guess something magical happens in
1489 2014 where today they are going to have to drop--they can't
1490 even comply with the law. But in 2014, somehow everything is
1491 going to be rosy, and then they can comply with the law even
1492 though nothing has changed because all of these other
1493 companies have said they can't comply. They are going to
1494 have to dump the health care that their employees liked.

1495 Ms. {Glied.} 2014 will have a new, much more
1496 competitive, patient-centered insurance marketplace in which
1497 people will be able to get coverage they can afford so--

1498 Mr. {Scalise.} Hopefully by 2014, the law is repealed,
1499 and then people really can keep what they like that they
1500 currently have. Thanks, I yield back.

1501 Mr. {Stearns.} Gentleman yields back. I have a series
1502 of questions here. Dr. Glied, are you familiar with the
1503 recent rule HHS released on accountable care organizations?

1504 Ms. {Glied.} Yes, sir, I am.

1505 Mr. {Stearns.} Are you aware that a number of premier
1506 organizations, such as the Mayo Clinic, wrote the
1507 administration saying that more than 90 percent of its
1508 members would not participate because the rules as written

1509 are so burdensome it would be impossible to succeed?

1510 Ms. {Glied.} Yes, sir. That is exactly why we want to
1511 have a robust public comment after we put forward a notice of
1512 proposed rulemaking.

1513 Mr. {Stearns.} Okay, if less than 90 percent of the
1514 groups that you need to participate would not do so, how did
1515 it come about that a rule was ever released?

1516 Ms. {Glied.} There are many--we have received many,
1517 many comments on the notice of proposed rulemaking, and they
1518 vary considerably in what they think should and should not be
1519 in the rule. The administration has to chart a course
1520 between all the different goals that we are trying to do
1521 here, and we really want to bend the cost curve and change
1522 the delivery system. So we are listening to all the
1523 comments, and we will incorporate them in the final rule.

1524 Mr. {Stearns.} But wouldn't you think that the reaction
1525 was pretty dramatic here that the Mayo Clinic--I mean if you
1526 try to create these efficient rules and balance the competing
1527 interests, so-called, versus the government versus the
1528 private sector, you know, shouldn't the reaction to a rule
1529 like this not be so harsh? I mean wouldn't you--doesn't that
1530 tell you something?

1531 Ms. {Glied.} There are--this is a very important rule.
1532 This is one of the main goals of the administration is to

1533 bend the cost curve by changing the incentives that face the
1534 health care system today. And, of course, there are lots and
1535 lots of opinions about how it ought to be done. It is not at
1536 all a surprise that we have heard a lot of feedback. We also
1537 took a lot of public comment before we wrote the rule that is
1538 incorporated in it already.

1539 Mr. {Stearns.} The complete rejection of this rule by
1540 organizations you would need to rely on for its simple
1541 success seems quite lopsided. I mean that is our opinion.
1542 Do you agree?

1543 Ms. {Glied.} It will be very--it is important to wait
1544 until the final rule is promulgated, the program is supposed
1545 to take effect at the beginning of next year. And I think we
1546 should wait and see what happens at that point. We are
1547 really working on improving the rule and listening to the
1548 comment, and I can't really speak to it any much more than
1549 that.

1550 Mr. {Stearns.} I think this quote is from the ''Wall
1551 Street Journal.'' It called it, ``these regulations have
1552 been called overly prescriptive, operationally burdensome,
1553 and the incentives are too difficult to achieve to make this
1554 voluntary program attractive.'' In light of these
1555 statements, shouldn't this rule be completely reworked?

1556 Ms. {Glied.} We are responding to the rule by looking

1557 at the comments that we have received. Remember that we have
1558 to balance the protection of the Medicare trust fund against
1559 our desire to change the incentives in the health care
1560 system. Both of those are competing interests, and we are
1561 working on them.

1562 Mr. {Stearns.} So you don't think the rule should be
1563 reworked?

1564 Ms. {Glied.} Mr. Chairman, after an NPRM, we rework a
1565 rule before we finalize it. We listen to the comments, and
1566 we change it around.

1567 Mr. {Stearns.} So it can be reworked?

1568 Ms. {Glied.} That is the point of this process.

1569 Mr. {Stearns.} Does the President's executive order
1570 require you to do this? Do you consider that, or is this
1571 just part of your normal procedure?

1572 Ms. {Glied.} It is part of our normal procedure.

1573 Mr. {Stearns.} Yeah, okay. One thing many have
1574 wondered in the aftermath of the rule, how did this rule come
1575 to be? For example, we talked earlier about you
1576 communicating with stakeholders. Evidently you didn't
1577 communicate with stakeholders in this case. Is that true you
1578 didn't communicate with stakeholders? That is why the
1579 reaction was so harsh?

1580 Ms. {Glied.} No, sir, we had extensive communications

1581 with stakeholders, and this has actually been an area where
1582 there has been tremendous public comment.

1583 Mr. {Stearns.} The stakeholders didn't alert you to the
1584 problems back then before you issued it?

1585 Ms. {Glied.} Different stakeholders had different
1586 opinions, sir.

1587 Mr. {Stearns.} Okay, so you are going to reach out to
1588 these same groups again, I guess, and does that mean that--
1589 did you reach out to the Mayo Clinic?

1590 Ms. {Glied.} The rule is closed for comment on June 6.
1591 We received many, many comments on the rule.

1592 Mr. {Stearns.} Okay, so you are saying to me this
1593 morning that--this afternoon you will probably redo this
1594 rule?

1595 Ms. {Glied.} We are looking at the comments, and we
1596 will revisit the rule and look at what we need to do to
1597 address those comments.

1598 Mr. {Stearns.} Okay, I think I will probably conclude
1599 here shortly much to the loyal opposition's concern. I want
1600 to talk about the Data Quality Act.

1601 Ms. {Glied.} Sure.

1602 Mr. {Stearns.} To comply with President's January
1603 executive order, doesn't HHS have to base its regulation on
1604 the best available science?

1605 Ms. {Glied.} We endeavor to do so at all times.

1606 Mr. {Stearns.} Sure, okay, what is this best available
1607 science that you use?

1608 Ms. {Glied.} That would depend, sir, on the question
1609 that is, you know, the question that is being addressed by
1610 the scientists.

1611 Mr. {Stearns.} In addition to or prior to the
1612 President's executive order, did HHS have to base its
1613 regulation on the best available science pursuant to the Data
1614 Quality Act?

1615 Ms. {Glied.} We have always tried to base our
1616 regulations on the best available science.

1617 Mr. {Stearns.} I will take that as a yes. Since that
1618 is the case, can you represent to the committee today that
1619 all HHS regulatory efforts since you have assumed office have
1620 applied the Data Quality Act and are in compliance with the
1621 Data Quality Act?

1622 Ms. {Glied.} I believe so, but let me get back to you
1623 because I am not familiar with the precise details of the
1624 Data Quality Act.

1625 Mr. {Stearns.} That is a fair answer. Would you agree
1626 that if HHS is to base regulations or regulatory decisions on
1627 the best available science that HHS cannot act on the basis
1628 of conflicting studies? For example, if you decide on

1629 certain areas and you have conflicting studies, I guess the
1630 question is how are you going to make your regulatory
1631 decisions?

1632 Ms. {Glied.} Chairman Stearns, if we waited for science
1633 to come to a definitive conclusion on everything, we would
1634 never be able to act. It is always going to be--there are
1635 always going to be conflicting studies. The best available
1636 evidence doesn't mean that there are no conflicting studies.
1637 I means that the preponderance of sensible evidence leads in
1638 a particular direction. Scientists thrive on controversy.

1639 Mr. {Stearns.} Okay, Mr. Scalise brought up the
1640 McKenzie study, and I think your indication was that you
1641 weren't discrediting it, but you said there is more than one
1642 studies. And I think the White House has tried to discredit
1643 this study calling it an outlier and implying that the
1644 McKenzie study isn't a respected, independent organization.
1645 Did you know of that criticism?

1646 Ms. {Glied.} I think one of the concerns that we have
1647 about that study is that we haven't been able to see the
1648 methods that they used, and they haven't made those public.
1649 So I can't speak to whether that is a good study or not
1650 because I personally have not seen the methods used.

1651 Mr. {Stearns.} So you are not implying that the
1652 McKenzie Organization is not a credible organization?

1653 Ms. {Glied.} I believe the McKenzie Organization is a
1654 credible organization. I can't speak for this specific
1655 study.

1656 Mr. {Stearns.} Okay, and I agree with you. The Federal
1657 Government has awarded McKenzie and Company over \$182 million
1658 in government contracts to perform consulting and analysis
1659 work. And as you are aware, that \$182 million that is
1660 disclosed on U.S. spending, more than \$122 million of it
1661 comes from the Obama Administration, \$21 million of which are
1662 contracts with HHS. So clearly the Obama Administration
1663 thinks McKenzie is doing reliable and honest work or they
1664 wouldn't employ them and they are spending money with them.

1665 Doesn't McKenzie say what distinguishes this study from
1666 others is that McKenzie educated respondents on the
1667 President's health care requirements that will take effect in
1668 2014? What I am trying to establish is once McKenzie went
1669 out and explained the implications, that is how they got
1670 their study, and that distinguished many other studies which
1671 just do analysis without asking and educating people about
1672 the impact of the President's health care plan? So I guess
1673 the answer is yes or no. So all I am saying is--

1674 Ms. {Glied.} We don't know how they educated them, so I
1675 don't know what that--I can't--I don't know what I can say
1676 about that.

1677 Mr. {Stearns.} Okay, so you can't answer it. Okay, I
1678 think we have covered most of the questions here. We thank
1679 you for your patience and with nothing else, no more on the
1680 minority side, the subcommittee is--before I adjourn, I would
1681 just like to let all members have an opportunity to offer
1682 their opening statements, and I ask unanimous consent that
1683 the written opening statements of all members be introduced
1684 in the record. Without objection, and I ask unanimous
1685 consent that the slide we had be put in part of the record.
1686 And with that, the subcommittee is adjourned.

1687 [Whereupon, at 3:25 p.m., the subcommittee was
1688 adjourned.]