

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 1

NEAL R. GROSS & CO., INC.

RPTS MICHON

HIF035140

EXAMINING IMPLEMENTATION OF THE BIOLOGICS

PRICE COMPETITION AND INNOVATION ACT

THURSDAY, FEBRUARY 4, 2016

House of Representatives

Subcommittee on Health

Committee on Energy and Commerce

Washington, D.C.

The subcommittee met, pursuant to call, at 10:30 a.m., in Room 2123 Rayburn House Office Building, Hon. Joe Pitts [chairman of the subcommittee] presiding.

Members present: Representatives Pitts, Barton, Guthrie, Whitfield, Shimkus, Blackburn, Lance, Bilirakis, Long, Ellmers, Bucshon, Brooks, Collins, Green, Schakowsky, Butterfield, Castor, Sarbanes, Matsui, Schrader, Kennedy, Cardenas, and Pallone (ex officio).

Staff present: Leighton Brown, Press Assistant; Rebecca

NEAL R. GROSS
COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 2

Card, Assistant Press Secretary; Paul Edattel, Chief Counsel, Health; Carly McWilliams, Professional Staff, Health; Katie Novaria, Professional Staff, Health; James Paluskiewicz, Professional Staff, Health; Graham Pittman, Legislative Clerk, Health; Chris Sarley, Policy Coordinator, Environment and Economy; Jennifer Sherman, Press Secretary; Adrianna Simonelli, Legislative Associate, Health; Heidi Stirrup, Policy Coordinator, Health; John Stone, Counsel, Health; Sophie Trainor, Policy Advisor, Health; Christine Brennan, Minority Press Secretary; Jeff Carroll, Minority Staff Director; Tiffany Guarascio, Minority Deputy Staff Director and Chief Health Advisor; Samantha Satchell, Minority Policy Analyst; Matt Schumacher, Minority Press Assistant; Kimberlee Trzeciak, Minority Health Policy Advisor; Arielle Woronoff, Minority Health Counsel.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 3

1 Mr. Pitts. The subcommittee will come to order. The
2 chairman recognizes himself for an opening statement. Biologics
3 are used to treat a number of serious diseases and conditions and
4 have improved the lives of millions of Americans. They are
5 produced from living cells using biotechnology and are often
6 significantly more time consuming and resource intensive to
7 consistently manufacture than small molecule chemical drugs.
8 Due in large part to these complexities, biologics tend to be more
9 expensive and why the traditional generic approval pathway is not
10 suited for bringing lower-cost alternatives to market.

11 In 2009, this committee passed the Biologics Price
12 Competition and Innovation Act, BPCIA, by a vote of 47 to 11.
13 Enacted in 2010, BPCIA established a new abbreviated pathway at
14 FDA for biological products determined to be biosimilar to or
15 potentially interchangeable with a previously approved reference
16 product.

17 FDA approved the first biosimilar in March 2015. It is
18 convening an advisory committee next week to consider a second
19 application. And while there are close to 60 additional proposed
20 biosimilar products enrolled in FDA's Biosimilar Development
21 Program, the Agency has yet to issue guidance documents on several
22 key policy issues that could have a significant impact on patient
23 safety, prescriber decision making, and market competition.

24 I look forward to hearing from Dr. Woodcock about where these

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 4

documents are in the review process. And I would like to walk away from today's discussion with a better understanding of the Agency's current thinking on issues such as naming, labeling, and interchangeability.

Meanwhile, in preparation for biosimilars coming to market, the Centers for Medicare and Medicaid Services recently issued payment guidance related to Medicare Part B for biosimilars. Members will want to understand the implications of this broad-payment policy and if it will account for variations and differences between biosimilar products and moreover, what might that payment policy mean for the eventual growth in this market and innovation.

With both witnesses here, we will be able to explore how could or should pending issues before FDA, for example, naming and interchangeability, impact the reimbursement policy under the Medicare program as well as access and portability for beneficiaries.

The committee will have an opportunity to hear directly from FDA and CMS on their progress with implementation of BPCIA and future outlook.

I yield the balance of time to Chairman Emeritus, Mr. Barton.

Mr. Barton. Thank you, Mr. Chairman, for holding the hearing. And thank you for holding it at 10:30 where I can actually be on time. I appreciate that.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 5

49 Six years ago, I co-authored, along with Congresswoman Anna
50 Eshoo, the Biologics Price Competition and Innovation Act,
51 commonly known as BPCIA, which just as an aside you would have
52 thought we would have come up with a better name than something
53 like that.

54 Today, we sit as a subcommittee with numerous concerns about
55 the implementation or more appropriately the lack thereof of this
56 important piece of legislation. Only one biosimilar has been
57 approved. Numerous products are waiting to proceed through the
58 approval process and many physicians, patients, and concerned
59 individuals like myself are concerned with the lack of progress.

60 We all agree that it is important for FDA to get it right,
61 but most of us think it is also time for FDA to get on down the
62 road and decide exactly how to proceed with the approval process.
63 There have been seemingly unending delays that are frustrating
64 to legislators, innovators, doctors, and patients. I have sent
65 letters to the FDA, the OMB, CMS, expressing these frustrations.
66 I am concerned that the CMS decision regarding reimbursement for
67 biosimilars to be the average sales price for all biosimilars plus
68 six percent of the Reference Product ASP. This approach
69 undermines the real intent of the legislation.

70 We want to foster a robust biosimilar market. CMS' approach
71 eliminates any financial incentives in reimbursement for
72 biosimilars by potentially forcing doctors and patients to use

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 6

73 one non-interchangeable biosimilar in place of another based on
74 price alone. This is detrimental because all biosimilars, as we
75 all know, are not equal. By definition, they are not equal. I
76 cannot overstate the importance of treating each biosimilar
77 individually rather than as if they were a generic drug.

78 I am also concerned about the lack of FDA guidance regarding
79 interchangeability in naming. Due to the absence of any such
80 guidance, the FDA approved a biosimilar, Zarxio, with a
81 placeholder name 6 years after the bipartisan, bicameral BPCIA
82 was signed into law. We are still waiting and this is simply
83 unacceptable.

84 Thank you, Mr. Chairman.

85 Mr. Pitts. The chair thanks the gentleman and now
86 recognizes the ranking member on the subcommittee, Mr. Green, for
87 5 minutes for his opening statement.

88 Mr. Green. Thank you, Mr. Chairman. Before I start, I
89 would like to have unanimous consent to place in the record a
90 letter from Biosimilar Council and ask unanimous consent.

91 Mr. Pitts. With no objection, so ordered.

92 Mr. Green. Thank you and good morning. Dr. Woodcock,
93 welcome again, and Mr. Cavanaugh, thank you for being here.

94 Today's hearing is the first we have had in the House of
95 Representatives on biosimilars since the passage of the Biologics
96 Price Competition and Innovation Act, or BPCIA, as part of the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 7

97 Affordable Care Act in 2010. It is particularly timely because
98 the FDA is both developing the standards for approval of
99 biosimilars and reviewing and acting on a growing number of
100 applications for approval. At the same time, CMS recently
101 released its final Physician Pay Schedule, PFS rule, which
102 detailed the Medicare Part B payment methodology for biosimilars.
103 Determinations on biosimilars that are approved, regulated, and
104 reimbursed is critical to the success of this new and emerging
105 market and must be in alignment to facilitate our robust, safe,
106 and competitive marketplace.

107 As we know, biologics place an important and growing role
108 in our healthcare system. They arguably represent the future of
109 therapeutics and hold immense promise to further transform the
110 way we treat and prevent diseases.

111 According to the RAND Corporation, world-wide sales of
112 biologics were \$46 billion in 2002, representing 11 percent of
113 the global pharmaceutical market. Experts are predicting that
114 by 2017, biologics are expected to grow to between \$205 to \$235
115 billion, representing approximately 20 percent of the global
116 pharmaceutical marketplace.

117 Recognizing a need for non-innovative biologics is analogous
118 to the generic drug market facilitated by Hatch-Waxman. And I
119 worked with then Representative Tammy Baldwin and former
120 representative and now governor, Jay Inslee, years ago to

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 8

121 introduce a bill proposing a pathway for approval of biosimilars,
122 not long after the BPCIA became law, paving a way for injection
123 of competition in the biologics space.

124 I know we all agree that competition is good for patient
125 safety, consumer choice, and drive savings for consumers and the
126 healthcare system at large. There are a number of outstanding
127 issues on how these will be evaluated and treated by the FDA
128 including naming, interchangeability, labeling, and exploration.

129 The complexity of these issues are difficult to overstate
130 and I thank FDA for their on-going efforts to develop policies
131 on these questions. However, decisions on these major questions
132 should not be on a case-by-case basis and it is time for the FDA
133 to articulate clear guide rails and principles to industry and
134 the public so that rules of the road are established and
135 understood.

136 Public and provider trust in the safety of biosimilars is
137 vital to the success of this market. Acceptance of some generics
138 did not happen overnight. Only through a public, transparent
139 process of developing guidelines and rulemaking will the public
140 trust be earned. I look forward to hearing from FDA on the
141 status of these policies and how the Agency is moving these efforts
142 forward.

143 Recently, CMS detailed how biosimilars would be treated
144 under Medicare Part B and I have serious concerns about the final

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 9

145 rule. While I appreciate the Agency's desire to control costs,
146 I fear that in this instance it would undermine this infant market
147 and create a race to the bottom. If all biosimilars are on the
148 same blended code, we actually disincentivize companies for
149 investing in further trials for additional indications and would
150 drive folks away from this market that we are trying to foster.

151 Robust competition will ultimately realize the most
152 sustainable, significant savings for the program and the best for
153 patients. This rule seems in conflict with the efforts of the
154 FDA to foster the biosimilars marketplace. I look forward to
155 hearing from CMS on how this determination was made, responses
156 to the concerns about potential undermining of the biosimilars
157 market and I thank you all for being here today. And I yield back
158 the balance of my -- well, does anybody want a minute on our side?
159 No? Okay. I yield back my time, Mr. Chairman.

160 Mr. Pitts. Thank you. And I would like to ask unanimous
161 consent to submit the following documents for the record:
162 Statements from the Global Healthy Living Foundation and the
163 National Association of Chain Drug Stores. Without objection,
164 so ordered.

165 The chair now recognizes the vice chair of the full
166 committee, Ms. Blackburn, for 5 minutes for her opening statement.

167 Ms. Blackburn. Thank you, Mr. Chairman. And I want to say
168 welcome. We are delighted to have you all here. And we do have

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 10

169 some questions about what is transpiring.

170 And Dr. Woodcock, I want to come to you first. As you have
171 heard from statements on both sides, we realize that this is
172 essential, that the biosimilars are going to fill a place. It
173 is an emerging component, but I want to go to one thing you said
174 in your written testimony. And that is this, "Stakeholder
175 confidence is essential to the success of the biosimilar program."
176 This is something I am going to come back to you on.

177 When I talk to innovators that are in Tennessee, what they
178 are confused about is the lack of certainty. The chairman
179 mentioned to you about the documents and the lack of guidance,
180 where you all are in the process. So the hearing today is
181 important because of that. These innovators are looking to get
182 some certainty. These are complex decisions. We appreciate
183 that. We know that this is a new class of medicines.

184 And that brings me to my second point and Mr. Cavanaugh, I
185 will discuss this with you as we move forward with the hearing.
186 Looking at the realization, biosimilars and generics are not the
187 same thing. And we want to be certain that you all are addressing
188 this in the appropriate manner. We appreciate your written
189 testimonies. We look forward to digging down with you on some
190 questions and maybe some things that we are going to request for
191 a written answer.

192 And Mr. Shimkus, I am going to yield the balance of the time

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 11

193 to you.

194 Mr. Shimkus. You are so kind. Thank you. Because I want
195 to make sure that we submit for the record, Mr. Chairman, I have
196 two surveys both by -- for the Alliance for Safe Biologic Medicines
197 and one is a physician survey. One is a pharmacist survey. If
198 our goal is to ensure access to these products and to the
199 marketplace, shouldn't we enact a transparent labeling policy
200 that creates confidence in the healthcare market? So if you would
201 share these with the minority and accept these, I would for the
202 record appreciate it. And that is all I have. Thank you.

203 Mr. Pitts. All right, they will take a look at them and we
204 will come back to that.

205 The chair now recognizes the ranking member, Mr. Pallone,
206 for 5 minutes for opening statement.

207 Mr. Pallone. Thank you, Mr. Chairman. I want to thank you
208 for holding this hearing and also thank Dr. Woodcock and Director
209 Cavanaugh for being here to discuss the implementation of the
210 Biologics Price Competition and Innovation Act.

211 Biosimilars hold enormous potential to offer patients with
212 serious and life-threatening diseases access to more treatment
213 options and potentially lower cost options. And I look forward
214 to hearing your testimony today about how FDA and CMS are working
215 to establish a clear pathway for approval, as well as an
216 appropriate reimbursement structure. These are both critical

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 12

217 elements to ensuring the success of this market.

218 The use and sale of biologics continues to rise here in the
219 United States and elsewhere. By 2017, sales of biologics are
220 estimated to be between \$205 and \$235 billion, approximately 20
221 percent of the global pharmaceutical marketplace. And this is
222 why encouraging and facilitating competition is so critical.

223 While biosimilars have been available in Europe for some
224 time, Congress did not establish an abbreviated pathway here in
225 the U.S. until the passage of the act as part of the Affordable
226 Care Act in 2010. And I supported the creation of the pathway
227 for biosimilars and for empowering FDA with the authority and
228 resources to ensure that biosimilars are safely available here
229 in the United States for the patients that need them most.

230 I was pleased when FDA approved the first biosimilar, Zarxio,
231 in March 2015. And this action demonstrated that the approval
232 process is working. But I have also heard that greater clarity
233 is needed from the FDA.

234 Since 2012, FDA has issued important guidance meant to inform
235 industry sponsors that they consider developing biosimilar
236 products including scientific and quality considerations.
237 Additional guidance is still needed though, particularly in the
238 areas of developing and marketing biosimilars, guidance on
239 interchangeability, labeling, and naming are still outstanding.
240 And FDA's thinking in this area will be vital to companies looking

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 13

241 to enter the biosimilars market.

242 We have seen how our healthcare system has benefitted from
243 the competition that comes with a robust market. Competition has
244 helped to lower healthcare costs for small- molecule drugs, saving
245 the U.S. health system \$254 billion in 2014. And it is my hope
246 that we continue to do all we can to lay the foundation for these
247 types of savings.

248 Our federal health programs will also play a large role. CMS
249 has the ability, through both Medicare and Medicaid, to encourage
250 this new marketplace and that is why I was concerned that CMS
251 finalize the Part B payment policy for biosimilars last year
252 combining all biosimilars into one average sale price calculation
253 and payment code. I worry that this inappropriately treats
254 biosimilars like generic drugs and will disincentivize
255 manufacturers from entering the biosimilars marketplace because
256 biosimilars are not generics. Each is its own unique product.
257 And biosimilars go through a much more stringent approval process.
258 In fact, Medicare Part D and Medicaid both acknowledge this in
259 their respective programs.

260 This marketplace is only just emerging with only one approved
261 biosimilars, so it is important that we hear from both FDA and
262 CMS, not only about what they are doing in the space, but how they
263 are coordinating to ensure that the biosimilar marketplace is both
264 safe and robust.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 14

265 I just wanted to add one thing. I think all of you know that
266 the issue of drug pricing continues to rise in terms of the
267 concerns of the American public. Our Democratic Steering and
268 Policy Committee actually had a hearing on drug pricing. And at
269 that hearing, I was concerned to hear -- I think I asked a question
270 about generics and I was told by the witnesses there that generics
271 increasingly are not a way of reducing prices because of the
272 changes that are occurring in the marketplace. And so I do worry
273 that it is important in the case of biosimilars or generics that
274 that continue to be a way of reducing drug pricing. If it isn't,
275 then we are going to have even more of an outcry that prices are
276 too high and that there should be some kind of intervention by
277 Congress or by the Federal Government in the marketplace.

278 So I think that this is an issue. Even though we are talking
279 about biosimilars today, Mr. Chairman, this is part of a larger
280 issue of Americans being very concerned about drug pricing. And
281 of course, it has entered into the presidential sweepstakes or
282 whatever, as well. So you know, this is an important hearing,
283 not only in terms of what is happening to biosimilars, but just
284 the larger issue of drug pricing. Thank you, Mr. Chairman.

285 Mr. Pitts. The chair thanks the gentleman. That concludes
286 the prepared opening statements. As usual, all members' written
287 opening statements will be made a part of the record. Without
288 objection, the two documents that Mr. Shimkus asked to enter in

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 15

289 the record are ordered to be entered into the record.

290 We have one panel today. On our panel, we have Dr. Janet
291 Woodcock, Director, Center for Drug Evaluation and Research, Food
292 and Drug Administration; and Sean Cavanaugh, Deputy Administrator
293 and Director, Centers for Medicare and Medicaid Services. Thank
294 you very much for coming today. Your written testimony will be
295 made a part of the record. You will each have 5 minutes to
296 summarize your written testimony.

297 And Dr. Woodcock, you are recognized first for 5 minutes.

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 16

298 STATEMENT OF JANET WOODCOCK, M.D., DIRECTOR, CENTER FOR DRUG
299 EVALUATION AND RESEARCH, FOOD AND DRUG ADMINISTRATION; AND SEAN
300 CAVANAUGH, DEPUTY ADMINISTRATOR AND DIRECTOR OF THE CENTER FOR
301 MEDICARE AT THE CENTERS FOR MEDICARE AND MEDICAID SERVICES

302

303 STATEMENT OF JANET WOODCOCK, M.D.

304 Dr. Woodcock. Thank you, Mr. Chairman and members for
305 allowing me to be here today and testify.

306 Biological products are used to treat patients who have
307 serious and life threatening medical conditions such as
308 rheumatoid arthritis, cancer, serious gastrointestinal diseases,
309 and so forth. It is important for the health of the public to
310 have access to safe, effective, and affordable biological
311 products. Biosimilars can provide more treatment options to
312 patients and possibly lower treatment costs resulting in better
313 access.

314 FDA, in general, and I personally have long supported getting
315 the availability of a biosimilar pathway and we were very pleased
316 when Congress enacted this pathway. I have been involved in the
317 developing of biological therapeutics myself for about 30 years
318 and I have seen the transformation they have caused in healthcare
319 in some areas.

320 I am a rheumatologist and the biologics have totally changed
321 the face of rheumatology. We used to have patients in wheelchairs

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 17

lined up in our clinics. And we are talking about joint replacements. We are talking about nursing home care. And now instead of talking about that, we talk about treating to remission, how to make the disease go away, how to make those folks function as if they weren't sick. It has been a miraculous transformation. But this needs to be accessible to all Americans, not inaccessible to some because of cost.

Since the biosimilars pathway was created in 2010, we have actually seen a lot of progress. Now much of this progress is under the hood, so to speak, because the law required that the biosimilar drugs be found biosimilar to a reference U.S. product which meant that they had to study it to the products that were on the U.S. market and it takes an amount of time. But we did prove the first biosimilar in 2015.

We have an advisory committee coming up next week for another biosimilar for the advisory committee to consider and there are almost 60 programs under development in various stages. They have talked to us and we know of perhaps several dozens of others where they have reached out to us, but haven't engaged in our process.

I know people are anxious to see more progress and more certainty. I do understand that about the pathway.

Now if you look at small-molecule generics, as we just said, they have been successful. Over 88 percent of dispensed

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 18

346 prescriptions in the U.S. are generic drugs and actually they are
347 continuing to save a lot of money. There are a small number of
348 products that do not have generic competition still and they may
349 have price increases. But this has been a very successful
350 program, a generic program. But if we compare it, we did not have
351 success overnight in that program. It took a while to establish
352 the parameters, to get the industry to the state they need to be
353 and to get acceptance of the clinical community. So I think
354 maturity of the industry and gaining confidence of the healthcare
355 community was really critical to this 88 percent of dispensed
356 prescriptions being generics.

357 To earn and to sustain both physician and patients'
358 confidence in biosimilars and interchangeable products, we must
359 apply scientifically rigorous review process and approval
360 standard that people believe in and trust because these products
361 have been life changing for many people and they don't want to
362 sacrifice any performance. And we don't intend that they would
363 sacrifice any performance if they take a biosimilar.

364 Although the first biosimilar is now marketed, there are a
365 lot of legal, technical, and policy challenges ahead. Some of
366 them you have raised about various policy issues that must be
367 resolved. We fully recognize that and intend to do it, but I will
368 assure you that there is a bright future ahead for our biosimilars
369 program and I believe it is going to provide the same access to

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within
may be inaccurate, incomplete, or misattributed to the speaker.
A link to the final, official transcript will be posted on the
Committee's website as soon as it is available. 19

370 important medications that our current generics program is doing
371 and really a benefit of the health of the public.

372 I am happy to answer questions.

373 [The statement of Dr. Woodcock follows:]

374

375 *****INSERT 1*****

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 20

376 Mr. Pitts. The chair thanks the gentlelady.

377 I now recognize Mr. Cavanaugh for 5 minutes for your summary.

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 21

STATEMENT OF SEAN CAVANAUGH

Mr. Cavanaugh. Thank you, Mr. Chairman, and members of the subcommittee. I appreciate you inviting me here today to talk about Medicare Part B payment policy for biosimilars.

As you know, the Affordable Care Act created an abbreviated pathway for approval of biosimilars by the FDA and it created a provision for the establishment of Medicare payment policies for these products. Biosimilars hold great promise for all Americans including Medicare beneficiaries and we are committed to policies that will provide fair payment in a healthy marketplace.

In 2014, Medicare Part B spent \$21.5 billion on prescription drugs with the top 15 products accounting for \$11.5 billion in its total. Eleven of those 15 products were biologics and the top 6 products were all biologics and each one of those contributed over \$1 billion in spending.

CMS has an obligation to make sure taxpayers' dollars are used responsibly. This includes creating good payment policy and making appropriate coverage decisions that provide access to innovative services and treatments while incentivizing these treatments and delivery models that are efficient.

When the first biosimilar entered the market last year, we quickly assigned a billing code to facilitate Medicare beneficiaries' access to this new therapy. And we began an

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 22

402 outreach process to the provider community to make sure we could
403 share with them guidance on how to submit claims for the new
404 biosimilar product.

405 Also as several of you have noted, last year in our annual
406 Physician Fee Schedule rulemaking, we proposed and finalized a
407 policy that promotes fair payment in a healthy marketplace. It
408 was important that we implement a Medicare payment policy for
409 biosimilars now before the second biosimilar for any reference
410 product becomes available to provide certainty for providers and
411 suppliers who will be billing Medicare for these products in the
412 near term.

413 The statute provides for payment for biosimilar products in
414 the same manner as the statutory methodology for multi-source
415 drugs where more than one drug product is included in the same
416 billing code. We are confident that our interpretation of the
417 law is sound and it represents good policy that will facilitate
418 innovation and competition in the market.

419 We implemented this new policy through our normal rulemaking
420 process. We solicited, thoroughly reviewed, responded to, and
421 in some cases modified our proposed policy based on comments from
422 the public. For example, in collaboration with our colleagues
423 at the FDA and in response to public comments, we implemented a
424 requirement for claims for biosimilars to include a modifier that
425 identifies the manufacturer of the specific product. We recently

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 23

published guidance on the use of this modifier on our website.

This will allow us and others to track which specific biosimilars a beneficiary receives.

Overall, the availability of generic drugs in competition with each other and with branded products, has improved price and availability of drugs. Competition among biosimilars can do the same for Medicare beneficiaries. Like multiple-source drugs, CMS sees biosimilars competing for market share with each other as well as competing with the referenced product. Encouraging this competition reflects a top priority at CMS.

The field of biosimilars holds great promise for future improvements in health, value, and outcomes. We believe patients, manufacturers, providers, insurers, and government all share a common goal to foster a healthcare system that leads in innovation, delivers affordable high quality medicines, and results in healthier people. CMS policies will continue to ensure Medicare beneficiaries have access to biosimilars and other innovative treatments.

As more biosimilars are approved, we will monitor developments in the market and consider refinements to our policy as needed based on experience with this new segment of the market. We look forward to continuing to work with this committee, to gathering information from providers, suppliers, and other stakeholders to better inform our guidance and regulations in the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within
may be inaccurate, incomplete, or misattributed to the speaker.
A link to the final, official transcript will be posted on the
Committee's website as soon as it is available. 24

450 future.

451 Thank you and I look forward to your questions.

452 [The statement of Mr. Cavanaugh follows:]

453

454 *****INSERT 2*****

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 25

455 Mr. Pitts. The chair thanks the gentleman. Thank you for
456 your opening statements. I will begin the questioning. I
457 recognize myself for 5 minutes for that purpose.

458 Dr. Woodcock and Mr. Cavanaugh, can you please explain how
459 your two agencies have been coordinating on implementation
460 efforts and discussing policies that could impact each of your
461 agencies' decisions?

462 Dr. Woodcock.

463 Dr. Woodcock. Yes. We work very closely together on those
464 matters where our jurisdictions may interact with one another or
465 where they impact. We certainly have had long conversations
466 about the need for safety tracking of these products and I think
467 CMS was very helpful to us in enabling this identifier so that
468 claims data will have some sort of identification so that we can
469 track these products that are paid by Medicare.

470 We have worked together on numerous activities where needed,
471 but generally, we are on a scientific track and they are taking
472 care of beneficiaries.

473 Mr. Cavanaugh. Yes, I would add to that that as the FDA has
474 worked through its processes for the naming convention for
475 biosimilars, they have repeatedly kept us in the loop to make sure
476 we understood what was going on, solicited comments. We actually
477 don't take a position on the naming convention, but they have been
478 generous in their consultation.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 26

479 This really -- and biosimilars, our collaboration really
480 builds on a legacy of work. We collaborate in the regulation of
481 lab safety. We recently implemented a process of parallel review
482 when the FDA is approving products and we can do a coverage
483 decision for Medicare at the same time. So I am sure there are
484 improvements, but there is a history here of working together and
485 a commitment to continuing that.

486 Mr. Pitts. Has FDA ever sat down with CMS to walk through
487 the many fundamental differences between biosimilars and generic
488 drugs?

489 Dr. Woodcock. Yes. Yes, members. Medical staff at CMS
490 are very well aware of all these and have been privy to many of
491 our discussions about them.

492 Mr. Pitts. Dr. Woodcock, FDA has spent several years now
493 grappling with policy decisions on how a biosimilar should be
494 named and labeled in relation to its reference product,
495 particularly if it is approved for different indications and if
496 there are other biosimilars for the same disease or condition.
497 Are you concerned that these nuanced decisions could be undermined
498 by CMS' decision to lump them all together for coverage and
499 reimbursement purposes like they were generic drugs?

500 Dr. Woodcock. Being able to track for purposes of safety
501 and attributability is different than the payment. So the issue
502 of tracking has been resolved by what CMS has done with the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 27

503 modifiers. And I am not competent to talk about how reimbursement
504 is arranged.

505 Mr. Pitts. Mr. Cavanaugh, in its draft naming guidance, FDA
506 seems to make the case that distinguishing biosimilars from their
507 reference product and other biosimilars is critical to patient
508 safety. If this is the case, why did CMS not share this view and
509 take the opportunity to have different billing codes?

510 Mr. Cavanaugh. As Dr. Woodcock said, they have been very
511 generous in their time helping us make sure we understand
512 completely the clinical and therapeutic distinctions between
513 generics and biosimilars. What CMS has put policy out though is
514 on payment and coding and physicians don't typically look through
515 billing codes in order to understand which product they are
516 ordering. It is a very different process.

517 So as Dr. Woodcock suggested, and I would agree with, there
518 is really no disagreement here and no conflict in that payment
519 policy which has to be informed by the clinical, but it doesn't
520 have to be entirely reflective of the clinical distinctions.

521 Mr. Pitts. Well, combining all products under one code
522 inherently removes some incentive for biosimilar companies to
523 develop data on specific indications or seek interchangeability.
524 Did CMS consider these impacts on innovation?

525 Mr. Cavanaugh. We did. The purpose of our policy was to
526 spur innovation and we believe it will do that. You know, the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 28

527 fact that there are multiple products under the same billing code
528 in the generic market has not, I think, depleted innovation or
529 competition. In fact, the history of the generic market is robust
530 competition and a lot of products being developed, not immediately
531 as Dr. Woodcock said, but we think it is a sound policy and we
532 think it will spur innovation, not hinder it.

533 Mr. Pitts. Thank you. The chair now recognizes the
534 gentleman, Mr. Pallone, for 5 minutes for questions.

535 Mr. Pallone. Thank you, Mr. Chairman. I wanted to ask Dr.
536 Woodcock some questions. FDA has been criticized for not being
537 transparent in the development and implementation of the BPCIA.
538 FDA has also been criticized for not releasing guidances more
539 quickly and not doing enough to educate patients and healthcare
540 professionals. Obviously, these critiques are significant,
541 given that the BPCIA was enacted in 2010. I guess we had an
542 estimate from the Congressional Budget Office of the \$7 billion
543 savings in the first 10 years, okay? So a lot is at stake. And
544 of course, I talked earlier about the whole issue of drug pricing,
545 being sort of a national priority right now.

546 So how much money did Congress appropriate for the program
547 that has the potential to provide so much savings? And will the
548 funding FDA has received from Congress and industry be sufficient
549 to keep up with the growing interest in the development of
550 biosimilars?

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

551 Dr. Woodcock. Congress did not appropriate any additional
552 funding for us to do the biosimilar program.

553 Mr. Pallone. I didn't hear you, Dr. Woodcock.

554 Dr. Woodcock. Congress did not appropriate any additional
555 funding for the biosimilar program. When the user fee program
556 -- they put in place the ability 2 years later for us to enact
557 a user fee program. When that user fee program was put in place,
558 it was stipulated that we take \$20 million out of our existing
559 BA budget and put it into the base. But that was not additional
560 funds. That was the funds we had to take from other activities
561 such as OTC monographs, compliance activities, and so forth.

562 And of course, when we put the user fee program into place,
563 there really wasn't an existing market unlike the prescription
564 drug user fee.

565 Mr. Pallone. Right.

566 Dr. Woodcock. Or the PDUFA or GDUFA, and so we couldn't bill
567 an industry that didn't exist. So we put in place a staggered
568 fee structure for development meetings that we have been enacting
569 and we have collected monies from that to help build the program.
570 But of course, that has been only in the latter parts of the
571 program.

572 Mr. Pallone. Well, then I guess the larger question which
573 I am trying to get at is to what extent is this funding or lack
574 of funding not working and making it more difficult in terms of

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 30

575 having a backlog of applications, increasing review time lines,
576 and contributing in some way to some of the criticism? And what
577 do you need? What do you suggest we do so that you have enough
578 money?

579 Dr. Woodcock. We have begun to collect more monies under
580 the user fee program. In FY13, we finally had collected \$6
581 million, so that was the extent of the program. In fiscal year
582 '14, we collected \$13 million; and last year, FY15, \$23, million,
583 \$23.8 million. So we are beginning to build. And as drugs get
584 on the market, biosimilar drugs, we will be able to have a
585 different, perhaps more robust funding for this program. But
586 this program was not funded by appropriations.

587 Mr. Pallone. Okay, but I guess what I wanted to ask and I
588 don't have a lot of time, specifically, to what extent, because
589 you don't have this money, is that contributing to the backlog,
590 you know, the not releasing guidance, not having enough education,
591 development implementation of the program? And what do you
592 suggest we do in order -- we are getting all these criticisms,
593 and it sounds to me, although you haven't said so, that part of
594 it is a lack of funding?

595 Dr. Woodcock. Well, you know, what has been as water under
596 the bridge, going forward, we do expect to release drafts or many
597 finals of this guidance in this current year, this coming year.
598 So hopefully, some of these criticisms will be addressed, although

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 31

599 these are controversial issues.

600 Clearly, had we had more staffing and funding at the get go
601 and we could have set up a program in 2010, that we would have
602 been better off now. However, what I am concerned about is that
603 this program is going to explode, that we are going to have --
604 we are seeing multiple entries potentially for many of the
605 existing biosimilars. Those top 6 or 11 or whatever. Naturally,
606 there are people who would like to have a part of that market or
607 compete into that market. And I am concerned that we will not
608 have the staff because we are always waiting to catch up.

609 Mr. Pallone. All right, well, this sounds -- I have got 3
610 seconds left. Sounds to me like you need some kind of
611 appropriation and having the industry pay a fee is not good enough.
612 But I guess you are not going to tell me you need the appropriation.

613 Dr. Woodcock. I can't comment on that.

614 Mr. Pallone. I know you can't. But that is what it sounds
615 like. Thanks.

616 Mr. Pitts. All right. The gentleman's time has expired.
617 The chair now recognizes the chair emeritus of the full committee,
618 Mr. Barton, 5 minutes for questioning.

619 Mr. Barton. Thank you, Mr. Chairman, And I wish that
620 Congresswoman Eshoo was a member of the subcommittee because while
621 I know a little bit about this, Anna is really the expert on this
622 issue. She and I are the authors of the bill that got put into

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 32

623 the Affordable Care Act on biosimilars.

624 It looks to me like we have two issues here. We have an FDA
625 issue, you are right, seeing Ms. Woodcock. We have an FDA issue
626 about how to approve them and then we have a CMS issue on how to
627 charge for them. If you don't get the approval process right,
628 it doesn't matter what you charge for them because there is nothing
629 to be used. But if we can get the approval process right, it
630 doesn't matter unless we get the charging reimbursement process
631 right because if you set a reimbursement process that there is
632 no incentive to create the drug in the first place, the biosimilar,
633 nobody is going to do it.

634 And on the approval, I would give the FDA a C+, maybe a B-.
635 I think your heart is in the right place. I know you, ma'am, based
636 on my interchanges with you in the past, plus what you said in
637 your opening statement, you want to get it right and you want to
638 get it done.

639 With regard to CMS, I would give you a D-. The only reason
640 I won't give you an F is because at least you are trying. You
641 have got something out there. I guess to go back to the FDA, we
642 need some labeling guidance.

643 The first biosimilar, Ms. Woodcock, that the FDA has
644 approved, the labeling is just not as complete as it should be,
645 as transparent as it should be. Could you comment on that? Does
646 your agency plan to address the labeling issue and try to get it

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

647 better?

648 Dr. Woodcock. Yes. We do plan to issue draft guidance. We
649 have many opinions on how the label should be. We have received
650 much input from stakeholders and that is one of the guidances that
651 we would like to get out this year as a draft.

652 Mr. Barton. So to clarify, you do plan on changing that
653 specific label?

654 Dr. Woodcock. We will issue a draft and then we need to issue
655 a final and get a policy together. And then the labels will
656 conform, all labels would conform to that. If you recall, the
657 statute that was enacted was considered to be self-implementing,
658 as I understand, without guidance.

659 Mr. Barton. But you still have to do it.

660 Dr. Woodcock. Well, we are approving, as they become
661 available, we will approve biosimilars regardless whether we have
662 final guidance out or not. That does create more ambiguity and
663 so perhaps the language in the statute that considered, it was
664 a self-implementing program, was a little optimistic in the sense
665 that --

666 Mr. Barton. That is true. I will accept that.

667 Dr. Woodcock. There were a lot of policy issues that we
668 needed much more detailed discussion and settling on to move
669 forward with the robust program and I think that always happens
670 with these type of complex programs. But we do plan to get

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 34

671 labeling. I have been personally involved in many discussions
672 about this. We understand the issues and the positions of the
673 various parties and we will put something out that people can
674 comment on.

675 Mr. Barton. Okay, now I need to ask Mr. Cavanaugh a
676 question, but before I get off of FDA, can you comment on the
677 interchangeability that basically nothing has happened with
678 regard to interchangeability and what the FDA's plans are? I am
679 talking to the FDA representative.

680 Dr. Woodcock. Yes. We also plan to put out guidance on
681 interchangeability draft guidance. We have discussed
682 interchangeability in our scientific considerations and our Q&A
683 guidances already that are out there. So there is quite a bit
684 of discussion because companies may need to do the scientific work
685 during their development program. But we plan to put out a
686 specific guidance on interchangeability and we hope to get that
687 out this year as well as a draft.

688 Mr. Barton. And finally, Mr. Cavanaugh, I apologize for
689 lack of time here, but I understand where CMS is coming from. You
690 want to have a fair pricing scheme, reimbursement scheme, but
691 biosimilars are different than generics. You understand that and
692 your agency understands that?

693 Mr. Cavanaugh. We do.

694 Mr. Barton. If you don't allow for some differentiation

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 35

695 since it is more expensive to create, you are not going to create
696 an incentive to do the drug and to do the biosimilar in the first
697 place. Does your agency have any plans to go back and revisit
698 their initial decision on how these are priced?

699 Mr. Cavanaugh. Thank you for the question. In the
700 regulation we published last year, we did indicate that we would
701 monitor the market closely and that we would do rulemaking in the
702 future. We thought that our payment policy was not as well --
703 was not accomplishing what we were expecting it to. So there is
704 that possibility.

705 I want to return to your point though. From a clinical
706 perspective, you are right and CMS knows biosimilars are not the
707 same as generics. However, from a regulatory and market
708 perspective, there are some similarities. These similarities
709 were pointed out in the Senate Committee Report that they are
710 approved in similar processes and that they refer to an existing
711 product's evidence. So there is multiple -- they are going to
712 compete a reference product and against each other. So from a
713 market and a regulatory perspective, there are similarities.
714 From a clinical therapeutic perspective, there are similarities
715 and differences. And we recognize all of that and we think that
716 translates into the payment policy.

717 We created similarities to how generics are priced, but there
718 are differences as well. We don't have the original reference

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 36

719 product in the same code with the same ASP. So there are
720 differences, but we did think the analogy to generics from a
721 payment perspective was reasonable.

722 Mr. Barton. My time has expired. I thank the chair for the
723 courtesy.

724 Mr. Pitts. The chair thanks the gentleman and now
725 recognizes the gentleman from Oregon, Mr. Schrader, for 5 minutes
726 for questions.

727 Mr. Schrader. Thank you, Mr. Chairman, I appreciate that.
728 I appreciate the witnesses being here.

729 I am concerned about the market developing. You have
730 testified, both of you, to that effect and it seems to be a nascent
731 market that has yet to be mature and don't want to stifle the
732 competition, don't want -- and you are struggling with payment
733 policy, trying to figure out what is the best way to encourage
734 good competition, hopefully to build the market and ultimately
735 at the end of the day, drive down prices safely for people. It
736 is nice that the ACA allows this opportunity and we are able to
737 get this type of legislation and apparently it has been on a dais,
738 if you will, for a long, long time. So that is good.

739 Dr. Woodcock, you are not in the payment policy business
740 particularly, but could you talk a little bit about interaction
741 between you and CMS in terms of how to interpret the previous
742 generic policies and since this is not a generic situation, how

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 37

743 you came about working with Mr. Cavanaugh, your contemporary on
744 the other side, to develop the best payment policy for the
745 biosimilars?

746 Dr. Woodcock. CMS consulted us more on what the biosimilars
747 were medically and clinically rather than how they should be paid
748 for because that is not our expertise. And we interact with their
749 medical staff who have a very clear understanding, I think, of
750 the parameters of how we are analyzing the biosimilarity, what
751 the standards are for biosimilarity and what the standard is going
752 to be for interchangeability and the clinical performance that
753 is expected from both of those. And the fact that in some cases
754 we may not include all the indications in a biosimilar's label
755 that are in the innovator label for various reasons. So they are
756 aware of all of the scientific and clinical parameters in the
757 course of making their decisions.

758 Mr. Schrader. I guess for Mr. Cavanaugh, you talked a little
759 bit about these modifiers. Could you elaborate? I am concerned
760 by lumping all the biosimilars together that if there is adverse
761 reactions and stuff that can happen to any product, for goodness
762 sakes, how are you going to tease that out? Could you elaborate
763 a little bit?

764 Mr. Cavanaugh. Certainly, and thank you for the question.
765 This is an issue that we were sensitized to through our
766 conversations with the FDA which is when they are trying to monitor

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 38

767 adverse reactions, they often look in large databases of claims
768 to try to figure out which patients receive which product and then
769 look in future claims or in other databases to see whether they
770 had adverse reactions. And they made us sensitive to if the only
771 indicator of multiple biosimilars was a common number, they would
772 not be able to distinguish between the product which is important
773 here.

774 So what we did was working with them say well, we will keep
775 the same billing code, but we will have a modifier that is specific
776 to each manufacturer so that when you do query our databases and
777 you see a patient that had an adverse consequence, you will know
778 which manufacturer's product they got. And so that is how we
779 expect it to work and we have confidence that it will work.

780 Mr. Schrader. Biosimilars are paid for by the Government
781 in several different programs, such as Medicaid Part D and Part
782 B, apparently. Why do we have different methodologies in each
783 of those? I understand some are intrinsic to the programs
784 themselves, but there is enough variation. Biosimilars are
785 treated, frankly, very differently in the other two programs than
786 they are here. And they are kept individual. One biosimilar is
787 not treated the same as another biosimilar. Why have you chosen
788 to do it differently in Part B?

789 Mr. Cavanaugh. Thank you for that question. The answer is,
790 as you were suggesting, there are different programs, but more

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 39

791 importantly than being different programs, there is different
792 statutes behind each of the programs. I have responsibility for
793 both Medicare Part B, but also Part D.

794 The statute that created the payment methodology for
795 biosimilars in Part B is Section 1847A, large A. That is very
796 specific to Part B and has nothing to do with Part D and rebates
797 and payment prices there. So I think it all derives from very
798 different statutes. In an ideal world, you would have
799 harmonization across these, but occasionally we find that there
800 are not consistencies across programs and that is not always a
801 bad thing. I think here it created an opportunity for good
802 policy.

803 Mr. Schrader. I think the policy is being put ahead of the
804 marketplace right now, maybe down the line as you alluded to, but
805 that might be appropriate. But I am very worried that with all
806 the differences that we currently have, it is confusing and makes
807 it difficult for drug manufacturers to step up and try and create
808 these wonderful drugs for our citizens. With that, I will yield
809 back, Mr. Chairman.

810 Mr. Pitts. The chair thanks the gentleman. I now recognize
811 the gentleman from Kentucky, Mr. Guthrie, for 5 minutes for
812 questions.

813 Mr. Guthrie. Thank you, Mr. Chairman. Thank you both for
814 coming. I guess my questions are similar to what Mr. Pitts has

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 40

815 said and what Mr. Barton asked Mr. Cavanaugh. And it is the
816 payment policy. We are using a similar policy for generic small
817 molecule drugs are you said for biosimilars. And you said, I
818 think to Mr. Barton, there are similar market characteristics you
819 are looking at and you recognize there are different clinical
820 characteristics that the FDA is concerned with. And that gets
821 to all biosimilars are not tied -- not all biosimilars are tied
822 to the same product or the same reference product.

823 And so my question is this. It is the concern about the
824 payment policy and the clinical differences that you recognize
825 exist? And we have heard from physicians. We have heard from
826 patient groups, biosimilar manufacturers, a lot of different --
827 at least one insurer, that this policy could lead to a couple of
828 unintended consequences. One would be inappropriate switching
829 between biosimilars, switching to a lower cost that is not the
830 same, and as well as a less vibrant biosimilar market altogether.

831 I believe some of these were stakeholder concerns that were
832 raised during the process and wonder why you moved forward and
833 did you consider these warnings?

834 Mr. Cavanaugh. Thank you for these questions. We did
835 consider these because we received these in the public comment
836 process and we thought very deeply about each of those issues.

837 First of all, the concern about a less vibrant market. I
838 mentioned some statistics earlier, but in Part B the top six drugs

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 41

839 that we spend money are all biologics. We spend over \$1 billion
840 on each of them. I think that alone creates the opportunity for
841 a very vibrant market in biosimilars and I think that is why you
842 are seeing the level of interest that the FDA is seeing in
843 approving products.

844 As far as inappropriate switching, first and foremost,
845 physicians do not order biologics or other drug products by
846 billing code. And Dr. Woodcock is a physician and can extrapolate
847 on that. And similarly, pharmacists do not derive what switching
848 they are allowed to do based on billing codes. There are other
849 conventions in place. So we fought long and hard about that
850 concern. We talked to our pharmacists. We talked to our
851 physicians. We talked to the FDA and thought that we had heard
852 that publicly that that was not a concern.

853 Mr. Guthrie. So FDA is not concerned that that could come
854 to pass, those -- the two things I just mentioned could happen?

855 Dr. Woodcock. Well, again, what we are seeing would be that
856 a biosimilar would be either written by a physician, by the name,
857 right, or it would be switched. If it were interchangeable, it
858 would be switched at the pharmacy level based on our Purple Book
859 where we said it was interchangeable. So those are the processes
860 we see and with the e-prescribing and so forth, there are menus
861 that come up and those have to do with the name of the product.

862 Now I don't know, I have been out of practice too long to

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 42

863 know how this reimbursement loop which has really gotten very
864 complex recently, how that would impinge. But that is how the
865 ordering would be done.

866 Mr. Guthrie. Well, thanks. I have another question. So
867 Mr. Cavanaugh, I noticed that you treat biosimilar as a
868 multi-sourced product for the purpose of payment. However, they
869 are treated as a single source for the purpose of the Medicaid
870 rebate. Can you explain the contradiction or apparent
871 contradiction, I guess?

872 Mr. Cavanaugh. Certainly. It all derives from these being
873 different programs and different statutes that authorize payment.
874 I am on the Medicare side of CMS so I am not as conversant in the
875 Medicaid statute, but as I mentioned earlier, the statute that
876 created the authority for payment for biosimilars is very specific
877 to Part B drugs. And so it by definition would not apply to
878 Medicaid or Part D and so I think any difference is derived from
879 the statutory differences.

880 Mr. Guthrie. It is kind of a contradiction to have
881 multi-source one way and single the other. Something needs to
882 be corrected or fixed. Maybe it needs to be fixed statutorily?

883 Mr. Cavanaugh. They are not consistent, but again, the
884 statutory authorities are different.

885 Mr. Guthrie. Okay. Well, Mr. Chairman, I yield back the
886 balance of my time.

887 Mr. Pitts. I thank the gentleman. I now recognize the
888 gentlelady from Illinois, Ms. Schakowsky, for 5 minutes for
889 questions.

890 Ms. Schakowsky. It is really exciting that in recent years
891 that we have seen such breakthroughs in drugs entering the market
892 that creates such hope for treatment or cure for illnesses of
893 millions of Americans. But the cost of these drugs, I want to
894 focus on that because I think it is simply unaffordable for far
895 too many people.

896 In 2013, the average cost of specialty drugs was over
897 \$53,000, an increase of 193 percent from 2005. And this average
898 drug cost is greater than the median U.S. household income, more
899 than double the median income for Medicaid beneficiaries and
900 nearly time and a half -- as much as the average Social Security
901 retirement benefit. And a recent Kaiser poll found that 73
902 percent of Americans believe the cost of prescription drugs is
903 just simply unreasonable.

904 And so it is clear that we need additional federal
905 authorities to combat this growing problem and that is why I
906 introduced the Medicare Fair Drug Pricing Act which would require
907 HHS to negotiate the price of biologics and sole-sourced drugs
908 covered by Medicare Part D, one possible solution.

909 The high drug costs are a problem for both Medicare Part D
910 and Part B. Mr. Cavanaugh, you well know, in 2010 biologics

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 44

911 accounted for \$8.3 billion or nearly 43 percent of all Part B drug
912 spending and that number is likely to rise. High-cost biologics
913 are continued to enter the market. I am happy that the biologics
914 are entering the market. Medicare beneficiaries are also
915 struggling to afford the copays that are associated with these
916 drug prices.

917 In addition to enhancing HHS's ability to control drug costs,
918 we need to ensure that we have a robust marketplace for
919 biosimilars. Several studies estimate the projected savings
920 from the approval of biosimilars for current high-cost biologics
921 to be anywhere from \$44 billion to \$250 billion over 10 years.
922 We have an opportunity here to expand access to life-saving drugs
923 and lower costs for patients.

924 Dr. Woodcock, as a rheumatologist, you were talking about
925 the exciting new drugs, but you were also talking about the cost.
926 Are you aware of people who have been actually turned down, in
927 other words, walking away from the pharmacy? I have talked to
928 some pharmacists about people who do walk away.

929 Dr. Woodcock. Yes, I am aware of it. And I am aware of what
930 my colleagues currently go through now to try to get their patients
931 drugs that are indicated for the condition by FDA.

932 Ms. Schakowsky. It is a huge concern. Mr. Cavanaugh, how
933 have biologics, I know you talked a bit about that, contributed
934 to the increase in Part B spending on drugs, Medicare Part B?

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 45

935 Mr. Cavanaugh. So Part B, like the rest of the drug world,
936 has been going up faster than the rest of the healthcare economy.
937 It has put a strain on the Medicare program. The biologics in
938 Part B are the vast majority of the spending. I mentioned that
939 the top six drugs in total spending each individually is over \$1
940 billion and they are all biologics.

941 And so the Agency shares your concern and I think you have
942 expressed the right balance which is as Dr. Woodcock said,
943 therapeutically some of these are terrific products and they
944 change lives and improve lives and we don't want to lose that at
945 all. But we want to balance it with making sure everybody has
946 access and that comes through affordability.

947 Ms. Schakowsky. I just want to say in some ways I feel like
948 the feelings of an individual that is almost worse and more painful
949 to know that there actually is a treatment or a cure out there
950 that they can't afford and thinking there isn't one. It is right
951 there, I can see it, I can feel it, I know it would help me, but
952 I simply can't afford to get that. And I think that we have to
953 address that problem.

954 What are the solutions so that Part B, Part D is not going
955 to go bankrupt, that insurance companies will be able to afford
956 to provide the help that people are going to get. What are we
957 going to do? Either one, both.

958 Mr. Cavanaugh. Again, I just want to reiterate that we share

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 46

959 your concerns. As you may know, last year, Secretary Burwell and
960 Administrator Slavitt convened a listening session. So we have
961 been hearing from patients, from pharmaceutical manufacturers,
962 from pharmacies and others about ideas they have. And we are
963 hopeful that some of those ideas can come to fruition. I don't
964 know that the silver bullet has been discovered yet, but I think
965 there is a conversation going on that could produce something that
966 we could all support and achieve that balance that we are looking
967 for between affordability, but still have access to these
968 live-changing drugs.

969 Ms. Schakowsky. Well, I know that members want to be part
970 of that conversation, so I appreciate that. I know you recognize
971 the problem and I yield back.

972 Mr. Pitts. The chair thanks the gentlelady and now
973 recognizes the gentleman from Kentucky, Mr. Whitfield, for 5
974 minutes for questions.

975 Mr. Whitfield. Thank you, Mr. Chairman, and I thank both
976 of you for being with us today. We all recognize the important
977 responsibility that you have, both of you.

978 I am going to touch on something a little bit different.
979 Certainly, it is my understanding that biosimilars are many times
980 more complicated to consistently produce than generic drugs, but
981 a couple of days ago I was reading an article and there have been
982 many articles about drug shortages. And the American Society of

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 47

983 Health System Pharmacists currently lists inadequate supplies of
984 more than 150 drugs and therapeutics for reasons ranging from
985 manufacturing problems to federal safety crackdowns, to drug
986 makers abandoning low profit products. As a result of that,
987 doctors and hospitals are doing rationing and sometimes they make
988 decisions about who gets a drug based on weight, sometimes on the
989 age of the patient. And in this same article, it talks about that
990 in a survey of cancer doctors, 83 percent of them said over the
991 last 6 months that they had had to -- they were unable to provide
992 the preferred chemotherapy agent at least once during the last
993 6 months and that a third of them said they had to delay treatment
994 and make the difficult choice of which patient they are going to
995 give it to, so rationing these shortages,

996 So both of you are well respected in your field. Would you
997 just make a brief comment about this shortage problem and whether
998 or not you all are working with manufacturers because biosimilars
999 is even more complicated than generics?

1000 Dr. Woodcock. Clearly, this situation is unacceptable,
1001 that people with cancer or others would not be able to access
1002 life-saving treatment. We have had a very robust shortage
1003 program for many years where we try to anticipate and respond.
1004 I think the fundamental problem is the number of drugs that have
1005 a single source or perhaps maybe only one competitor.

1006 If you look at this chart, this shows all the drugs, and I

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1007 can put this in the record, Mr. Chairman.

1008 Mr. Pitts. Without objection.

1009 Dr. Woodcock. And you can see that for the 99 drugs that
1010 we have, there is only one generic competitor. All right? So
1011 there is only two on the market.

1012 And then we have another chart here that shows for 125
1013 innovator drugs, they have no patent or exclusivity protection,
1014 there is no generics. And this isn't a result of FDA's backlog
1015 or anything. Nobody sent in any applications.

1016 So there is a problem in the market that other entrants don't
1017 come in and sometimes we get generic entrants and they don't market
1018 the drug. And so then if the single manufacturer has a problem
1019 or they decide to raise the price greatly, there is no competition
1020 there.

1021 Now our generic user fee program is accelerating the approval
1022 of generics overall to a 10-month clock for review. So that will
1023 help somewhat with new entrants, but in the meantime it may be
1024 that no one is interested in entering that market even though it
1025 is a critical shortage of a life-saving drug. And I can't tell
1026 you why that is. I don't understand those factors, but that is
1027 the reality that we are facing.

1028 Mr. Cavanaugh. I would concur with everything that Dr.
1029 Woodcock said and just add that if folks believe that there are
1030 CMS policies that are contributing to shortages, I would like to

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1031 know and I would like to think about what we could do to be part
1032 of the solution. The reason many of us came to work at CMS is
1033 to help our beneficiaries. And if they are being denied because
1034 of market failure, because of policies, we would like to be part
1035 of that solution. So I appreciate you raising the issue. It is
1036 of concern to me.

1037 Mr. Whitfield. Thank you. I yield back my time.

1038 Mr. Pitts. The chair thanks the gentleman. I now recognize
1039 the gentleman, Mr. Butterfield, for 5 minutes for questions.

1040 Mr. Butterfield. Thank you so much, Mr. Chairman. Mr.
1041 Chairman, let me first talk about my district and then build out
1042 from there. The health disparities that face African-American
1043 communities in my district in eastern North Carolina and across
1044 the country are absolutely alarming. The FDA knows that. Anyone
1045 who watches this, knows it for sure. We could just talk endlessly
1046 about the chilling statistics that show black Americans are more
1047 susceptible to serious illnesses than another demographic.
1048 Serious diseases such as HIV, diabetes, and cancer more frequently
1049 occur in African-American communities. Rare diseases like
1050 sickle cell anemia occur more often in African Americans. The
1051 sooner that affordable, safe, and reliable treatments are
1052 discovered, the better we are all going to be.

1053 Like most, I see the potential that biosimilars can have in
1054 combatting health disparities. The Affordable Care Act is

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 50

1055 helping to make that possibility a reality. And so the Biologics
1056 Price Competition and Innovation Act which is part of the ACA has
1057 helped set up a framework to enable the development of new
1058 biosimilar drugs. Since 2010, the FDA has worked diligently to
1059 implement the program. Biosimilars are complex and we have heard
1060 that testimony today. And I agree with Dr. Woodcock that their
1061 regulation must be bullet proof. It is critical, therefore, that
1062 the public can depend on approved biosimilars and that we
1063 encourage the development of new treatments. And so it is my hope
1064 that the creation of new biosimilars can make safe treatments more
1065 affordable for those in need. I thank both of the witnesses
1066 for their testimony today.

1067 Dr. Woodcock, it is my understanding that current FDA
1068 guidance allows biosimilar applicants to extrapolate efficacy
1069 information based on the reference product. I don't fully
1070 understand that, but I am sure that you do. If you would expand
1071 on that, please.

1072 Dr. Woodcock. Well, basically, the biosimilar pathway
1073 itself is an extrapolation, all right? What is done is it is an
1074 abbreviated pathway. So if you can show your product is
1075 biosimilar through various means that we have established to the
1076 reference product, then you may be able to, depending on what you
1077 have shown, have a label that looks exactly like the innovator
1078 label. Or you may only have some of the indications, depending

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1079 on what you have shown.

1080 So there are two kinds of extrapolations people are talking
1081 about. One is the basic abbreviated pathway which means we find
1082 the evidence that is submitted by the biosimilar and we say yes,
1083 this means that you have the same properties as an innovator drug.
1084 And then many of the brand drugs have multiple indications. For
1085 example, next week it would be ulcerative colitis, Crohn's Disease
1086 and rheumatoid arthritis, all right? Those are different
1087 diseases. And so what many people are talking about is
1088 extrapolation across from one disease to another.

1089 What amount of data that we need to grant all those
1090 indications is a scientific matter and may be of some dispute,
1091 obviously, because there is a lot at stake there. But I will tell
1092 you, we are not going to approve biosimilar drugs that we don't
1093 think have the same performance as the innovator. That is what
1094 we are going to do. If a patient is started on a biosimilar, they
1095 should expect the same results as if they had started on a brand
1096 drug.

1097 Mr. Butterfield. Now there are a lot of stakeholders and
1098 a lot of people have an interest in this subject. I am beginning
1099 to appreciate that and I see the room full today and I am sure
1100 there are a lot of people here who are listening very carefully.

1101 Are there concerns that stakeholder groups have? And are
1102 there any concerns that have been shared about extrapolating

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 52

1103 clinical safety and efficacy data for biosimilars which treat
1104 special populations including children or certain fields
1105 including rheumatology?

1106 Dr. Woodcock. Certainly. People have concerns still about
1107 generics and there are certain groups such as the neurology
1108 community still isn't convinced they should do generic
1109 substitution. Recently, we have sponsored studies to show that
1110 there is no outcome difference between a generic and an innovator
1111 drug for seizures. So there is going to be concern and there is
1112 going to be ongoing concern regardless of what we do. But right
1113 now we do extrapolate often for regular drugs, whatever biologics
1114 for the brand drug. We may extrapolate to children based on
1115 dosing information if the disease is similar enough, rather than
1116 subjecting children to randomized clinical trials. If we have
1117 enough scientific data, we will extrapolate after finding out what
1118 the right dose with the equivalent doses are in children of
1119 different ages.

1120 Mr. Butterfield. Thank you. I yield back, Mr. Chairman.

1121 Mr. Pitts. The chair thanks the gentleman. I now recognize
1122 the gentleman from Illinois, Mr. Shimkus, for 5 minutes for
1123 questioning.

1124 Mr. Shimkus. Thank you, Mr. Chairman. I know we are
1125 getting close to calling of votes, but I want to first of all
1126 address Mr. Cavanaugh.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1127 I appreciate your answers, but I don't think they are totally
1128 accurate because I think under the law and especially the report
1129 language of the bill passed, the report language and the
1130 congressional intent was that there would be separate billing
1131 codes for reimbursement at the ASP of biosimilars. So I mean your
1132 comment saying I can't do this because of statutory intent we feel
1133 is inaccurate. So I am going to move most of my comments to there
1134 and I hope you would take that back because we think you do have
1135 the authority to do that.

1136 And the other thing just as a comment, listening to
1137 testimony, biosimilars, the efficacy and the ability, the cost
1138 benefit, the return on investment, Dr. Woodcock, as you mentioned
1139 earlier as a rheumatologist and wellness versus treatment, there
1140 is a great return on that investment that somehow has to be put
1141 into this pricing decision, right?

1142 But I want to get to a couple of questions in this whole process.

1143 Let me start, Dr. Woodcock. I understand the FDA has not
1144 provided details on specifics of interchangeable products. Is
1145 it possible that FDA might approve an interchangeable product
1146 without first issuing guidance or interchangeability?

1147 Dr. Woodcock. Yes, it is. In an interchange with Mr.
1148 Barton, the statute allows us to execute the statute without
1149 guidance is my understanding.

1150 Mr. Shimkus. Under current law, a new biologic product can

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 54

1151 be brought to market either by being approved as a new drug or
1152 being licensed a biological product. How, if at all, does a
1153 manufacturer's decision to use one pathway or another affect
1154 pre-market review of a product?

1155 Dr. Woodcock. The body of evidence that is submitted for
1156 a biological license application, a standalone, right, is
1157 different than the body of evidence that is submitted for a
1158 biosimilar.

1159 Mr. Shimkus. So how?

1160 Dr. Woodcock. Okay, a biological --

1161 Mr. Shimkus. So what is the answer?

1162 Dr. Woodcock. I am sorry. A biological product, stand
1163 alone, must demonstrate free-standing safety and efficacy of that
1164 product. A biosimilar must demonstrate biosimilarity to a
1165 reference listed, already approved biological product. Those
1166 are conceptually, fundamentally, two different things.

1167 Mr. Shimkus. So really the question is if they choose one
1168 pathway or the other -- I mean right now, how are they making the
1169 decision which pathway to choose or how can they?

1170 Dr. Woodcock. We have around --

1171 Mr. Shimkus. Let me just go to the next question because
1172 they are all kind of in line. What about the post-market
1173 obligations if they choose one pathway or another?

1174 Dr. Woodcock. It is unlikely a biosimilar product would not

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 55

1175 have additional questions that would be post-market commitments,
1176 but they have the same safety surveillance requirements as other
1177 marketed products.

1178 Mr. Shimkus. Let me just go to another one then and I will
1179 tell you why I am asking these specific questions. Does the FDA
1180 consider the Purple Book to be part of a biological product's
1181 labeling?

1182 Dr. Woodcock. Does it consider what?

1183 Mr. Shimkus. Do you consider the Purple Book to be a part
1184 of the biological products labeling?

1185 Dr. Woodcock. No.

1186 Mr. Shimkus. Okay, so these are all questions asked by U.S.
1187 Senators in your testimony in November which they still have as
1188 they have asked me to restate these questions. Do you know why?
1189 Because you all haven't responded to their questions in writing.

1190 Dr. Woodcock. Well, okay. Well, we will certainly do that.

1191 Mr. Shimkus. And the point being is there is great confusion
1192 out there in the healthcare sector on how we are going to move
1193 forward. And this hearing is going to have follow-up questions
1194 and they just need to be answered. And so again, all these are
1195 follow-up, and there was a lot more. I have got four or five pages
1196 of them from bipartisan questions that need to be addressed so
1197 we can help -- that is actually the same questions that you are
1198 being asked by the stakeholders. And so I would ask you to respond

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 56

1199 timely to the questions posed by my colleagues. And I yield back
1200 my time, Mr. Chairman.

1201 Mr. Pitts. The chair thanks the gentleman. I now recognize
1202 the gentleman, Mr. Cardenas, for 5 minutes for questions.

1203 Mr. Cardenas. Thank you very much, Mr. Chairman. Thank
1204 you, Dr. Woodcock, and Deputy Administrator Cavanaugh for joining
1205 us today.

1206 Dr. Woodcock, under BPCIA, interchangeable biologic
1207 products must demonstrate that they can be expected to produce
1208 the same clinical result as the reference product in any given
1209 patient. A biosimilar determined to be interchangeable can be
1210 substituted. So therefore my question is will you discuss
1211 generally the types of questions the Agency is thinking through
1212 as they are considering guidance to industry in this space?

1213 Dr. Woodcock. Certainly. This issue was before us even
1214 before the statute was passed which is one of the differences of
1215 biologics for most generics is something called immunogenicity.
1216 In other words, the ability to stimulate an immune response in
1217 a patient, a reaction. And this can be insignificant or it can
1218 cause serious problems. And one of the concerns is under a
1219 scenario of interchangeability, what we see in the generics world
1220 people get all different kind of products, generics, they switch
1221 at the pharmacy based on their plan. And the concern is if you
1222 are switching back and forth could you set up an immune response

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1223 that would be negative to the person? And how you have to address
1224 that concern for interchangeability is contingent on a number of
1225 factors. A number of these drugs are not -- biologic drugs --
1226 are not that immunogenic. And some of them they are, but the
1227 consequences have not been severe. Others, the consequences
1228 could be catastrophic. So we take all those factors in in talking
1229 to companies about how much evidence they have to show that
1230 switching back, people back and forth, wouldn't cause terrible
1231 harm.

1232 And the problem we have is the science isn't far enough
1233 advanced for us to predict this from say test tube experiments.
1234 We have to look in people because we don't understand the immune
1235 system well enough. So there has to be some human testing of
1236 switching ordinarily to give confidence that, in fact, if you
1237 switch the people back and forth, they are not going to have some
1238 unprecedented problem.

1239 Mr. Cardenas. Thank you. This question is to Deputy
1240 Administrator Cavanaugh. I would like to reiterate the concerns
1241 voiced by my colleagues on both sides of the aisle and the final
1242 rule for the position fee schedule which places biosimilars that
1243 reference the same biologic into single HCPCS code. Biosimilars
1244 are not generic drugs because they are not the same copies of one
1245 another and I appreciate how hard you and your colleagues at CMS
1246 are working to create a robust biosimilars market.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1247 However, because biosimilars are so complex, I fear that this
1248 may discourage manufacturers from entering the biosimilars
1249 market. How do you feel about those dynamics?

1250 Mr. Cavanaugh. So thank you for the question. I think it
1251 is important to recognize a couple of things. As I said, the
1252 important therapeutic differences which the FDA has educated us
1253 about and we recognize them, but there are also regulatory and
1254 marketplace similarities. And in fact, the congressional
1255 history here shows that the approval processes were mirrored or
1256 paralleled off of generic approval processes. We expect them to
1257 work in the marketplace much like generics in that there will be
1258 a low-cost alternative to a higher cost innovative product. And
1259 for that reason and also for statutory reasons, the statute said
1260 that for products where there is multiple products under the same
1261 billing code, they should have the ASP average.

1262 I want to emphasize why we think this is a successful policy.
1263 One, to Congress' credit from the physician perspective when they
1264 are ordering the drug, Congress created a payment where they are
1265 still getting the six percent markup from the innovative product.
1266 So the physician is not invested in a higher cost product. They
1267 are made whole either way and I think that was a terrific policy
1268 that Congress made.

1269 But secondly, they are going to choose the therapeutically
1270 successful product at a fair price and we will have these

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 59

1271 biosimilar products competing on price with each other. So the
1272 last thing I would say is even though they are using a methodology
1273 similar to generics, that doesn't mean the resulting price will
1274 be similar to generics. The biosimilar companies set their own
1275 average sales price. So they can set it at a market-bearing price
1276 that results their costs whether it is research or other input
1277 costs. So I don't think the fact that they are the same
1278 methodology means you will end up with the same price.

1279 Mr. Cardenas. Thank you. With my 5 seconds I just want to
1280 remind the American public that what we are talking about here
1281 cannot be put in one page, so I want to thank my colleagues and
1282 also the process for understanding that laws aren't necessarily
1283 one or two paragraphs. These are very important issues and
1284 protection of the public is very important to our country.

1285 Thank you so much, Mr. Chairman.

1286 Mr. Pitts. The chair thanks the gentleman. We are voting
1287 on the floor, so we will continue as long as we can. The chair
1288 recognizes Mr. Collins for 5 minutes for questions.

1289 Mr. Collins. I want to thank the chairman and I know we are
1290 now trying to hold the votes down so thank you for letting us cut
1291 into this just a bit. I thank both the witnesses, Dr. Woodcock,
1292 Mr. Cavanaugh, for coming.

1293 I think what I have heard is some 30,000 foot Cliff Notes
1294 discussions on biosimilars, generics, biologics, etcetera.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 60

1295 And Dr. Woodcock, as you are sitting there, I know you must
1296 have some level of frustration because we are under time
1297 constraints to get the point out. And so in my time, I think we
1298 have pretty much established that generic is for all practical
1299 purposes, 99.999 percent the same as the brand name. It is a
1300 compound. It is usually a pill. It is the same and therefore
1301 doctors prescribe that.

1302 But Dr. Woodcock, in what testimony you have given, in
1303 thinking about the differences in a biologics and a small molecule
1304 which are two different worlds and a biosimilar which will never,
1305 ever, ever be the same, and while you have explained and I think
1306 it is true, the FDA's emphasis is safety and efficacy and I guess
1307 you would say safety, safety, safety, safety, safety. And we have
1308 got to know it works as well. But safety is always first.

1309 In 2 or 3 minutes, for the purpose of this committee
1310 educationally, what would you like to add as far as how the FDA
1311 is looking at and even maybe explain to the committee the basic
1312 difference in why a biosimilar will never be a generic and even
1313 the manufacturing process of a biologic, the sterility process
1314 or give us 2 or 3 minutes of education which I think would be
1315 helpful to this committee having heard already some of the
1316 questions.

1317 Dr. Woodcock. Well, the biologics are very large molecules.
1318 In other words, it would be like maybe a little house compared

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 61

1319 to the Empire State Building as far as the comparative size of
1320 a regular drug to a biologic. And if you just think about the
1321 brand biologics, most of them they are not exactly the same from
1322 batch to batch. I know that is very disappointing, but they are
1323 made by cells, usually.

1324 Mr. Collins. The manufacturing process is unique.

1325 Dr. Woodcock. Yes, they are biosynthesized by cells and
1326 those cells are subject to conditions we don't understand very
1327 well fully or can't fully control. And so they are slightly
1328 different from batch to batch to batch. Our job in regulating
1329 them is to make sure that those variabilities in the brand product,
1330 I am still talking about, don't affect safety, safety, safety or
1331 effectiveness, okay? So that they stay in a band where from the
1332 clinic, if you are a doctor treating patients, it doesn't make
1333 any different. But it isn't like the small molecule where every
1334 tablet we know exactly what is in there.

1335 Mr. Collins. And to interrupt, isn't it also true that in
1336 the intellectual property protection, etcetera, a manufacturer
1337 is not required to tell the world exactly how they are making it?

1338 Dr. Woodcock. Never, and that is true with the generics as
1339 well.

1340 Mr. Collins. And that is what I think some people miss. You
1341 have to put enough information in your intellectual property to
1342 say I can replicate it, but you don't -- a manufacturer is going

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 62

1343 to protect his price point.

1344 Dr. Woodcock. Well, it is considered trade secret.

1345 Mr. Collins. Right, and it will always be trade secret. So
1346 when a generic or a biosimilar comes out, they don't know the 16
1347 steps that the brand name is doing to make that product.

1348 Dr. Woodcock. Right.

1349 Mr. Collins. And hence, in the case of a biosimilar, it can
1350 never be the same.

1351 Dr. Woodcock. What they do and what we found, okay, is for
1352 the generics does this too. They have to buy the reference
1353 product on the market and reverse engineer it and then develop
1354 a process of their own that will replicate that avoiding any
1355 patents that might be preexisting that may be on process and so
1356 forth.

1357 Mr. Collins. And it is just like reverse engineering
1358 anything. You don't know and don't have the prints of the
1359 original company to know the tolerances of every item and how they
1360 interact.

1361 Dr. Woodcock. That is correct.

1362 Mr. Collins. So I think in defense of the FDA and what they
1363 are doing in the safety, safety, safety, but also looking at
1364 efficacy, the folks making a biosimilar don't have the prints.
1365 They don't have the process.

1366 Dr. Woodcock. That is correct.

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 63

1367 Mr. Collins. They are trying to reverse engineer it and
1368 yet the FDA has to make sure in reverse engineering it safety is
1369 not compromised, efficacy is there. And that is why it is -- you
1370 have got a very, very, very difficult job in bringing biosimilars
1371 to market knowing that the person making it doesn't have the
1372 benefit of the drawings, the process. They are guessing. They
1373 are reverse engineering. They are hoping they get it right and
1374 you have to make sure at the end of the day it is safe and the
1375 efficacy is there.

1376 Dr. Woodcock. And also what we found to your point, it is
1377 a very good point, what we found as we work with these companies
1378 they are going to have to get more lots of the reference drug
1379 because generics usually --

1380 Mr. Collins. The variation.

1381 Dr. Woodcock. Because they have to be within the variation.
1382 If you just pick a small sample, it might be outliers.

1383 Mr. Collins. My time is up. I thank you for that. I think
1384 the education piece is very valuable.

1385 Mr. Pitts. Thank you. I am sorry to rush you. We have 8
1386 minutes left. So we are going to have to try to hurry as much
1387 as possible. Dr. Bucshon, you are recognized for 5 minutes.

1388 Mr. Bucshon. Yes, Mr. Chairman, I will be brief and just
1389 make a comment and maybe a brief question. I am glad that you
1390 are both here. Thank you very much for your work. That

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 64

1391 said, Mr. Cavanaugh, this is kind of directed at CMS. It appears
1392 to me, as a physician and I was a practicing cardiovascular
1393 surgeon, that CMS has become the rate-limiting step in getting
1394 innovative products to the marketplace and to patients. A brief
1395 example, a treatment for glioblastoma for brain tumors, for
1396 example; a bionic prosthetic to benefit veterans and others. And
1397 it also seems to me that frequently on reimbursement decisions
1398 that comments and recommendations of experts outside of CMS have
1399 been ignored. And unfortunately in my view, decisions are being
1400 based on financial reasons, not based on medical benefit of the
1401 products.

1402 I am talking about products that have been approved by the
1403 FDA and other organizations around the world and subsequently are
1404 also reimbursed frequently by the private sector insurers and then
1405 are not reimbursed by CMS or it has been dragged out so long that
1406 some of the innovative companies have almost gone bankrupt because
1407 CMS hasn't approved their payment.

1408 So the question I have is is it the role of CMS or the FDA
1409 to determine the safety and efficacy of medical products including
1410 biosimilars?

1411 Mr. Cavanaugh. To me, sir?

1412 Mr. Bucshon. Yes.

1413 Mr. Cavanaugh. No. It is the role of the FDA to determine
1414 that.

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 65

1415 Mr. Bucshon. Okay, so once these are proven to be safe and
1416 show efficacy for patients, why is frequently CMS dragging its
1417 feet on reimbursing it? What is the reason?

1418 Mr. Cavanaugh. Is the question specific to biosimilars or
1419 broadly?

1420 Mr. Bucshon. Broadly.

1421 Mr. Cavanaugh. First of all, as I said, on the first
1422 biosimilar, we acted very quickly and in fact, we had a billing
1423 code and coverage guidance before it was actually even marketed.
1424 You have raised other examples though that are broader than
1425 biosimilars.

1426 Mr. Bucshon. I was just throwing those out there. Let me
1427 just tell you as a physician, many, many people talk to me about
1428 medical issues, right, because I was a practicing physician. And
1429 it is not just -- I mean I have literally heard from hundreds of
1430 people frustrated with CMS because there have been -- and these
1431 are coming from patients, from physicians, from companies,
1432 everywhere, telling me that these products are approved by the
1433 FDA. They are frequently reimbursed by the private sector and
1434 that CMS has either decided to not reimburse them or dragged their
1435 feet or put up a price that is not competitive for the production
1436 and maintenance of a company or the product to be actually on the
1437 market place at all. And it is very frustrating for me as a
1438 physician to know that there are products out there to benefit

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1439 patients.

1440 And I know you have a tough job. I am just on my soap box
1441 a little bit here. But I just don't get it because if things are
1442 approved by the FDA, they are frequently approved by the same
1443 organizations in the European Union and around the world, and
1444 these patients are not available to people in the United States
1445 because not that they are not proven to be effective and safe,
1446 but Medicare hasn't decided how they are going to pay for it.

1447 And so if you are not making decision on safety and efficacy,
1448 how can you decide not to pay for it?

1449 Mr. Cavanaugh. Sure. I think it is a terrific question and
1450 allows me to talk about the Medicare process. FDA approves safety
1451 and efficacy. When it comes to the Medicare, there are two
1452 standards they need to meet, any product or service. One is, it
1453 has to meet one of the statutorily-defined benefit categories.
1454 So the statute has to say this is something -- this falls into
1455 a category that applies to Medicare coverage.

1456 Mr. Bucshon. I am going to briefly interrupt you. That has
1457 already been determined by the FDA. There has been clinical
1458 studies that they have gotten that have shown efficacy, that have
1459 shown benefit to patients. So that seems like reinventing the
1460 wheel to me.

1461 Mr. Cavanaugh. With all due respect, the benefit category
1462 is not about safety and efficacy. The Medicare statute specifies

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 67

1463 the covered services and benefits. And what I am saying is no
1464 matter how safe and effective FDA finds it, it can only come into
1465 Medicare if it meets the statutory definition of something that
1466 Medicare covers. And after it makes it past that criteria, the
1467 secondary criteria is it reasonable and necessary for --

1468 Mr. Bucshon. Understood. Since I only have 10 seconds, I
1469 just want to say that, in my view, every product that is approved
1470 by the FDA should be available to America's seniors and the
1471 limiting factor should not be the ability of CMS to stonewall and
1472 not pay for it. And I am just telling you it is a very frustrating
1473 situation. I yield back.

1474 Mr. Pitts. The chair thanks the gentleman. There are 3
1475 minutes left on the floor clock. The chair recognizes Ms. Ellmers
1476 for questioning.

1477 Ms. Ellmers. Thank you, Mr. Chairman, and I will be very
1478 brief. I want to thank the panel. Thank you, Dr. Woodcock, for
1479 being here again, and Mr. Cavanaugh.

1480 I actually just have two letters that I would like to submit
1481 and ask unanimous consent to do so.

1482 Mr. Pitts. Without objection, so ordered.

1483 Ms. Ellmers. One is actually from our Doctors Caucus.
1484 Twelve members of the Doctors Caucus submitted a letter on
1485 December 21st to the acting Secretary, excuse me, Commissioner
1486 Ostroff. And we have not yet received a response to those

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 68

1487 questions.

1488 And so Dr. Woodcock, we will be submitting questions for you
1489 and I know that this is an interim, but we would look forward to
1490 some of the answers. You both have answered many of the questions
1491 that we have already had.

1492 Now the other letter that we have that I would like to submit
1493 under unanimous consent is from the Coalition of State
1494 Rheumatology Organizations. This is a letter that I would like
1495 to submit.

1496 Mr. Pitts. Without objection, so ordered.

1497 Ms. Ellmers. Thank you very much. And again, thank you to
1498 our panel. This is a very, very important issue to all of us and
1499 I know that we all agree that we need to get to the bottom of this
1500 so that we can help those folks out there that need the help.
1501 Thank you.

1502 Mr. Pitts. The chair thanks the gentlelady. That
1503 concludes the questions that we have here. We have follow-up
1504 questions. We will submit those to you in writing. We ask that
1505 you please respond promptly. Members have 10 business days to
1506 submit questions for the record, so members should submit their
1507 questions by the close of business on Thursday, February 18th.

1508 A very important hearing, thank you very much for your
1509 testimony today. Without objection, the subcommittee is
1510 adjourned.

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available. 69

1511

[Whereupon, at 12:02 p.m., the subcommittee was adjourned.]