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6 EXAMINING IMPLEMENTATION OF

7 THE COMPOUNDING QUALITY ACT

8 TUESDAY, JANUARY 30, 2018

9 House of Representatives

10 Subcommittee on Health

11 Committee on Energy and Commerce

12 Washington, D.C.

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16 The subcommittee met, pursuant to call, at 11:00 a.m., in
17 Room 2123 Rayburn House Office Building, Hon. Michael Burgess
18 [chairman of the subcommittee] presiding.

19 Members present: Representatives Burgess, Guthrie, Barton,
20 Upton, Shimkus, Latta, McMorris Rodgers, Lance, Griffith,
21 Bilirakis, Long, Bucshon, Mullin, Hudson, Collins, Carter, Green,
22 Schakowsky, Matsui, Sarbanes, Schrader, Eshoo, DeGette, and
23 Pallone (ex officio).

24 Staff present: Adam Buckalew, Professional Staff Member,

25 Health; Karen Christian, General Counsel; Kelly Collins, Staff
26 Assistant; Zachary Dareshori, Staff Assistant; Paul Eddatel,
27 Chief Counsel, Health; Margaret Tucker Fogarty, Staff Assistant;
28 Adam Fromm, Director of Outreach and Coalitions; Ali Fulling,
29 Legislative Clerk, Oversight & Investigations, Digital Commerce
30 and Consumer Protection; Jay Gulshen, Legislative Clerk, Health;
31 Ed Kim, Policy Coordinator, Health; Bijan Koohmaraie, Counsel,
32 Digital Commerce and Consumer Protection; Katie McKeogh, Press
33 Assistant; Mark Ratner, Policy Coordinator; Jennifer Sherman,
34 Press Secretary; Danielle Steele, Counsel, Health; Tiffany
35 Guarascio, Minority Deputy Staff Director and Chief Health
36 Advisor; Samantha Satchell, Minority Policy Analyst; Kimberlee
37 Trzeciak, Minority Senior Health Policy Advisor; and C.J. Young,
38 Minority Press Secretary.

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39 Mr. Burgess. [presiding] I would like to call the
40 subcommittee to order.

41 And I recognize myself for an opening statement.

42 Today's hearing marks the Health Subcommittee's first look
43 at the Compounding Quality Act, which passed under Title I of the
44 Drug Quality and Security Act nearly 5 years ago. Prior to then,
45 the last time Congress examined the drug compounding issue was
46 in 1997, when it passed the Food and Drug Administration
47 Modernization Act, touching upon the Food and Drug
48 Administration's authority to regulate compounded drugs and
49 establishing Section 503A in the Federal Food, Drug, and Cosmetic
50 Act.

51 A tragic outbreak of fungal meningitis in 2012, when the New
52 England Compounding Center shipped over 17,000 contaminated vials
53 of a compounded steroid medication throughout the country,
54 resulted in one of the worst and most fatal drug safety incidents
55 in the history of the United States, where more than 750 people
56 developed fungal infections in 20 states and, subsequently, 60
57 people lost their lives. This outbreak prompted Congress to act,
58 with the Energy and Commerce Committee taking the lead in the
59 House, through a series of investigations and a series of hearings
60 on the issue.

61 Today we will convene two panels of witnesses. And I do want
62 to welcome back Dr. Gottlieb, Commissioner of the Food and Drug

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63 Administration. Thank you for coming back to our subcommittee
64 this morning.

65 The agency has been very active over the last several months
66 on drug compounding, most recently, releasing the 2018
67 Compounding Policy Priorities Plan. Your insights today, Dr.
68 Gottlieb, are certainly appreciated.

69 Later in our second panel, we will hear directly from
70 representatives of the pharmacies, physicians, patients, and
71 manufacturers who will share their perspective on the
72 implementation of Title I under the DQSA. We will also have a
73 patient of the New England Compounding Center to share her
74 personal story from the 2012 incidents and her experience since
75 that time. All of the testimony from today's hearing are critical
76 in our understanding of the compounding issue as the Food and Drug
77 Administration works to strike the proper balance that would
78 continue to advance patient safety while ensuring patients access
79 to compounded medication.

80 Being a physician who has worked with compounding
81 pharmacists during my time in practice, I know the important role
82 and the value that these individuals serve in the delivery of
83 patient care. Compounded drugs serve a unique need of patients
84 that cannot utilize an FDA-approved product due to, for example,
85 an allergy to one of the product's ingredients or the primary route
86 of the product's administration. Many of us remember the swine

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87 flu epidemic of 5 years when compounding for the anti-flu
88 medications in an elixir form was absolutely critical to protect
89 children who had been recently infected.

90 Because of the process involved in creating a compounded
91 medication, we all acknowledge the fact that proper oversight is
92 necessary, whether by the Food and Drug Administration itself or
93 a state's regulatory body, such as its board of pharmacy.
94 Preventing poor compounding practices that can lead to
95 contamination or erroneous product strength, quality, and purity
96 is the goal we all aspire to, so that another New England
97 Compounding Center does not happen. Thinking back to that fungal
98 meningitis outbreak, I was not only heartbroken by the patients'
99 lives lost or harmed, but I was also troubled by what seemed to
100 be missed opportunities that could have prevented the tragedy.

101 Title I of the DQSA accomplished two things. First, the law
102 further clarified the Food and Drug Administration's authority
103 to regulate traditional pharmacy compounding practices under
104 Section 503A, which had seen several court challenges. Second,
105 it added Section 503B to the Federal Food, Drug, and Cosmetics
106 Act, creating a new category of drug compounders known as
107 outsourcing facilities. These outsourcing facilities engage in
108 larger-scale, national distribution of sterile drugs in bulk
109 quantities and have, thus, heightened statutory requirements,
110 such as complying with good manufacturing processes and being

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111 subject to certain registration, reporting, and inspection
112 requirements.

113 Over the last 4 years, the Food and Drug Administration has
114 issued numerous draft and final guidance documents, proposed and
115 final rules, and a draft memorandum of understanding to implement
116 the Title I provisions. There has been discussion and debate over
117 the manner that the agency has used to implement Title I.

118 In my home state of Texas, there already exists in statute
119 the framework and manner in which a compounding pharmacy should
120 conduct its practice. Other stakeholders have also expressed
121 concern around office-use compounding and the prescription
122 requirement. I hope these and other issues in the drug
123 compounding space will be discussed today.

124 So, I am encouraged by the interest of all the stakeholders
125 involved in this important debate, many of whom are represented
126 today. I am certainly encouraged by the commitment of the Food
127 and Drug Administration with Dr. Gottlieb's commitment to work
128 with Congress in ensuring that patients have access to products
129 that are tailored to their clinical needs while equipping agency
130 officials with the requisite tools to protect public health.

131 Again, I want to welcome our witnesses and thank you for being
132 here.

133 And I will recognize Mr. Green, 5 minutes, for an opening
134 statement.

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135 Mr. Green. Thank you, Mr. Chairman, for having this
136 hearing.

137 In 2012, the interstate distribution of contaminated
138 compounded drug products led to an outbreak of fungal meningitis
139 in 20 states, which tragically resulted in 64 deaths and left 750
140 people with infections that were often severe and cause long-term
141 damage. The New England Compounding Center, the NECC, the entity
142 responsible for the compounding and shipping of the contaminated
143 drugs, had been the subject of prior complaints and had been
144 investigated by both the FDA and the Massachusetts State Board
145 of Pharmacy. However, in part, because of uncertainty over the
146 validity of Section 503A of the Food, Drug, and Cosmetics Act,
147 it was not clear which copy, the FDA or the state, was on the beat,
148 and the NECC continued to operate.

149 Unfortunately, while it was the most fatal incident to date,
150 the NECC outbreak was not a one-off event. It certainly wasn't
151 the first tragedy and hasn't proven to be the last. Just last
152 year, we learned that at least 43 patients were left with
153 diminished vision from a steroid antibiotic injection compounded
154 by a Texas pharmacy. FDA studies have found quality problems with
155 drugs compounded in other pharmacies, including sub- and
156 super-potent drugs and contamination. According to one report,
157 from 1990 to 2005, FDA became aware of almost 240 serious illnesses
158 and deaths associated with improperly compounding products, with

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159 the actual number likely to be greater since pharmacies are not
160 required to report adverse events to the FDA. The Pew Charitable
161 Trust published a report in 2014 that identified more than 25
162 reported compounding errors or potential errors linked to more
163 than a thousand adverse events between 2001 and 2013.

164 Following that NECC outbreak, Congress finally took action
165 with the Compounding Quality Act, CQA, and the Drug Quality and
166 Security Act, DQSA, was signed into law in 2013. In a sideline,
167 I want to thank my colleagues Congressman Griffith and
168 Congresswoman DeGette because we worked together on a bipartisan
169 basis to solve this problem. It sound to protect patients and
170 provide industry with clarity for drawing a distinct line between
171 the authority between state boards of pharmacy and the FDA. CQA
172 made two key changes in reestablishing the FDA role regarding
173 traditional compounding under Section 503A, creating a new
174 category of drug compounders deemed outsourcing facilities under
175 Section 503B.

176 The NECC outbreak and other adverse events underscored the
177 need to establish a strong legal framework to provide for safe
178 compounded medications that meet patients' needs while clarifying
179 and strengthening oversight of such drugs to protect public
180 health. There was an obvious need to address the growing number
181 of enterprises that had cropped up during the time of legal
182 uncertainty between the states and the FDA. Many of these

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183 enterprises had come to act like drug manufacturers operating
184 outside FDA's standard oversight, often failing to meet current
185 good manufacturing practices and skirting oversight by
186 inappropriately operating under the guise of 503A pharmacy.

187 DQSA was not perfect, and like all compromises, not every
188 problem was solved to everyone's satisfaction, and not everyone
189 got exactly what they wanted. During bipartisan, bicameral
190 negotiations, we tried to address as many discrepancies as we
191 could and satisfy the needs of patients, providers, pharmacists,
192 and manufacturers. What is ultimately important is that DQSA
193 fixed the problems that led to the deadly fungal meningitis
194 outbreak and required the FDA to succeed where in the past it had
195 not.

196 Compounded medications fill an important role in our
197 healthcare system, offer patients an option when an approved drug
198 does not fit their needs. Patients' ability to timely access safe
199 compound drugs is vital, and pursuit of this goal is something
200 I believe we all share. I understand questions remain about the
201 office stock, bulk lists, the memorandum of understanding, the
202 interstate distribution, and copies of FDA-approved products, and
203 other issues. More needs to be done to foster a robust 503B
204 sector, support traditional pharmacists, ensure patient access
205 to needed medications, and inform providers on how they can get
206 the drugs they need when they need them, so they can successfully

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207 treat their patients.

208 As the FDA and stakeholders continue to work on the
209 implementation of DQSA, and the agency, patients, providers, and
210 industry continue to learn and adjust, I hope we can work together
211 to refine the rules of the road, so patient access isn't unduly
212 diminished and patient safety is upheld.

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

214 Mr. Burgess. The Chair thanks the gentleman. The
215 gentleman yields back.

216 Pending the arrival of the full committee chairman, Mr.
217 Walden, let me recognize the gentleman from New Jersey, 5 minutes
218 for an opening statement.

219 Mr. Pallone. Thank you, Mr. Chairman.

220 I would like to submit to the record a joint statement from
221 the Association for Accessible Medicine's Biotechnology
222 Innovation Organization, the National Association of County and
223 City Health Officials, Pew Charitable Trusts, Pharmaceutical
224 Research and Manufacturers of America, PharMEDium, and Trust for
225 America's Health. If I could ask unanimous consent to have a copy
226 of it --

227 Mr. Burgess. Without objection, so ordered.

228 Mr. Pallone. Thank you.

229 [The information follows:]

230

231

***** COMMITTEE INSERT 1*****

232 Mr. Pallone. Mr. Chairman, thanks for holding today's
233 hearing on the Compounding Quality Act, which passed with broad
234 support from stakeholders and bipartisan, bicameral support in
235 Congress in 2013. Passage of the Compounding Quality act was
236 about patient safety. Congress came together in response to the
237 horrible tragedy of actions by the New England Compounding Center,
238 or NECC, that led to 64 people losing their lives. And despite
239 a history of complaints and investigations by both the FDA and
240 the Massachusetts State Board of Pharmacy, NECC was allowed to
241 continue compounding products given to patients on a scale and
242 in a manner that should never have been allowed. The new law was
243 meant to clarify drug compounding laws. It was also supposed to
244 make clear the lines and requirements for traditional pharmacies
245 that want to compound and those pharmacies that compound on a
246 larger scale.

247 I think we all agree and support maintaining patient access
248 to compounded drug products. Undoubtedly, there are patients
249 with unique medical needs for which a traditional prescription
250 drug product is not appropriate, whether for pediatric patients,
251 seniors, or those with allergies. However, we must all remember
252 that compounded drug products are not without risk. Compounded
253 drug products are not reviewed by FDA prior to coming to the market
254 for safety and effectiveness. Traditional compounding
255 pharmacies are also not required to report on the compounded drug

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256 products they produce or report adverse events.

257 While this law was intended to prevent another tragedy like
258 the one at NECC, adverse events associated with compounded drug
259 products are still occurring. Since passage of the law, there
260 have been more than 140 recalls associated with compounded drugs.
261 We have also seen reports of serious health events. For example,
262 just last summer, 43 patients suffered vision impairment after
263 receiving compounded eye injections of a drug containing a
264 combination of a steroid and an anti-infective agent. Also, last
265 year three infants received a compounded morphine preparation
266 that was 25 times the strength that was indicated on the label,
267 resulting in at least one hospitalization. These are just two
268 examples of why clearly identified standards and requirements
269 must be maintained if we are going to protect patient health.

270 Recently, FDA released the agency's 2018 Compounding Policy
271 Priorities Plan identifying next steps the agency will be pursuing
272 in regards to implementing the Compounding Quality Act, including
273 revisions to current guidance. As FDA moves forward, I would
274 caution the agency to ensure that any revisions that it makes do
275 not enable an environment that could allow for another NECC to
276 occur. We must maintain appropriate patient safeguards and clear
277 lines between what activities are permissible for traditional
278 pharmacies and what activities are permissible for outsourcing
279 facilities. Patient safety and the protection of public health

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280 must be at the forefront of any guidance revisions that the FDA
281 considers, and the American people deserve confidence that the
282 drug products they receive are safe and held to strong quality
283 standards.

284 So, I want to thank Commissioner Gottlieb and all of our
285 witnesses for being here today. I want to go beyond just today's
286 hearing, Commissioner, and mention that you have been really great
287 at trying to reach out to Members of Congress, much more so than
288 most of the agency leaders. So, thank you for that. And I look
289 forward to a robust discussion about the implementation of the
290 Compounding Act.

291 I yield back, Mr. Chairman.

292 Mr. Burgess. The Chair thanks the gentleman. The
293 gentleman yields back.

294 The Chair now recognizes the gentleman from Michigan, Mr.
295 Upton, 5 minutes for an opening statement.

296 Mr. Upton. Well, thank you, Mr. Chairman, and I would ask
297 unanimous consent to put Chairman Walden's full statement into
298 the record.

299 Mr. Burgess. Without objection, so ordered.

300 [The prepared statement of the chairman follows:]

301

302 ***** COMMITTEE INSERT 2*****

303 Mr. Upton. And also, a letter from our colleague, Mr.
304 Bishop, enter the letter into the record.

305 Mr. Burgess. Without objection, so ordered.

306 [The information follows:]

307

308 ***** COMMITTEE INSERT 3*****

309 Mr. Upton. So, Mr. Chairman, the 2012 outbreak of the fungal
310 meningitis resulting from contaminated steroid injections
311 manufactured by the New England Compounding Center, NECC, was
312 certainly a failure of epic proportions. Of the 753 people that
313 were sickened by the outbreak, 264 called Michigan their home.
314 Yes, we were the largest state hit. Nineteen of the 64 deaths
315 caused by the tragedy were from Michigan, and three of them were
316 constituents of mine.

317 I was chairman of the full Energy and Commerce Committee at
318 the time that this happened, and we immediately launched a
319 bipartisan investigation to find out what went wrong. I am not
320 going to go through the full history of what happened then, but
321 I will say that those at the NECC who were responsible were, in
322 fact, brought to justice. And this committee crafted legislation
323 to empower the FDA to ensure that the heinous acts of negligence
324 like this one would never happen again. We wanted to fix the
325 problem.

326 That legislation, the Drug Quality and Security Act, DQSA,
327 is currently being implemented by the FDA, and it takes a number
328 of measures to ensure safety, not the least of which are
329 much-needed restrictions on the use of bulk compounded material
330 as opposed to FDA-approved products when there is not a clinical
331 need to do so.

332 I am pleased to see the new Commissioner here to update us

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333 on how DQSA implementation is going and what we in Congress can
334 do to help move the process along. We appreciate cooperation,
335 and again, the cooperation of Members on both sides of the aisle.

336 And I will yield back the balance of my time.

337 Mr. Burgess. The Chair thanks the gentleman. The
338 gentleman yields back.

339 And we do want to thank all of our witnesses for taking time
340 to be here today and taking time to testify before the
341 subcommittee. Each witness will have the opportunity to give an
342 opening statement, followed by questions from members. We will
343 have two panels today.

344 The first panel, we will hear from Dr. Scott Gottlieb, the
345 Commissioner of the United States Food and Drug Administration.

346 Dr. Gottlieb, once again, we appreciate your being here
347 today, and you are recognized for 5 minutes for your opening
348 statement, please.

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349 STATEMENT OF SCOTT GOTTLIEB, COMMISSIONER, UNITED STATES FOOD AND
350 DRUG ADMINISTRATION

351

352 Dr. Gottlieb. Thank you, Chairman Burgess, Ranking Member
353 Green, members of the subcommittee. I appreciate the invitation
354 to testify at today's hearing on implementation of Title I of the
355 Drug Quality and Security Act.

356 We are all here together today because, more than 5 years
357 ago, we grappled with the devastating consequences of the 2012
358 outbreak of fungal meningitis caused by the manufacturer that was
359 compounding under the guise of a state-licensed pharmacy that
360 shipped contaminated compounded drugs throughout the country.
361 It led to more than 750 illnesses and 60 deaths in 20 states.

362 Because of this tragedy, Congress acted to ensure that
363 something like this would never happen again. No one wants to
364 see another such outbreak occur, and I am personally committed
365 to ensuring that FDA does its part to help prevent future deaths
366 from poor quality compounded drugs.

367 The 2012 outbreak as well as other issues we have seen through
368 our compounding oversight underscore the need to improve
369 compounding practices and more robust oversight of compounders,
370 supported by close federal and state collaboration. It also
371 highlighted the need for a clear legal framework that would
372 provide for compounding to meet patients' needs while also

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373 equipping the FDA with authorities to address unlawful practices
374 that threaten the public health.

375 Unfortunately, since enactment of DQSA, there have been
376 other tragedies and cases of serious and unnecessary patient harm
377 which reinforce why our work is so critical. The FDA's
378 compounding program is a priority for the FDA, given its profound
379 public health implications, and we are committed to implementing
380 the DQSA framework.

381 We have issued 24 draft guidances and final guidances, a
382 final rule, and three proposed rules, and a draft MOU with the
383 states. We have held eight meetings with the Pharmacy
384 Compounding Advisory Committee to discuss 48 bulk drug substances
385 nominated for use in compounding, as well as six categories of
386 drug products nominated for the list of drugs that present
387 demonstrable difficulties for compounding.

388 On the oversight and enforcement front, since enactment of
389 the DQSA, the FDA has conducted nearly 500 inspections and we have
390 issued more than 180 warning letters advising compounders of
391 significant violations of federal law. We have overseen more
392 than 150 recalls involving compounded drugs, and we have worked
393 with DOJ on multiple civil and criminal enforcement actions and
394 set up a joint task force with them.

395 But I know there is still a lot left to be done, and I know
396 that there are some who say we haven't implemented certain aspects

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397 of DQSA with the speed you had hoped. We have had our own
398 challenges addressing certain aspects of this complex framework,
399 including our constant challenge to make sure we are striking the
400 right balance between safety and access, and addressing the
401 oftentimes very divergent views on these issues. I want you to
402 know I am personally committed and involved in these efforts and
403 committed to getting these things right, to making sure that we
404 strike a careful balance and take measure of your concerns.

405 In implementing the DQSA over the years, FDA has aimed to
406 develop policies that support the growth of the outsourcing
407 facility sector. Compounding pharmacies and outsourcing
408 facilities can help meet the legitimate patient needs when an
409 FDA-approved drug is not available to meet such medical needs.
410 We know that we must balance the critical role that compounding
411 plays in helping patients and providers advance public health
412 while ensuring that compounders do so in a manner that protects
413 patients from poor quality compounded drugs and does not undermine
414 the drug approval process.

415 And so, our actions to date, as well as the comprehensive
416 2018 Compounding Policy Priorities that we unveiled a few weeks
417 ago, focus squarely on protecting patients from harm and
418 establishing regulatory clarity, so our outsourcing facilities
419 can meet important protections in Section 503B and our quality
420 standards.

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421 One of my key goals is to make it more feasible and lower
422 cost for a large swath of pharmacies to transition to becoming
423 outsourcing facilities, which are subject to greater FDA
424 oversight. We are also working to help ensure patient access to
425 compounded drugs when they need them. For instance, we are taking
426 steps to help providers identify outsourcing facilities that
427 make, or would be willing to make, compounded drugs for office
428 stock to treat patients who have medical need for them.

429 Let me be clear on one thing. I am committed to getting the
430 things we have committed to done. All of the commitments made
431 under the plan I released two weeks ago will be completed in 2018.

432 I would like to just close by briefly mentioning another
433 critical public health matter. Today we took new action to
434 address the epidemic of opioid addiction. We took steps to limit
435 the dispensing of Loperamide, an OTC drug, that is increasingly
436 being abused for its opioid-like qualities when it is taken at
437 very high doses and dangerous doses. I hope you will take the
438 time to look at the statement we issued, as we continue to work
439 together to address this critical public health crisis. There
440 is no magic bullet to solving this crisis. It is only going to
441 be through continued and vigilant steps, like the one we took
442 today, that I can hope we can start to reverse some devastating
443 trends.

444 I look forward to answering your questions today and

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445 continuing to share more with you during the year ahead, as we
446 build on our past efforts as part of our public health mission.

447 [The prepared statement of Dr. Gottlieb follows:]

448

449 ***** INSERT 4*****

450 Mr. Burgess. The Chair thanks the gentleman for his
451 testimony, and we will move into the question portion of the
452 hearing. I will begin with questioning and recognize myself for
453 5 minutes.

454 Commissioner, in the information you provided us, you had
455 a list of adverse events associated with drugs prepared by
456 compounding facilities in the past 5 years. Presumably, that is
457 the lifetime of the DQSA. The one at the top of the list has been
458 mentioned by a couple of people on the dais this morning, in Texas,
459 some steroid antibiotic eye injections that caused problems with
460 vision loss. Is there something more that could have been done
461 in DQSA to prevent this or was the problem found more rapidly
462 because of the tools that you were given in the DQSA? Help us
463 sort of understand. Here is something that happened in my
464 backyard. Is it something that we should have worked harder to
465 prevent or was, in fact, the outbreak less than it would have been
466 because you had tools to use?

467 Dr. Gottlieb. Well, thank you for the question,
468 Congressman.

469 I think, as we start to exercise these new authorities, we
470 are learning a lot. The scope of the kind of enforcement
471 activities we take have also changed. In the early days of
472 implementation and historically, a lot of the focus has been on
473 issues of sterility with things like eye drops or things that are

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474 used intravenously or intramuscular injections.

475 I think what we are seeing more and more, and where we are
476 starting to focus more of our inspectional activities, is on
477 formulations that are compounded in ways where they might be
478 super-potent. The challenge is that, when the pharmacies make
479 potency errors, it is usually a logarithmic, log error, so thereby
480 a factor of 10 or 20. So, you can get potencies that can cause
481 significant harm.

482 I think this underscores the need to make sure that, when
483 drugs are being compounded on a wide basis and distributed on a
484 wide basis, it is done in facilities where we can apply GMP
485 standards to them. And this is, in part, why I think Congress
486 contemplated the whole creation of the 503B structure, where drugs
487 that would be used on a wider scale would be compounded under that
488 kind of supervision.

489 Mr. Burgess. Let me ask you a question. Obviously, it was
490 before your tenure when we had the hearings after the New England
491 Compounding Center problems. But it was clear to some of us
492 during the course of those investigations and the work that the
493 committee did -- and Chairman Upton was correct to reference it;
494 this committee, the full committee took the leadership on this
495 issue. But there were places where the FDA clearly fell short
496 of its responsibility to protect public health, despite what
497 appeared retrospectively to be clear warnings that the New England

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498 Compounding Center was engaged in dangerous activities. So, are
499 you confident that the FDA now has the clear authority it needs
500 to ensure that we don't see a repeat of those things that happened
501 in 2012?

502 Dr. Gottlieb. I testified at those hearings as a private
503 citizen in 2013 here in Washington. I was working at a think tank
504 at the time and weighed in at the time. I think I felt what
505 Congress contemplated was a framework that gave the FDA the proper
506 tools to provide oversight over this industry. But I think we
507 need to keep in mind that we are now implementing a framework on
508 an industry that is vast, that grew up, that was allowed to grow
509 up largely outside regulatory purview for a long period of time,
510 and retrofitting a regulatory framework back onto an already
511 existing industry is always a difficult task.

512 Do I believe the authorities and the tools that we are able
513 to exercise are robust? I do. I think that it is going to take
514 time to get them fully implemented and get the kinds of tools and
515 practices we want applied over that industry. And it is
516 superimposed on an environment where, admittedly -- and people
517 have good arguments on both sides of this debate -- there has been
518 some discussion around how FDA is using those authorities and
519 whether they are using them in an appropriate fashion. I believe
520 we are and I believe we need to continue to move forward.

521 Mr. Burgess. Yes, I expect we may hear about that this

522 morning in our second panel. I guess that is the concern. Or
523 what I would like to ask is the efforts that you and the agency
524 have taken to engage the physician community, patient community,
525 other stakeholders, where they may have perhaps the feeling that
526 things have tightened up too much.

527 Dr. Gottlieb. Well, this isn't going to work unless we are
528 working closely with the providers and the state authorities.
529 This law, Congress contemplated a framework that very much was
530 envisioned where FDA would have close collaboration with medical
531 societies and state authorities, and there was a lot of shared
532 jurisdiction between the federal and the state framework around
533 both the 503A and the 503B facilities. States dually inspect a
534 lot of the 503B facilities.

535 So, I think it is going to be very important for us to continue
536 to work closely with the state communities and the provider
537 groups. I believe we have. I think that there is more alignment
538 there than perhaps is widely perceived, as obviously some 503A
539 pharmacies that want to engage in certain practices where there
540 is a line that we need to draw to make sure that we are providing
541 the proper oversight, and I think we are going to hear about that
542 tension today. I think that is a large place where we still have
543 some area of disagreement.

544 Mr. Burgess. Very well. I want to be respectful of
545 everyone's time because we do have a long hearing today. I am

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546 going to recognize Mr. Green for 5 minutes for questions.

547 Mr. Green. Thank you, Mr. Chairman.

548 Thank you, Dr. Gottlieb, for being here this morning, but
549 also the good work you are doing at the FDA.

550 I appreciate the continued emphasis the FDA has put on the
551 issue of compounding drugs and hope to keep working with the agency
552 on implementation in our shared goal of striking the right
553 balance, so we can promote patient access without compromising
554 patient safety. I am encouraged to see the FDA is actively
555 working to implement the patient safety measures that are included
556 in the DQSA.

557 In particular, I am pleased to see that FDA is taking steps
558 to encourage registration of 503B outsourcing facilities. In
559 your 2018 Compounding Policy Priorities Plan you suggested the
560 FDA will be taking a more risk-based approach to the development
561 and implementation of current good manufacturing practices, or
562 CGMPs. I understand FDA is working on revising the 2014 draft
563 guidance to apply CGMP requirements in a way that is tailored to
564 the nature of the specific operations conducted by an outsourcing
565 facility and move away from one-size-fits-all. I appreciate the
566 agency's goal of improving patient safety by making the regulatory
567 framework more flexible by recognizing volume as a factor in its
568 risk-based evaluation.

569 Can you elaborate more about the agency's thinking around

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570 what has been referred to as "503B-light"?

571 Dr. Gottlieb. Thanks for the question, Congressman.

572 What I am envisioning is a framework where -- the GMP
573 standards are not a fixed standard. It is a risk-based standard.
574 We want to try to devise that framework in a way where we could
575 titrate the level of the regulatory touch to what the facility
576 is doing, the size of the facility, how many drugs they are
577 developing, how they are shipping them, whether the drugs are oral
578 drugs or they are parenteral drugs that are going to be injected,
579 which would be sterile drugs and have higher risk.

580 The idea is that, by trying to adjust the level of the
581 regulatory oversight to the level of risk, we could potentially
582 allow more 503A facilities to make the conversion into being 503B
583 facilities. That is why we are taking the time to revise that
584 guidance.

585 There are things where we have some flexibility, like
586 retention of samples, lot release, the stability studies that we
587 require, where if it is a pharmacy doing something on a small
588 scale, not shipping widely, compounding drugs that are relatively
589 low-risk, we might be able to dial back some of that level of
590 regulatory oversight versus someone who is engaging in
591 larger-scale manufacturing. But, again, with the goal of seeing
592 more 503A pharmacies become 503B pharmacies where they are able
593 to engage in the kinds of things that some pharmacies want to do.

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594 We want to bring down the cost of doing that. We have done
595 some economic analysis around what it would cost. I think it is
596 still a little bit too expensive to see some of the small 503A
597 pharmacies opting into that. So, we are trying to take another
598 crack at that.

599 Mr. Green. Okay. Thank you.

600 And I do have concerns about the possibility of creating a
601 two-tiered system. In the pursuit of flexibility, I am concerned
602 of the impact this may have on 503B facilities that compound
603 biologics, which are especially vulnerable to degradation.

604 How would you respond to these concerns? Can you tell me
605 how you plan to ensure that CGMPs that apply to 503Bs will hold
606 these facilities to the highest standards of sterility and
607 stability?

608 Maybe I didn't understand that language.

609 [Laughter.]

610 Dr. Gottlieb. I understand your concerns. I share them.
611 The first thing I am going to do is come up with a better name
612 for it than "503B-light," before that takes hold.

613 But I will tell you that we are very mindful of that. So,
614 for example, you reference biological products. They are
615 particularly vulnerable to contamination and to bacterial growth.
616 That would be something that would be higher-risk, where we would
617 apply more oversight.

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618 We are talking about trying to create a standard that is
619 flexible, as is all our GMP oversight. It is a risk-based
620 framework. If a pharmacy is engaging in small-scale
621 manufacturing of relatively low-risk products, they wouldn't be
622 subject to all of the same requirements that someone who is
623 engaging in large-scale manufacturing of higher-risk sterile
624 products would be. As they move through the continuum of risk,
625 our level of oversight would increase. It needs to be a flexible
626 standard. It is a flexible standard in every other realm of our
627 regulation. It ought to be here. But you are absolutely right
628 that there is a continuum of risk, and we need to be very mindful
629 that we are matching our regulatory touch appropriately to that
630 level of risk.

631 Mr. Green. Could you provide, submit your economic analysis
632 for the record, for the committee?

633 Dr. Gottlieb. I can provide it just off the cuff right here.
634 I mean, when we looked at it -- and again, this was very preliminary
635 work and it is in draft form -- but when we looked at it, we
636 estimated that it would cost a large manufacturer about a million
637 dollars to become a 503B facility, a large pharmacy, and a
638 medium-sized pharmacy, about \$600,000. We think that there are
639 things we can do to further titrate the level of regulatory touch,
640 that there are more buckets. Because, again, a 503A pharmacy that
641 wants to engage in relatively low-risk compounding but still ship,

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642 but they are developing low-risk products on a small scale in small
643 batches, there are ways, I think, to adjust the level of regulation
644 to more appropriately match the level of risk that they are
645 creating.

646 Mr. Green. Well, I understand you want to use resources
647 where the problem is.

648 Dr. Gottlieb. Exactly.

649 Mr. Green. And I appreciate that.

650 Dr. Gottlieb. We want to be efficient.

651 Mr. Green. Thank you, Mr. Chairman. I know I am out of my
652 time.

653 Mr. Burgess. The Chair thanks the gentleman. The
654 gentleman yields back.

655 The Chair recognizes the gentleman from Texas, the vice
656 chairman of the committee, full committee, Mr. Barton, 5 minutes.

657 Mr. Barton. Thank you, Mr. Chairman.

658 And, Commissioner, thank you for being here. I want to echo
659 what Mr. Pallone said. You have been accessible, and we
660 appreciate your personal availability to the members of the
661 subcommittee.

662 I have been on this committee for 32 years. We have got an
663 ongoing sense of friction or tension between the FDA and the
664 compounding pharmacist. It is kind of a love-hate relationship.

665 A lot of my compounding pharmacists in Texas are fairly

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666 active in the national compounding associations. They have a
667 feeling that the big, old bad federal FDA picks on them. How would
668 you respond to that? Do you think your FDA picks on compounding
669 pharmacists? Or do you think that they are being a little bit
670 too sensitive?

671 Dr. Gottlieb. Well, I am not going to comment on their
672 feelings and their motives. I am certainly sensitive to the
673 concerns; I would say that, Congressman. This is an important
674 reason why we want to make sure we are working closely with the
675 states. Because I think if we are working cooperatively with the
676 states, and the states are able to assert their responsibilities
677 and obligations under DQSA, but in concert with us, I think that
678 the more that we can rely on local regulation, the more that local
679 pharmacies are going to feel that they have a closer continuity
680 to the nexus of the oversight, if you will.

681 Mr. Barton. Okay. Well, that leads to my next question.
682 It is almost like you and I coordinated. I was going to ask this;
683 you were going to answer that; then, I would follow up.

684 What is the current relationship in terms of a working
685 relationship or a cooperative relationship between the FDA and
686 the state regulatory authorities that oversee compounding
687 pharmacists? Do you think it has improved? When we had the
688 problem back in 2010-2011 that led to the bill that you have talked
689 about, Massachusetts and the federal FDA didn't seem to get along

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690 at all. They didn't talk to each other, didn't share information.
691 Today would you say that that relationship has improved, is good?
692 How would you characterize it?

693 Dr. Gottlieb. Well, I will tell you the relationship is a
694 lot better today and gets better with time. I think it is
695 continuing to expand in terms of the scope of the collaboration
696 and just through the contact we are having with state authorities.
697 Those relationships are important to sound regulation being
698 built. We invite states to join us on inspections. We hold
699 monthly meetings with the National Association of Boards of
700 Pharmacy. We provide training to state compliance officers.
701 There are frequent telecons with state officials.

702 You don't have to take my word for it. You could look at
703 the GAO report in 2016 that looked at this very question of what
704 the perception was of the states of FDA's communication with the
705 states, and 60 percent said very or somewhat satisfied. They were
706 very or somewhat satisfied with the communication. Now a "D"
707 usually doesn't sound good, but in this context I think it was.
708 It was supportive of my contention that the relationships are much
709 improved from where they were when I was at FDA the last time,
710 prior to NECC. Twenty-three percent reported they were
711 dissatisfied. We want to work on that. I think, hopefully, if
712 I come back here a year from now and we are talking about this,
713 we are going to be able to talk about an even more cooperative

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714 environment.

715 Mr. Barton. With respect to the opioid crisis, are there
716 some special task forces, special programs, extra effort being
717 utilized right now between the FDA and the state regulatory
718 authorities? And kind of as a secondary question, would you
719 consider the opioid crisis more of a federal issue or a state
720 issue, or is it about 50/50?

721 Dr. Gottlieb. Well, I think it is an everything issue. I
722 have said before that I think that this is beyond the scope,
723 certainly, of any one agency, but even the federal government,
724 to try to tackle it. We are going to need to work closely with
725 local officials to try to address this crisis. And we have been
726 doing that. We have had a lot of conversations with local
727 officials, state AGs, on different things that we could be doing
728 in collaboration with the states around various aspects of this
729 crisis.

730 I would say that the one thing that I am still very concerned
731 about is the level of federal oversight in the IMFs, in the
732 international mail facilities. I have spoken with some of the
733 Members about this, and trying to get more resources into those
734 facilities, particularly FDA resources. We play an important
735 role in those facilities doing track and trace and analysis on
736 some of the synthetic fentanyl coming in and doing investigations
737 to trace them back to their source. And that is a big concern

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738 of mine.

739 Mr. Barton. The last question, the Pharmacy Compounding
740 Advisory Committee currently has no one on it who is a compounding
741 pharmacist. Don't you think there should be at least one voting
742 member who is an actual compounding pharmacist on that committee?

743 Dr. Gottlieb. I am going to be, we are going to be issuing
744 a solicitation probably within days -- the FR notice is with my
745 office -- to solicit a new member or members on that committee.
746 So, there will be an opportunity to expand the composition of that
747 committee. As you know, there are 12 members on that committee.
748 One is appointed by the NABP, one by USP. It leaves 10 members.
749 Of those, seven are licensed pharmacists. I think five are
750 physicians in total. So, there is good clinical representation.
751 To the extent that someone with a business perspective of being
752 a pharmacist can add to the composition of that committee in a
753 thoughtful way, that is something we would certainly think about.

754 There is one compounding pharmacist on the committee. He
755 is the industry rep.

756 Mr. Barton. But he doesn't get to vote.

757 Dr. Gottlieb. He doesn't get to vote, you are right. We
758 will certainly take this into consideration. I have heard the
759 concerns of Members on this. We will certainly take it into
760 consideration as we think about the new solicitation.

761 Mr. Barton. I would encourage that.

762 And I yield back.

763 Mr. Burgess. The gentleman yields back. The Chair thanks
764 the gentleman.

765 The Chair recognizes the gentlelady from California, Ms.
766 Eshoo, for 5 minutes, please.

767 Ms. Eshoo. Thank you, Mr. Chairman, for holding this
768 hearing.

769 And, Commissioner Gottlieb, it is good to see you, and thank
770 you for your testimony and your work on this issue.

771 We spoke, I think it was last summer, about -- at that point,
772 there was a recent incident of patients being harmed by compounded
773 products. Specifically, there were 50 patients, some of whom
774 went blind after receiving a compounded antibiotic during
775 cataract surgery last July.

776 I was talking to a doctor friend this last week. I said,
777 "What's the most common surgery in the country?" And he said
778 cataracts. So, that really broadens this out when you think of
779 50 patients, some of whom went blind during their cataract
780 surgery. It wasn't too regular for them.

781 Obviously, we need to do everything we can to protect patient
782 safety, so that these incidents stop happening, including, I
783 think, following up on the warning letters.

784 There are two areas that I have always thought that are
785 absolutely fundamental to what we do, both when I was in county

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786 government and here in the House of Representatives. That is
787 public health and public safety. The two are combined in this
788 issue.

789 So, what I want to ask you is, of the dozens of warning letters
790 posted by FDA, how often have you pursued enforcement action? And
791 what else can the agency do with its enforcement resources to
792 ensure that compounded drugs are safe?

793 Dr. Gottlieb. I appreciate the question. It gets at
794 something that we are trying to work, which is to improve our
795 collaboration with DOJ to try to make sure that we can bring
796 enforcement action when we see something particularly egregious,
797 so we issue a warning letter and a firm is non-compliant. That
798 was the genesis of the task force that we formed with DOJ. It
799 is early days; I think it is yielding dividends in terms of our
800 ability to work cooperatively. But this is something that we are
801 looking at, pushing on, trying to do more of.

802 Ms. Eshoo. Have there been any enforcement actions?

803 Dr. Gottlieb. There has absolutely been enforcement
804 actions, and there is activity that we have in progress.
805 Obviously, we are always working on various activities. But I
806 am hopeful that we will be able to continue to work effectively
807 with DOJ in this regard.

808 Ms. Eshoo. In the two sections of the Compounding Quality
809 Act -- you know, let me say something, because I listened to the

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810 conversation earlier about the FDA, what Congress did, what
811 happened, and then, what Congress did. I think it is important
812 for all of us to recall that the FDA had not been given authority
813 by the Congress in this very area when the tragedy that took place
814 out of Massachusetts, that spread out over the country, took
815 place. So, I know there are a lot of questions to be raised, but
816 the FDA did not have the authority. In my book, I think that the
817 Congress didn't maybe on a proactive basis examine the issue and
818 give the agency the authority.

819 At any rate, in the two sections of the Compounding Quality
820 Act, it defines that drugs may only be compounded from bulk drug
821 substances when FDA-approved drugs are in shortage. Now,
822 recently, the agency announced enforcement discretion related to
823 an interim list of substances that include more than a hundred
824 approved drugs.

825 So, what specific steps are you going to take to ensure that
826 there is a legitimate clinical need for the bulk drug substances
827 currently being used by compounders and how are you going to
828 enforce this?

829 Dr. Gottlieb. I think you are referring to the 503B bulk
830 drugs list, right?

831 Ms. Eshoo. Right. Right.

832 Dr. Gottlieb. So, as you know, we received about a thousand
833 nominations for different drugs to be on that list. We have

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834 selected 200 that we allowed onto that list under what we call
835 Category I drugs. Now what we need to do is go through and
836 reexamine all 200 to make sure they belong on that list. And we
837 believe some of them are going to fall off and perhaps many will
838 fall off. Some might be added, but probably many are going to
839 fall off.

840 We are going to issue in March a guidance document that I
841 outlined in the 2018 plan we put out that is going to define the
842 parameters in which we are going to do those assessments. And
843 then, we need to go through and assess each drug individually,
844 which, as you know, is a resource-intensive process. Each
845 evaluation is between 20 and 80 pages long.

846 Probably the first complement of drugs that we will render
847 a decision on will be this fall. It is probably going to be a
848 small number. It may be five drugs. But we need to go through
849 that entire list.

850 But it is important to put in perspective where that 200 came
851 from. Those were drugs that were currently being compounded off
852 of bulk substance at the time that this law was implemented. So,
853 what we effectively did was freeze the market. What we said was
854 we don't want to create more compounding, but we also don't want
855 to start pulling things out of the marketplace and create access
856 issues, especially with respect to the outsources, because we want
857 to see this industry grow up, for one. And on the second hand,

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858 we have now new regulatory tools to assert good manufacturing
859 practices. So, we can provide more oversight. So, the idea was
860 to freeze the market while we, then, did those assessments, which
861 is what we are doing now.

862 Ms. Eshoo. Thank you very much, Commissioner. I couldn't
863 mean that more. You are in such an important role in the life
864 of our country. So, thank you very much.

865 Thank you, Mr. Chairman.

866 Mr. Burgess. The Chair now would like to recognize the
867 gentleman from Kentucky, the vice chairman of the Health
868 Subcommittee, Mr. Guthrie.

869 Mr. Guthrie. Thank you, and thank you, Mr. Chairman.

870 Thank you, Commissioner, for being here today.

871 I kind of want to follow up on what was just said. Five years
872 ago there was a judge in Kentucky, a very prominent citizen, Eddie
873 Lovelace of Albany, Kentucky, who went in for a routine procedure
874 and was contaminated with medicine from the New England
875 Compounding Center and died just shortly after what was going to
876 be a routine procedure. Obviously, his family and the whole
877 community is devastated, and Dr. Lovelace is just one person who
878 was affected by this awful outbreak. And this was tragic and it
879 is the reason I believe we must ensure compounded drugs are safe
880 while striking a good balance of access to compounded drugs.

881 It is kind of the theme of what you have said this morning,

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882 but I thought I would just give you kind of a more open-ended look
883 at it. Because in your testimony you mention the balance that
884 is needed. And so, I just want to give you the floor to, how are
885 you ensuring that Americans have access to lawfully-marketed
886 compounded drugs while ensuring safety? You have kind of
887 addressed that just earlier, but I just kind of give you the time.

888 Dr. Gottlieb. I think the way to ensure that, to be very
889 direct, is to make sure this law gets implemented. I think that
890 this was a good vision by Congress and it is a good framework that
891 provides FDA with the tools that it needs to provide proper
892 oversight. We need to now make sure it gets implemented.

893 I think where we are going to be able to continue to improve
894 sort of the posture of the industry, and the ability of this
895 industry to provide the critical products that patients need and
896 access to drugs, is going to be to try to see the 503B outsourcing
897 sector become more viable. I think many of us, when this law was
898 first implemented, envisioned that that sector would grow much
899 more quickly than it has. And I think if there are things that
900 we can do through regulation, and I think that they are, to help
901 that industry continue to expand, that is going to be important
902 because, ultimately, that is going to provide more access to the
903 kinds of sterile drugs that some people need on a wider scale and
904 need to be distributed to institutions. The 503A facilities
905 provide a critical function on a local level, giving patients

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906 differentiated products through the practice of pharmacy, so that
907 they can get products that are individualized, tailored to their
908 clinical needs.

909 Mr. Guthrie. Do you think 503A should report adverse
910 outcomes to the FDA?

911 Dr. Gottlieb. As you know, the bulk of the adverse events
912 that are reported by 503 facilities are typically either not
913 reported or reported to the states. The states do share that
914 information with us. They are not directly reported to FDA.

915 Would it help FDA target its inspections better if they had
916 access to that information more readily? I would have to say it
917 would. It would make it more efficient. A lot of our inspections
918 of 503A facilities are for-cause inspections, are on the basis
919 of information. But I think that this is also an area where,
920 through our cooperation with the states, we are going to get access
921 to that information where we need it. Because if we are working
922 closely with the states, they are going to help guide us where
923 we should be inspecting. Because, for example, a 503A facility
924 might be engaging in activities that tip it over into being a 503B
925 and subject to the federal scheme.

926 Mr. Guthrie. Thank you. Thank you for those answers.

927 And if I could change the subject just for about a minute
928 or so left, I had an oncologist that contacted my office. Her
929 daughter is an intern in the office. I know her pretty well. And

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930 she was stating concern on the shortage of saline, so to change
931 it a little bit. She said it has been exasperated by the flu
932 epidemic this year. We see these shortages in just basic
933 medicines. And so, can you please provide the most recent FDA
934 developments of the saline shortage?

935 Dr. Gottlieb. There are two different components to this,
936 or, actually, three different components to this. There were
937 these small bags that were in shortage prior to the hurricane that
938 struck Puerto Rico, the 100-milliliter bags that are typically
939 used to dilute drugs and, then, administer drugs to patients.
940 That shortage was exacerbated by the hurricane because one of the
941 primary manufacturers of those bags is located in Puerto Rico and
942 was knocked out of production. That facility is now back in full
943 production. In fact, all the facilities that we have concerns
944 about in Puerto Rico are now back on grid power and most of them
945 are at full production.

946 And we have brought in additional supply from additional
947 facilities out of manufacturing sites, ex-U.S. manufacturing
948 sites, to make up for that shortfall. So, there should be much
949 more supply coming into the market.

950 There is also a shortage of the larger-volume bags. While
951 we haven't declared a shortage, there's spot shortages of the
952 1-liter bags that are used for volume repletion, and those are
953 also being strained by the flu, the flu outbreak. We have taken

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954 additional steps to bring in additional supply of the 1-liter bags
955 as well.

956 There is also some tight supply of the empty 1-liter bags
957 because a lot of compounding pharmacies and hospitals, when they
958 can't get access to filled bags, they buy empty bags and fill them
959 themselves in a compounding-type facility.

960 We have taken additional steps. We are going to have more
961 to say about this on Thursday. I was going to put it out today,
962 but we were delayed in getting our information out. We are going
963 to be putting out a statement on Thursday talking about the steps
964 we are taking to get more of those empty bags onto the market.
965 Some of those were manufactured in Puerto Rico.

966 I will just close by saying that the time it takes for a bag
967 to go from the manufacturing line to your hand in the hospital
968 as a clinician is about six weeks. I don't know this isn't a more
969 efficient supply chain, but that is what I have been quoted. It
970 takes weeks for it to make its way to the provider setting. And
971 so, the additional supply that we have brought on -- and it is
972 substantial -- is going to take some time to flow through the
973 market.

974 Mr. Guthrie. Thank you for your attention to that. You all
975 have been really good to work with.

976 Thank you.

977 Mr. Burgess. The Chair thanks the gentleman. The

978 gentleman yields back.

979 The Chair recognizes the gentlelady from Illinois, 5 minutes
980 for questions, please.

981 Ms. Schakowsky. Thank you, Dr. Gottlieb. But I want to
982 apologize that I missed much of your testimony. We have a number
983 of hearings going on that I had to be at.

984 I also wanted to thank you for meeting with some of us about
985 Essure, the contraceptive device that I know has harmed many
986 women, from meeting with some of those women. So, I hope we can
987 continue that conversation because I am very concerned about it.

988 Most people presume that the prescription that the doctor
989 writes for them, and they fill it, is safe and effective. This
990 is true because the FDA is considered the absolutely gold standard
991 in drug review.

992 We have all talked about now the 64 people who tragically
993 died because of this drug at the New England Compounding Center.
994 So, obviously, that was an impetus for passing the Compounding
995 Quality Act to improve safety.

996 And so, I wanted to just say that drugs that enter the
997 bloodstream, the eye, the spine, are supposed to be sterile, but
998 the FDA has received adverse events reports that these compounded
999 products were contaminated, reminiscent of the problems at the
1000 NECC.

1001 There have also been reports of sub-/super-potent drug

1002 products in 2016. Three babies received compounded morphine that
1003 was 20 times stronger than the label indicated. One of those
1004 infants had to be rushed by helicopter to a nearby children's
1005 hospital.

1006 So, here's my first question: Commissioner Gottlieb, the
1007 FDA has been active in implementing the Drug Quality and Security
1008 Act. There have been over two dozen guidance documents issued,
1009 four rules, numerous public engagements focused on proper
1010 implementation of this law. While these are meaningful steps,
1011 what more can we do to reduce the number of adverse events
1012 associated with compounded drug products?

1013 Dr. Gottlieb. I will just start out by echoing your
1014 concerns, Congresswoman. All drugs have risks. We know that.
1015 But I don't think anyone should be put at risk because a drug was
1016 improperly manufactured. At the very least, we should guarantee
1017 that a drug that purports to be manufactured in a certain way and
1018 purports to be sterile is actually a sterile product. That is
1019 the bedrock and the essence of what we are trying to achieve with
1020 respect to the authorities under this law.

1021 I think that there are things that we can do going forward,
1022 including continued implementation. We have heard the concerns
1023 of Congress that certain aspects of how we have implemented this
1024 have been slower than Congress expected. I think we didn't fully
1025 appreciate the complexity of this law. But I think, as we

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1026 continue to implement this framework, we are going to be able to
1027 exert even better and more efficient oversight. And that is going
1028 to increase the level of safety and assuredness that the public
1029 can have.

1030 I think there is more that we can do on the enforcement side
1031 as well, getting back to the other question. That is going to
1032 be an area that we continue to look at, both in terms of what we
1033 are doing, how we target our inspections based on what we are
1034 learning, looking at issues like potency now because we see those
1035 coming up more, as well as what additional resources we can put
1036 against it.

1037 This is a program -- and I don't want to get too deep into
1038 the resource question; I will save it for an appropriations
1039 hearing, but --

1040 Ms. Schakowsky. Feel free. Feel free.

1041 [Laughter.]

1042 Dr. Gottlieb. But this is a program where we do operate by
1043 in some cases begging, borrowing, and stealing from other aspects
1044 of the agency, other parts of the agency. For example, the team
1045 that I have, the policy team in the Drug Center that is working
1046 on the guidance development that you referenced and a lot of this
1047 policy development, is four people. They borrow resources from
1048 the review divisions, but, remember, those reviewers that they
1049 are tapping have PDUFA goals and BsUFA goals and GDUFA goals.

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1050 They have user fee goals against their time that they have to
1051 prioritize their time in certain ways.

1052 So, I think that there is certainly an opportunity to think
1053 about how we can grow this program in ways that could better
1054 address some of those safety issues.

1055 Ms. Schakowsky. What more do you think the FDA could and
1056 should do to ensure safety at 503A compounding pharmacies?

1057 Dr. Gottlieb. I think getting in place the MOU is going to
1058 be an important step. The MOU will provide for adverse event
1059 reporting back to FDA through the states. And so, I think that
1060 as we get that framework in place, I think that there is going
1061 to be a lot more we could do to better target our inspectional
1062 resources in areas of risk, in areas where the 503A facilities
1063 might be crossing into being a 503B facility that would be subject
1064 to GMP standards.

1065 So, I am hopeful. We are making good progress on that. We
1066 are going to have it out this year. I am hopeful that, as we get
1067 that agreement in place with the states, that is going to increase
1068 our level of oversight.

1069 Ms. Schakowsky. Well, we will be looking at that. Thank
1070 you very much.

1071 I yield back.

1072 Mr. Burgess. The gentlelady yields back. The Chair thanks
1073 the gentlelady.

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1074 The Chair recognizes the gentleman from Michigan, 5 minutes
1075 for questions, please.

1076 Mr. Upton. Thank you, Mr. Chairman.

1077 And, Dr. Gottlieb, it is good to see you here again. We
1078 appreciate your go-to attitude in trying to get things right. We
1079 understand that and we are with you every step. We appreciate
1080 your work on opioids, something that impacts every one of our
1081 districts.

1082 And I have to say, as we worked on the Cures legislation out
1083 of this committee, the \$500 million extra that we added to the
1084 FDA budget was almost a no-brainer. So, we appreciate the work
1085 of your crew, and we want to make sure that you have the resources
1086 to make sure that things, in fact, are safe and that you are not
1087 missing any steps.

1088 I have got a couple of specific questions for you.
1089 Hopefully, I can get through all three.

1090 It is critical that, until the clinical need list is issued,
1091 the FDA not permit bulk drug substances to be used in compounding,
1092 absent a final determination of clinical need, once all statutory
1093 criteria have been satisfied. Can you confirm that, once the FDA
1094 has identified its criteria for clinical need, that bulk drug
1095 substances, including those that the FDA has currently placed in
1096 Category I, would not be permitted to be used in compounding,
1097 absent such a determination?

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1098 Dr. Gottlieb. Well, we have put out the essential copies
1099 of this, which you know, the essential copies guidance. We are
1100 going to have the criteria for the development of the bulk drugs
1101 list for the 503B facilities, which is what I believe you are
1102 referring to, because we are further along on the bulk drugs lists
1103 for the 503B facilities, we will have that criteria out in March.
1104 And by the end of the year, we will have specified some bulk drugs
1105 that should either come on or off that list. There could be some
1106 that fall out pretty quickly from that list, based on safety
1107 considerations or a clear lack of clinical need. And so, we are
1108 going to do those assessments.

1109 Then, we are going to also have to contemplate how we change
1110 our inspectional priorities to prioritize inspecting or taking
1111 action on the basis of 503B facilities compounding drugs that
1112 might not be on that list. Right now, under our risk-based
1113 framework, we need to change some protocols in terms of how we
1114 go about looking for some of those other questions, to your point.

1115 Mr. Upton. Is the President's budget going to include more
1116 money for inspections?

1117 Dr. Gottlieb. Well, I don't want to get ahead of the
1118 President. So, I am not fully aware of what is going to end up
1119 in the budget. It is probably a question best put to OMB at this
1120 point.

1121 Mr. Upton. It was never Congress' intent that small tweaks

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1122 to approve drugs, like minor changes in concentration or inactive
1123 ingredients, would satisfy the criteria for clinical need and open
1124 the door to compounding from bulk substances under the DQSA.
1125 Would you agree that a clinical need can only be found where there
1126 exists a genuine patient need unable to be addressed by approved
1127 drug products requiring a significant change from the approved
1128 drug?

1129 Dr. Gottlieb. Well, again, Congressman, I don't want to get
1130 ahead of my career officials who right now are drafting guidance
1131 to define that very question. But the type of definition that
1132 you put forward would certainly seem to comport with a reasonable
1133 interpretation of what a final standard would be.

1134 Keep in mind, also, that we articulated in the essential
1135 copies guidance, and we are going to re-articulate in the guidance
1136 that we put out in March, that if there is an FDA-approved product
1137 available that you can compound from, you have to compound from
1138 that product. So, if a 503B facility is compounding from bulk,
1139 but they can otherwise be compounding from an FDA-approved
1140 product, for example, diluting it down if they are providing a
1141 more dilute formulation to satisfy a certain clinical need, they
1142 have to start with that FDA-approved product. That is a principle
1143 that we have put forward. I think that is going to address some
1144 of the issues that have been raised with respect to what is on
1145 and not on the 503B bulks list at this time.

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1146 Mr. Upton. And when do you think that order will be made?

1147 Dr. Gottlieb. That is a principle that I believe we put
1148 forward. I believe that is articulated in the copies guidance
1149 that we just put out, but it is going to be re-articulated in the
1150 March guidance that we put out. The question will, then, become,
1151 well, when are you going to take enforcement action solely on the
1152 basis of that issue? Because it is one thing for us to put out
1153 a guidance. If people don't follow our guidance, we have to take
1154 enforcement action. And that is where I mentioned that we are
1155 going to relook at protocols and how we prioritize our enforcement
1156 activity, on the basis of those kinds of considerations as well.

1157 But, as you know, we have a risk-based framework. We
1158 prioritize our limited inspectional resources and enforcement
1159 resources in places where we believe there is direct patient risk.
1160 And we are still in a realm where we are dealing with a lot of
1161 direct patient risk before we just look at, for example, economic
1162 harm, although that certainly is within the criteria that we look
1163 at and will be within our protocols.

1164 Mr. Upton. Thank you. I yield back.

1165 Mr. Burgess. The Chair thanks the gentleman. The
1166 gentleman yields back.

1167 The Chair recognizes the gentlelady from Colorado, Ms.
1168 DeGette, 5 minutes for questions, please.

1169 Ms. DeGette. Thank you, Mr. Chairman.

1170 As Mr. Green mentioned, he and Congressman Griffith and I
1171 worked really hard after that terrible tragedy of the New England
1172 Compounding Center to come up with our Compounding Quality Act,
1173 which was subsequently folded into the Drug Quality and Security
1174 Act. We are really proud of that bipartisan work. But, as we
1175 are seeing today, it takes constant tweaking and review to make
1176 sure that these pieces of legislation are working.

1177 Commissioner Gottlieb, one of the things that I am hearing
1178 from a lot of stakeholders about is what to do about office use.
1179 A lot of providers are saying that people are having difficulty
1180 accessing types of medication because of the requirement that we
1181 have for prescription. Now what they say is that these medicines
1182 are not lucrative enough to use 503B outsourcing facilities, but
1183 that the patients need them. And so, there are shortages.

1184 I want to be clear. I have got strong reservations about
1185 undermining or loosening the DQSA's prescription requirement in
1186 any way, given the consideration that any move in that direction
1187 could have an impact on patient safety. But I do want to make
1188 sure that patients with unique needs that cannot be met by
1189 FDA-approved medications can get the treatment that they need.
1190 It is really a balancing test.

1191 And so, I wanted to ask you if you think there are ways that
1192 we can resolve these potential access problems without
1193 undermining the prescription requirement and exposing patients

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1194 to unnecessary risk.

1195 Dr. Gottlieb. I appreciate the question, Congresswoman.
1196 To your point, this is one of the tensions that we are grappling
1197 with, because we care very much about these access issues that
1198 you have highlighted and need to preserve the practice of
1199 medicine. And we need to preserve the ability of physicians to
1200 get access to these drugs to use in their offices.

1201 We have seen an environment where we see more of the 503Bs
1202 doing small batches. About one-third of registered 503Bs do
1203 small batches. We are trying to take steps to better match
1204 clinicians with 503Bs that either are currently manufacturing
1205 drugs they might need, but also historically have manufactured
1206 drugs that would be needed, and are willing to run small batches.
1207 So, we are starting to post that information prospectively on our
1208 website.

1209 I think, as we also try to look at how we can create a more
1210 flexible framework for how we apply GMP standards to the 503Bs
1211 and see more smaller pharmacies that might want to make a business
1212 in doing small batches become 503B facilities, where they are
1213 still subject to GMP standards, I think that is going to also help
1214 address this.

1215 I made the comment earlier that the 503B sector has not grown
1216 as quickly as we had envisioned and had hoped at the time,
1217 including myself when I testified before this committee. But I

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1218 think that it is still early days, and I still think we are going
1219 to see a robust industry take shape here.

1220 Ms. DeGette. Do you think it would be helpful to work more
1221 on giving timely and transparent information for providers about
1222 which of these facilities are making these compounded
1223 medications?

1224 Dr. Gottlieb. I absolutely do. We are doing that. We do
1225 it now prospectively. We are just starting to really do it,
1226 because we are starting to get those reports electronically. One
1227 of the things we are considering is, can we go back and do it
1228 retrospectively, because we have the histories on what the
1229 facilities used to produce. That could be helpful as well.

1230 Ms. DeGette. It would help those facilities, too.

1231 Dr. Gottlieb. It would help the facilities.

1232 We are also going to be issuing either an FR notice to create
1233 a docket to solicit from provider groups input, in a more
1234 systematic way solicit input on where they are seeing access
1235 issues around certain products, so that we could, then, see what
1236 steps we could take to try to help provide more efficiency to 503Bs
1237 that might want to make those products. Because, right now, a
1238 lot of what we know is anecdotal.

1239 Ms. DeGette. Right. Right.

1240 Dr. Gottlieb. We want to develop that information on a more
1241 systematic basis.

1242 Ms. DeGette. In a systemic way.

1243 Now one last thing about drug pricing. Some people say that
1244 compounded alternatives to expensive medicines could actually
1245 provide financial relief to patients. But I think there is a real
1246 risk, in that marketing unapproved bulk compounded drugs could
1247 be really risky to patients. I am concerned that some press
1248 reports are already saying this is going on. I just wondered,
1249 I don't think that, certainly, the policies that this committee
1250 has endorsed are meant to be using compounded drugs to lower
1251 prescription drug prices if it is at the expense of patient safety.
1252 I am wondering if you can comment very briefly on that.

1253 Dr. Gottlieb. We believe that, if there is an FDA-approved
1254 option available, that is always the best option for the patient
1255 because it is going to provide the greatest assurance of safety
1256 and efficacy for the patient and to the provider. And I also
1257 believe, as you have seen me try to demonstrate through the actions
1258 we have been taking, that there are a lot of avenues we can go
1259 down to try to address the issues of cost and competition in the
1260 marketplace. And we will continue to do that.

1261 Ms. DeGette. So, it is not one or the other really?

1262 Dr. Gottlieb. It is not one or the other.

1263 Ms. DeGette. I thank you.

1264 Thank you, Mr. Chairman. I yield back.

1265 Mr. Burgess. The Chair thanks the gentlelady. The

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1266 gentlelady yields back.

1267 The Chair recognizes the gentleman from Illinois, Mr.
1268 Shimkus, 5 minutes for questions.

1269 Mr. Shimkus. Thank you, Mr. Chairman.

1270 And, Scott, it is great to have you here. I appreciate the
1271 testimony.

1272 This is a tough issue we have wrestled with for a long time.
1273 I think my colleague, Congresswoman DeGette, just actually kind
1274 of wove the story and the concerns that I have, and when we talk
1275 to some of our folks in different congressional districts.

1276 So, the 503A and the 503B issue, for me, it always comes down
1277 to the small-town, rural compounder and the way these rules will
1278 be etched or the memorandum of understanding or the batch size
1279 and the mileage distance, especially when you have got a rural
1280 district -- for me, it is 33 counties, five hours north and south
1281 drive, a three-hour east-to-west drive. It is a little different
1282 environment than a metropolitan area and a different area of the
1283 return on investment based upon what you are producing. You are
1284 not really going to manufacture for a large group, but in a small
1285 batch. And then, you might have across-state-line issues,
1286 especially in a rural area on the Illinois-Indiana border. I see
1287 my colleague, Mr. Griffith, nodding his head.

1288 So, can you kind of weave for the small pharmacist
1289 compounder, who I haven't had personally any problems as far as

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1290 I have represented that area -- he is trying to address this being
1291 able to provide what is being requested of him. Sometimes it is
1292 even these issues with the -- I am not a doctor -- you know, the
1293 eye drop issue for the optometrist who doesn't have the shots in
1294 the doctor's office, although it is something they need
1295 immediately, in essence. And there is not a prescription because
1296 the person hasn't come in yet to be able to get the prescription.
1297 And then, you have a delay of providing the medicine.

1298 So, for that small compounder, what should he take home from
1299 my vague question?

1300 [Laughter.]

1301 And what assurances can you give him that we are trying to
1302 allow him to continue the work he has been doing?

1303 And I know we have got our veterinarian here, too. These
1304 guys also use their compounding ability in veterinarian medicine.
1305 So, a veterinarian would ask the compounder in rural America. So,
1306 he needs to be there for not just humans, but also for the animal
1307 health that he also is able to provide for the veterinarian.

1308 Dr. Gottlieb. I can go a lot of different ways with this
1309 question.

1310 Mr. Shimkus. Well, I went a lot of ways with the questions.

1311 [Laughter.]

1312 Dr. Gottlieb. But I will go right to where I think you are
1313 going, which is the question of the prescription requirement and

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1314 whether or not that small-town pharmacist who is providing drugs
1315 over a large geographic area still needs to have a prescription
1316 in hand in order to provide a drug back and the difficulty of doing
1317 it over a large geographic expanse I think is the essence of what
1318 you are asking.

1319 The bottom line is that we believe that the line of
1320 demarcation for what constitutes the practice of pharmacy versus
1321 what constitutes drug manufacturing has to remain the
1322 prescription. I mean, the practice pharmacy, if you go and look
1323 at the bylaws of states and how they define a practice pharmacy,
1324 I did that before coming to the hearing. I spent my weekend
1325 looking at that. Embedded in the bylaws of state boards of
1326 pharmacies is the idea of the prescription and the named patient.
1327 That is the essence of what it means to be practicing pharmacy.

1328 We also understand that Congress contemplated other
1329 thresholds and struggled with it, and arrived back at the
1330 prescription being the line of demarcation, both 20 years ago when
1331 503 was originally drafted, as well as when it was recodified in
1332 DQSA. Because other kinds of schemes that were contemplated,
1333 volume-based schemes, for example, didn't provide the kind of
1334 delineation that you could apply a regulatory structure to. We
1335 can't regulate against "we'll know it when we see it." We need
1336 a clear line that we can force against and we can enforce against
1337 with our limited resources.

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1338 As far as veterinary medicine is concerned, as you know, we
1339 recently pulled the guidance that sought to define what our
1340 regulation was going to look like in that realm. And we pulled
1341 that for a variety of reasons, but, largely, because we don't think
1342 we got it right. I will say we will be reissuing that this year.
1343 But I will say that the issues around compounding in the veterinary
1344 space are different than issues around compounding in the human
1345 space. The practice of pharmacy in the veterinary space is a
1346 different kind of practice of medicine than it is in the human
1347 space. And so, our framework will also look different. It will
1348 be reflective of the practice of veterinary medicine.

1349 Mr. Shimkus. All right. Thank you.

1350 Mr. Burgess. The Chair thanks the gentleman. The
1351 gentleman yields back.

1352 The Chair recognizes the gentleman from Oregon, Dr.
1353 Schrader, 5 minutes for questions, please.

1354 Mr. Schrader. Well, thank you.

1355 And I thank my colleague for asking some good questions about
1356 veterinary medicine. That is near and dear to our heart.

1357 We use compounders a lot in our practice, I don't think
1358 inappropriately, but, as you alluded to, the size of the animal,
1359 the different metabolism of an animal, the lack of a particular
1360 drug that has worked historically that is affordable for my
1361 patients, I mean that is a different beast to some degree. I

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1362 appreciate the thoughtfulness that USDA under your guidance and
1363 FDA is actually approaching the whole veterinary guideline issue.
1364 So, I want to thank you for that.

1365 While I have had a lot of experience in using compounders
1366 in smaller communities to make sure my patients get the best
1367 medication possible, I am new to the regulatory framework with
1368 all this. I don't profess to be knowledgeable. So, my questions
1369 might be a little arcane and pretty obvious.

1370 But the whole 503B opens up a potential, as I think you have
1371 alluded to and some of the questions have alluded to, problem for
1372 circumventing a lot of the regulatory framework that our generic
1373 manufacturers, for instance, have to apply. What are the major
1374 differences -- well, first, I will say I fully support the
1375 continued definition of pharmacy prescription. It has to have
1376 a prescription to be able to do that. I think that is for the
1377 safety of any patient, human or animal. That is critical, and
1378 I urge you to continue to use that as a very bright line.

1379 But, having said that, then what do you see as the big
1380 demarcation between your 503B regulatory framework versus your
1381 generic regulatory framework? How do you see that as different,
1382 and what constitutes the guidelines there?

1383 Dr. Gottlieb. Right. By generic, I think you mean 503A,
1384 traditional pharmacy compounding, 503B being the outsourcing
1385 facility. And the difference is the prescription, whether or not

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1386 that the drug is being compounded on the basis of a named patient
1387 in response to a lawful prescription from a provider. That is
1388 the traditional practice of pharmacy. That is a 503A compounder.

1389 A 503B compounder is engaging in manufacturing. They are
1390 manufacturing either in small batches or on a larger scale, not
1391 in response to individual prescriptions that they have received
1392 from a provider, but in anticipation of orders, and they are doing
1393 advanced shipping. They might be doing what we all office stock.
1394 They might be shipping to providers to allow those products to
1395 be stocked inside the offices.

1396 That is traditional manufacturing. There is no way around
1397 it. Whether you do it with 10 units or you do it with 100 units,
1398 you are engaging in manufacturing, and those circumstances,
1399 instead of applying the traditional regulatory framework where
1400 they would be subject to regulations around the sanitary
1401 conditions, which is what you would apply to 503A pharmacy, in
1402 the context of the 503B setting you are applying GMP standards,
1403 some form of GMP, not GMP-light, but some form of GMP. I don't
1404 want to call it "GMP-light".

1405 Mr. Schrader. So, similar to the generic manufacturing that
1406 would go on?

1407 Dr. Gottlieb. Subject to good manufacturing practices, I
1408 mean, good manufacturing practices, as I said at the outset, are
1409 not a fixed standard. They are risk-based. And so, they look

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1410 different depending on the manufacturer that you are evaluating.
1411 But it would be some form of GMP standards that you would be
1412 applying. You would be doing lot release, sterility testing,
1413 batch testing. You would be retaining samples. You would
1414 provide for the compounding in a sterile environment if you are
1415 compounding a sterile product. So, you would be applying the GMP
1416 standards, traditional GMP standards.

1417 Mr. Schrader. Whatever level you are approaching that
1418 manufacturer?

1419 Dr. Gottlieb. There are basic principles of regulation with
1420 respect to the good manufacturing practices. So, when we say
1421 "level," I think that there are things you can do to make it less
1422 expensive if you are doing it on a smaller scale. So, for example,
1423 you require a lot of small batches. If you are only going to be
1424 making a small batch, if you are only shipping a small amount,
1425 you would require that facility to retain a lot of samples. There
1426 are ways that you can apply the GMP standards in fashion that
1427 comports with the level of the volume and the level risk you are
1428 creating. And that is what we are seeking to do in the more
1429 flexible framework that we are contemplating.

1430 Mr. Schrader. So, I guess the last question: what do you
1431 see as the role with the state regulatory framework versus the
1432 federal regulatory framework. The interstate commerce piece
1433 would, obviously, be a federal purview. How do you juxtapose the

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1434 state regulatory framework on these 503A and, more importantly,
1435 the 503B pharmacies?

1436 Dr. Gottlieb. The MOU is going to define sort of the
1437 interplay between the state and the federal scheme and the level
1438 of activity that a 503A can engage in that might cross it into
1439 being subject to federal oversight because it is engaging in
1440 interstate commerce, interstate activity. And we have talked
1441 about various thresholds, about how much product can cross a state
1442 line before a compounder should or ought to be subject to at least
1443 our attention, to make a decision on whether or not it is subject
1444 to, should be subject to FDA oversight.

1445 Here again, this is not going to be a fixed standard when
1446 we are contemplating this. It is not going to be, if you ship
1447 31 products, you are subject to the federal scheme, but if you
1448 had only shipped 30, you would be fine. We are going to try to
1449 take a risk-based approach here as well, and it is going to be
1450 based on volume, percentage of products you are shipping across
1451 the state line, the kinds of products you are shipping across the
1452 state line, the manner in which you are doing it. And so, we are
1453 going to have a threshold in which we want notification by the
1454 states, but, then, we are still going to make an independent
1455 decision whether or not it should be subject to a federal
1456 inspection because of the activity.

1457 And the essence is, if I could just close, the essence is

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1458 that, if a pharmacy is engaging -- if a pharmacy is subject to
1459 state regulation, but is shipping most of its product out of state,
1460 it can't be subject to state regulation anymore. Because if you
1461 are in New Jersey and you are subject to the New Jersey Board of
1462 Pharmacy and New Jersey inspectors, but most of your products are
1463 going to New York, the New York inspectors don't know. Then, they
1464 can't provide the oversight that they need to in a trace-back.
1465 So, it is important that the states be aware of what is going on
1466 within their states.

1467 Mr. Schrader. Very good. Thank you.

1468 And I yield back.

1469 Mr. Burgess. The Chair thanks the gentleman.

1470 The Chair recognizes the gentleman from New Jersey, Mr.
1471 Lance, 5 minutes for questions.

1472 Mr. Lance. Thank you very much, Mr. Chairman.

1473 And thank you for being here, Commissioner.

1474 The district I serve provides innovative medicines for
1475 patients across the country. Protecting these patients is, of
1476 course, a top priority for all of us, and so is protecting the
1477 FDA's gold standard. As the Drug Quality and Security Act is
1478 implemented, we need to ensure that we provide the incentive for
1479 innovator and generic manufacturers to go through the FDA process.
1480 To do this, we need to make sure that commercially-available drug
1481 products cannot be copied. How is the agency protecting patients

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1482 and the gold standard as you implement the Drug Quality and
1483 Security Act?

1484 Dr. Gottlieb. Well, Congressman, thanks for the question.
1485 I would like to assert that we are protecting the interest of
1486 patients by implementing this statute and making sure that we
1487 continue to move through the regulatory steps to, for example,
1488 finalize the 503B bulks list, finalize the guidance on sanitary
1489 conditions, finalize the list on bulk substances that the 503A
1490 facilities can compound from, make sure we get the MOU in place,
1491 so we can provide proper oversight of 503B and 503A facilities,
1492 in concert with the states, and work closely with our state
1493 partners. And so, we are going to continue to work through that.

1494 With respect to the first part of your question about just
1495 the sort of economic issues inherent in situations where a
1496 compounder might be copying a drug that is otherwise an
1497 FDA-approved product, we have asserted in the copies guidance
1498 certain activities that we would believe fall outside the scheme
1499 contemplated by DQDA. We are going to reassert those in the
1500 guidance that we issue in March with respect to the criteria for
1501 what should and shouldn't be on the bulk drugs list. Then, it
1502 is going to be a question of taking enforcement action where we
1503 see companies or compounders engaging in activity that falls
1504 outside that scheme that we both articulated in our guidance as
1505 well as Congress contemplated in the statute. That is what we

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1506 are going to be focused on doing.

1507 I will say, thought, our enforcement activities will be, as
1508 they should be, guided by patient risk, first and foremost. But
1509 we will be baking into our protocols in terms of how we take
1510 enforcement action the kinds of considerations that you talked
1511 about, because that is what Congress has asked us to do.

1512 Mr. Lance. Thank you.

1513 I was pleased to see that the agency's 2018 Compounding
1514 Policy Priorities Plan -- and I am interested to hear more about
1515 the forthcoming flexible risk-based approach to current good
1516 manufacturing practices. Recognizing the agency's goal to
1517 increase the number of 503B outsourcing facilities, recognizing
1518 the compliance costs for larger 503B facilities and the investment
1519 necessary to satisfy the statute, is the agency concerned that
1520 the multi-tiered 503B regulatory approach may affect incentives
1521 for these facilities?

1522 Dr. Gottlieb. Well, quite the opposite, we feel that we hope
1523 that by taking a tiered approach based on risk, we might provide
1524 the opportunity for more 503A pharmacies to step across the line
1525 into being 503B pharmacies and consider it worth the economic
1526 investment. Becoming a 503B pharmacy is not without some
1527 investment in cost for most 503A facilities. They don't have the
1528 kinds of facilities to be subject to GMP oversight. And so, it
1529 is going to require some investment. But we are hoping that we

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1530 could provide a framework where more facilities can find it, have
1531 the ability to make the capital investments and raise the capital
1532 necessary to make those investments because they see a better
1533 opportunity on the other side of that in terms of trying to
1534 increase their volume and increase the kind of activity that they
1535 are engaged in. We think by having more 503A facilities
1536 converting to being 503B facilities, it is going to facilitate
1537 access and, also, give them the ability to grow.

1538 A 503A facility that is trying to engage in some low level
1539 of manufacturing, even if they can do it under the radar of
1540 regulators, if they grow to a certain proportion, eventually, they
1541 are going to pop up. And so, they are basically capped under this
1542 legislation. If they step across that threshold and become a
1543 503B, they have much more latitude to engage in broader
1544 manufacturing.

1545 Mr. Lance. Thank you, Commissioner.

1546 And, Mr. Chairman, I yield back 27 seconds.

1547 Mr. Burgess. The Chair thanks the gentleman.

1548 The Chair recognizes the other gentleman from New Jersey,
1549 the ranking member of the full committee, Mr. Pallone, 5 minutes
1550 for questions.

1551 Mr. Pallone. Thank you, Mr. Chairman.

1552 I wanted to ask you about this issue of distribution versus
1553 dispensing. Section 503A of the law prohibits a pharmacist,

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1554 pharmacy, or healthcare provider from distributing compounded
1555 drug products across state lines that exceed 5 percent of the total
1556 prescriptions distributed or dispensed unless the product is
1557 compounded in a state that has entered into a memorandum of
1558 understanding with FDA that addresses the distribution of
1559 inordinate amounts of compounded drug products and provides for
1560 investigation by the state into complaints associated with
1561 compounded drug products that are distributed interstate. And
1562 FDA released a draft MOU in February 2015 that proposed defining
1563 inordinate amounts for purposes of interstate distribution to no
1564 greater than 30 percent of all products distributed or dispensed.

1565 So, in terms of this distribution versus dispensing,
1566 Commissioner, some have suggested that the MOU is only intended
1567 to apply to drugs that are distributed without a prescription.
1568 What is your view about the purpose of the MOU and the public health
1569 purpose it serves? Are there some drugs, such as those dispensed
1570 directly to patients, which could be excluded consistent with that
1571 purpose?

1572 Dr. Gottlieb. Well, in my weekend reading of pharmacy
1573 bylaws, the other observation that I had is that the bylaws make
1574 specific reference to the word "dispense" as part of their
1575 definition of what constitutes the practice of pharmacy. It is
1576 our view, and we feel strongly, that the practice of pharmacy
1577 always contemplates the dispensing of the drug. Now in certain

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1578 circumstances the drug is going to be dispensed and, then,
1579 distributed across state lines, and that is where the MOU comes
1580 into play. The MOU contemplates drugs that are dispensed and
1581 shipped across state lines, and shipping is a form of
1582 distribution, as I think you all agree. But we think that
1583 dispensing is part and parcel of the activity of practicing
1584 pharmacy, and no drug, no compounded drug can be distributed
1585 without first being dispensed, because dispensing is the act of
1586 creating that patient-specific prescription.

1587 And I will just say, and sort of to address the elephant in
1588 the room, because this has been contemplated as one of the sort
1589 of beliefs in terms of why DQSA might have contemplated something
1590 different with respect to office stock than FDA's current
1591 interpretation of how we perceive the law to have been written,
1592 I don't think that defining, redefining the practice of pharmacy,
1593 which involves the activity of dispensing a product to a patient,
1594 is a good way to try to create a framework for office stock. I
1595 am open to the debate about office stock and the merits of it.
1596 I think we have been clear from the agency's standpoint the risks
1597 that we feel it creates if a 503A facility is getting engaged in
1598 it. But I would hate to see the practice of pharmacy redefined
1599 as a sort of backdoor into that. I think if we are going to have
1600 a discussion about the merits of 503A facilities engaging in some
1601 level of manufacturing and shipping, we ought to just do that

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1602 directly.

1603 Mr. Pallone. All right. Then, let me get to my second
1604 question. Recently, you announced the agency's intention to
1605 modify the allowable percentage of compounded drug product
1606 distributed into a state to effectively eliminate the 30-percent
1607 threshold and, instead, implement certain reporting requirements
1608 that will be triggered at a 50-percent threshold. And this
1609 strikes me as a weakening of an important patient protection and
1610 in contrast to what you have noted in your testimony is the stated
1611 goal of this provision in the statute, which says, and I quote,
1612 "Preventing compounders reportedly operating under the
1613 exemptions in Section 503A from growing into conventional
1614 manufacturing operations making unapproved drugs and operating
1615 a substantial portion of their business interstate without
1616 adhering to current good manufacturing practice requirements and
1617 other provisions intended to ensure the manufacture of quality
1618 drugs." So, would you explain how increasing the allowable
1619 threshold for interstate distribution to 50 percent is consistent
1620 with the goal of the statute of preventing compounders from making
1621 unapproved drugs and operating a substantial portion of their
1622 business interstate without adhering to the CGMPs?

1623 Dr. Gottlieb. Well, I appreciate the question, Mr.
1624 Chairman. I don't see it as a weakening. I see it as a
1625 strengthening, because we are going from a hard threshold of 30

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1626 percent to a risk-based threshold of 50 percent. It is not 50
1627 percent -- it is not 49 percent and you are all good, and 51 percent
1628 and you are now subject to a different scheme. There are going
1629 to be other tests that we apply to make assessments about what
1630 the appropriate scheme is for a particular facility.

1631 It is the case, though, that there are facilities -- for
1632 example, a border-state pharmacy that develops TPN, total
1633 parenteral nutrition; a home infusion company that provides
1634 patient-specific, named patient products on a prescription basis
1635 and might ship more widely than are engaging in the traditional
1636 practice of pharmacy; they are doing it on the basis of named
1637 patients in response to an individual prescription, but they might
1638 be shipping more of those products. They might be lower-risk,
1639 too, depending on what they are doing.

1640 And so, the reality is that there is a lot of different kinds
1641 of pharmacies situated across the spectrum in terms of the
1642 activity that they are engaged in. And we don't think a sort of
1643 fixed standard where there is a fixed line based just on volume
1644 makes the most sense. We want a volume-based standard, but also
1645 a standard that allows us to make an assessment about what the
1646 kind of activity is. And it is another effort on our part to be
1647 risk-based. I think, ultimately, our enforcement is stronger
1648 when we are taking a risk-based approach.

1649 Mr. Pallone. All right. Thanks a lot.

1650 Thank you, Mr. Chairman.

1651 Mr. Burgess. The Chair thanks the gentleman. The
1652 gentleman yields back.

1653 The Chair recognizes the gentleman from Virginia, 5 minutes
1654 for questions, please.

1655 Mr. Griffith. Thank you very much, Mr. Chairman. I
1656 appreciate it greatly.

1657 Let me get the record a little bit straight because I think
1658 it was confused a little bit earlier. While we had criminal
1659 conduct by NECC, we also had timid lawyers at the FDA. Ohio had
1660 warned the FDA there was a problem. Colorado had outright banned
1661 NECC from putting products into their state. And FDA was aware
1662 of it and didn't even bother to seek a warrant to go in and see
1663 what was going on. So, as we move forward, let's continue on that.

1664 Also, I think in the next panel there will be some question
1665 about the intent, and you touched on that in your testimony with
1666 Mr. Shimkus a little bit earlier. But I want to go back to when
1667 the bill passed in September of 2013. At that time, now-Ranking
1668 Member Green said, in part, "While I believe the FDA dropped the
1669 ball with regards to the NECC, with this law they must succeed
1670 where in the past they failed." And I know you are working hard
1671 on that.

1672 This bill still lacks clarity in many important areas:
1673 office use, how nuclear pharmacies are regulated, and repackaging

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1674 of sterile products. I look forward to working with my colleagues
1675 to provide meaningful oversight of the FDA to make sure another
1676 NECC-type outbreak never happens again, and make sure they are
1677 using the type of enforcement discretion necessary to preserve
1678 patients' access to critical medicine.

1679 In that same press release -- because it was a bipartisan
1680 effort, as you heard earlier, Mr. Green, myself, and Ms. DeGette
1681 worked hard on trying to get this portion of the DQSA right, and
1682 to the best of our ability, although we had some disagreements
1683 with our Senate colleagues. I said on that occasion that, "The
1684 Drug Quality and Security Act leaves a large portion of existing
1685 law intact. It also leaves many areas of practice where
1686 clarification may still be needed, particularly as it relates to
1687 office use, repackaging, and nuclear pharmacies. Along with my
1688 colleagues, I will continue working to oversee the FDA's
1689 interpretation and implementation of this law."

1690 And I think that is what we are doing today. Some folks have
1691 characterized this, because I am leading the push for office use,
1692 as wanting to undo everything that DQSA stood for. Obviously,
1693 I wouldn't have drafted it and fought hard along with my colleagues
1694 to get it, if that was my intent.

1695 But I do have questions. And one of those was raised by your
1696 testimony to Mr. Shimkus in answering his questions where you
1697 indicated that twice they had decided that you had to have a

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1698 prescription in order to issue a drug, and that Congress had made
1699 that decision. But I am looking at 503A, little "a" to big "A",
1700 and it says, as one of the things, it says, "or is by a licensed
1701 pharmacist or a licensed physician in limited quantities before"
1702 -- before -- "the receipt of a valid prescription order for such
1703 individual patient."

1704 Obviously, the law -- and that was the old law, which was
1705 not changed and which we were assured that the practices weren't
1706 going to change at the times we were negotiating this by folks
1707 in the Senate saying they didn't want to do this because the FDA
1708 wasn't going to change anything. It clearly anticipates that in
1709 some cases you won't have a prescription until afterwards. We
1710 had debated making sure that a prescription was written within
1711 seven days at the time that we were negotiating it. But this
1712 seemed acceptable at the time, and the reason that I put that into
1713 my statement -- and others may have put it into their statement
1714 -- and the statement on the Floor was we were given the assurance
1715 that office use was going to remain pretty much the same, and for
1716 503A pharmacies I think that is important.

1717 So, how do you rectify that you think there needs to be a
1718 prescription with the actual wording of the law? There are also
1719 other references, future-looking references, in the next section.

1720 Dr. Gottlieb. Yes, thank you, Congressman, for the
1721 question. I appreciate your longstanding dedication to this

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1722 issue and your longstanding work on it. And you and I have had
1723 the time to talk about this on many occasions.

1724 With respect to the nuclear pharmacies, I will just say we
1725 will be putting out a guidance that will specifically address
1726 radiopharmaceuticals.

1727 But, in respect to your specific question about the language
1728 you quoted, I believe that that language and we believe that
1729 language was contemplating anticipatory compounding, basically,
1730 compounding on an expectation that you were going to receive a
1731 certain volume of prescriptions. Because we know, with the 503A
1732 pharmacies -- and I know you are very familiar with the practice
1733 of pharmacy -- sometimes when you mix up one batch, when you are
1734 mixing up a batch, you can't just mix up one drug. You mix up
1735 10 at a time or 15 at a time. And you can do that if there is
1736 an expectation that you know you get 30 prescriptions a month or
1737 40 prescriptions a month. So, we allow for that.

1738 What we have said in guidance is that you can mix up a level
1739 of volume in anticipation of what you your prescriptions might
1740 be over the course of a 30-day period to provide that kind of
1741 flexibility. That is what I believe the statutory language that
1742 you referenced was anticipating and that we have allowed for.

1743 Mr. Griffith. And I disagree, just based on the debate that
1744 we had when we were doing this a number of years ago in 2013,
1745 because we anticipated there would be continued office use. That

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1746 is why we were looking at putting in the seven-day requirement.
1747 And as Ms. DeGette said, there has got to be a balance. As Mr.
1748 Shimkus said, we are worried about rural areas.

1749 I do appreciate that you are concerned about the state lines
1750 because, having now been made famous by the GEICO commercial where
1751 the lizard jumps from Tennessee to Virginia and back and forth,
1752 and back and forth, that is my district. And so, you have got
1753 a pharmacy on either side of that state line. I mean, you just
1754 turn around and you cross the state line.

1755 The other day I was traveling in my district and I went from
1756 Virginia to West Virginia, to Virginia, to West Virginia, back
1757 to Virginia, then ended up the day going from Virginia to
1758 Tennessee, back into Virginia, and back into Tennessee, and then,
1759 back home in Virginia, just to try to talk to my constituents and
1760 do what I needed to do.

1761 So, I appreciate you paying attention to that as you look
1762 at the flexibility side, but I really believe that the existing
1763 law allows for some office use from the smaller folks. We were
1764 trying to get to the big guys and the larger guys because of the
1765 NECC problem, which was shipping into all the states, not just
1766 across the Tennessee line or the Virginia line.

1767 I yield back.

1768 Dr. Gottlieb. I understand and appreciate concerns,
1769 Congressman, the impact on small pharmacies.

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1770 Mr. Griffith. And I yield back. Thank you, Mr. Chairman.

1771 Mr. Burgess. The Chair thanks the gentleman.

1772 And the Chair recognizes the gentleman from a similar small

1773 state, Maryland, for 5 minutes.

1774 Mr. Sarbanes. Small, but powerful, and home to the FDA.

1775 Welcome, Commissioner.

1776 People have touched on kind of the partnership, regulatory

1777 partnership between your agency and what happens at the state

1778 level. I wanted to explore that a little bit more.

1779 I was looking at your testimony on page 3, where you talked

1780 about the 500 inspections that have been conducted, 503A and B

1781 facilities, since the passage of the new law and the end of the

1782 last fiscal year; how you have observed problematic conditions

1783 during the vast majority of these inspections, overseeing more

1784 than 150 recalls of compounded drugs, issued more than 180 warning

1785 letters. You have also worked in close coordination with our

1786 federal and state partners, sending more than 70 referral letters

1787 to state regulatory authorities for followup on certain

1788 inspectional findings.

1789 So, I am just curious how that is going. I mean, there must

1790 be some states that are better partners than others. Obviously,

1791 you have to rely to a certain degree on those followup inspections.

1792 And maybe without naming specific states, you could give me an

1793 example of a state that is engaged in this partnership in a very

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1794 productive and efficient way, and why that is the case, what you
1795 would point to as indicating kind of a high standard in terms of
1796 the partnership, and the followup, and all the rest of it. And
1797 then, maybe give me an example, again without naming the state,
1798 of a place where that is not going so well. And what does the
1799 agency do, either because it is required to in some element or
1800 just because you regard it as your responsibility to help states
1801 to get to where they can be the best possible partners in this
1802 effort at oversight?

1803 Dr. Gottlieb. Congressman, thanks for the question. To
1804 your point, there is a fair degree of variability. I think it
1805 would be risky of me to try to characterize a good state and a
1806 not-so-good state, because it is not something I have actually
1807 asked the question of my folks, and I would want to contemplate
1808 it in concert with them. Because the field people, the field team
1809 that is engaged in these efforts are going to have the best
1810 perspective. We could certainly get you that perspective, but
1811 I wouldn't want to mischaracterize the state.

1812 I will say, though, broadly, that what we are seeing
1813 directionally is that the states are starting to conform more to
1814 DQSA now. And so, there has been discussion, for example, of
1815 states' pharmacy bylaws that might allow for certain practices
1816 that DQSA we don't believe contemplates. We starting to see more
1817 of the states conform their practices, their inspectional

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1818 activity, as well as their laws, to be compliant with the DQSA,
1819 be consistent with the principles of the DQSA.

1820 For the states that might be moving in a different direction
1821 or not moving as quickly in the direction that was envisioned by
1822 DQSA, I think what it creates for us is more of a resource burden.
1823 Those are the states that we might have to put more resources into
1824 to make sure that we are providing the same level of oversight
1825 that we would be to a state that is sharing information with us
1826 very cooperatively and reporting to us, so we can target our
1827 inspections better.

1828 A lot of our inspections are for-cause inspections. A lot
1829 of them are based on information we derive from the states. If
1830 the states aren't reporting to us as efficiently, then we need
1831 to do more work to try to derive that information on our own. It
1832 is just a more resource-intensive process.

1833 Mr. Sarbanes. Is there an opportunity to provide, I don't
1834 know, technical assistance or other support to the states, as they
1835 are trying to come into compliance with this effort?

1836 Dr. Gottlieb. We do that. As the scheme contemplates, we
1837 provide a lot of resources or technical assistance within the
1838 context of the resources we have available to do this in terms
1839 of training to state inspectors, training around inspectional
1840 issues that they might need to be aware of as they start to inspect,
1841 for example, 503B facilities and do their own GMP inspections.

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1842 We do dual inspections with the states. We invite the states in
1843 on our inspections, so that they can both learn alongside of us
1844 as well as dually inspect some of these facilities and share
1845 information. So, there is a lot of stuff that we are trying to
1846 do in concert with the states.

1847 As I sunk deeper into this and understanding how we were
1848 applying this framework when I re-arrived at FDA 10 months ago,
1849 there were a lot of aspects of this that looked very similar to
1850 FISMA, the framework envisioned in FISMA, where the regulatory
1851 scheme is very much dependent upon a close federal/state
1852 partnership.

1853 Mr. Sarbanes. Thank you. I yield back.

1854 Mr. Burgess. The Chair thanks the gentleman. The
1855 gentleman yields back.

1856 The Chair recognizes the gentleman from Georgia, 5 minutes
1857 for questions, please.

1858 Mr. Carter. Thank you, Mr. Chairman.

1859 And thank you, Dr. Gottlieb, for being here. I want to
1860 commend you and thank you for your adherence to safety, and I think
1861 it is very important.

1862 It has been mentioned more than once during this hearing that
1863 there has to be a balance between accessibility and safety. I
1864 think that is perhaps one of the areas that I struggle with. And
1865 you and I have had many conversations.

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1866 I want to ask you, first of all, about the rulemaking process,
1867 because that is of great interest to me, being a relatively-new
1868 Member of Congress, only in my second term, my third -- I guess
1869 I am starting my fourth year now. So, I am getting older, but
1870 I am still learning about the rulemaking process.

1871 I noticed that, since the passage of DQSA, that you have used
1872 oversight guidance documents to really enforce this and to really
1873 enforce what you want the agency to see out there. Although we
1874 probably disagree, and we do disagree, you say it is with
1875 stakeholder input; I say it has not been with stakeholder input.
1876 And I am just wondering how you can justify that, particularly
1877 in light of the fact that just recently the Office of the Associate
1878 Attorney General issued a new policy to DOJ that guidance policies
1879 will not be converted into rulemaking. So, how are you justifying
1880 this, that you are going to use guidance policy for rulemaking
1881 here?

1882 Dr. Gottlieb. Thank you, Congressman.

1883 We have a long history of issuing non-binding guidance in
1884 many contexts. And our guidance practice -- and this question
1885 has come up in other contexts well outside this context -- our
1886 guidance practices, generally, have been used as a model for other
1887 agencies and for OIRA as well in terms of what we do, how we issue
1888 guidance, what we use guidance for under the Administrative
1889 Procedures Act.

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1890 So, I feel confident that, on the whole -- and we can have
1891 a debate around any individual guidance -- but I feel confident
1892 that, on the whole, we have adhered to good practices in terms
1893 of how we promulgated guidance in multiple --

1894 Mr. Carter. I don't mean to interrupt, but you even answered
1895 Mr. Upton's, Representative Upton's question about the guidance,
1896 that you expected it and that you were using the guidance for
1897 enforcement. I mean, you are, essentially, saying that this
1898 guidance is going to be enforced.

1899 Dr. Gottlieb. There is --

1900 Mr. Carter. Even though the DOJ has been told that, no, it
1901 cannot be converted into rulemaking. Quite honestly, I have not
1902 read this from the Associate Attorney General. Perhaps they said
1903 this is going to apply to the DOJ, but not to the FDA. I don't
1904 suspect that was the case; maybe it is.

1905 Dr. Gottlieb. Well, we could take enforcement action now.
1906 We don't need the guidance document in order to take the
1907 enforcement action. The guidance document is a way to provide
1908 public discussion around how we intend to take our enforcement
1909 action. So, we can both inform the public as well as learn from
1910 the public. The guidance document itself isn't the basis for the
1911 enforcement action, you are absolutely right. We have regulatory
1912 authority that has been given to us by Congress.

1913 Mr. Carter. Well, what about stakeholder input? Because

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1914 that is something that is very concerning to me, that I don't feel
1915 like we have had stakeholder input. I know that you are coming
1916 out with a new MOU. My hope is that you are going to have more
1917 stakeholder input into that. The existing MOU, although I was
1918 not here at the time, I don't think there was sufficient
1919 stakeholder input into that.

1920 One thing, in particular, about this is the difference
1921 between dispensing and distributing. As you know, the DEA has
1922 said that distributing is going to be overseen by the FDA, but
1923 the dispensing is going to be overseen by the state boards of
1924 pharmacies. Yet, you seem to want to oversee dispensing as well
1925 through the FDA.

1926 Dr. Gottlieb. I am not familiar with the particular
1927 definition of dispensing and distributing, probably under the
1928 Controlled Substances Act, that you have derived from -- I don't
1929 know, is it a regulation or a guidance document? So, I can't speak
1930 to how the DEA might have defined something in a certain context,
1931 again under the Controlled Substances Act, which is my
1932 presumption.

1933 We believe that, under this law and under the practice of
1934 pharmacy, with products that we regulate, and outside of the
1935 context of controlled substances, the practice of pharmacy
1936 involves the dispensing of a product, just like the practice of
1937 pharmacy involves a patient --

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1938 Mr. Carter. But why is it that the FDA thinks that they have
1939 to intercede the state boards of pharmacy? That has always been
1940 something that the state boards of pharmacies --

1941 Dr. Gottlieb. We need to work with them.

1942 Mr. Carter. Okay. I have got just a few minutes left, just
1943 a few seconds left. Now I want to ask you about something that
1944 has been brought up by Ms. DeGette, by Mr. Griffith, and that is
1945 office use. And that is something that I think you have
1946 absolutely got wrong here.

1947 But I want to ask you just from a perspective of a Member
1948 of Congress. It is my understanding that not once, not twice,
1949 but three times, through appropriations language, that the FDA
1950 has been instructed to revisit this and to look at this. In fact,
1951 in 2016, it said, "The committee understands the intent of the
1952 DQSA was not to prohibit compounding pharmacies from operation
1953 under existing 503A exemptions. Therefore, the committee
1954 directs the FDA to issue a guidance document on how compounding
1955 pharmacists can continue to engage in office-use compounding."

1956 Why do you ignore these? Why have you not ignored it once,
1957 not twice, but three times? I don't get it.

1958 Dr. Gottlieb. Congressman, those appropriation riders I
1959 believe preceded my arrival at FDA. I would be happy to work with
1960 this committee, or anyone in Congress, to contemplate if they want
1961 to have a discussion around the statute and what we can do to

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1962 continue to improve this on this legislation.

1963 But we have to keep patients in mind and make sure patient
1964 safety drives the decision we make. And remember why we are here.
1965 We are here because pharmacies were engaging in manufacturing
1966 without any standards in place.

1967 Mr. Carter. Dr. Gottlieb, I could not agree with you more.
1968 I commend you on your dedication to safety. Again, we get back
1969 to the balance between access and safety. And that is just you
1970 and I live in different worlds. I mean, you are in a different
1971 world than what I previously was in my career in pharmacy, and
1972 I saw firsthand the access issue and how people struggled with
1973 it. That is just a difference that we have and that I hope that
1974 you will take into consideration in the future.

1975 Thank you very much.

1976 Dr. Gottlieb. Thank you, Congressman.

1977 Mr. Burgess. The gentleman yields back.

1978 So, Dr. Gottlieb, once again, I think we have gotten everyone
1979 on the committee. I will just ask, Mr. Green, do you have a
1980 followup question before we leave?

1981 Mr. Green. No. Oh, I guess we do, Mr. Chairman.

1982 [Laughter.]

1983 Mr. Burgess. I could intuit that.

1984 Mr. Green. Okay. Commissioner, one of the most important
1985 ways FDA is conducting oversight and ensuring compliance with the

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1986 DQSA has been through inspections. Since the enactment of the
1987 Drug Quality and Security Act, FDA has conducted nearly 500
1988 inspections, issued more than 180 warning letters identifying
1989 significant violations of compounding pharmacies, issued more
1990 than 70 letters referring to inspectional findings to state
1991 regulatory bodies, and overseen more than 120 recalls of
1992 compounded products.

1993 Commissioner Gottlieb, as I noted, FDA has conducted
1994 hundreds of inspections in compounding pharmacies and identified
1995 numerous violations. Will you describe briefly for us some of
1996 the violations and conditions FDA found when they were inspecting
1997 both 503A compounding pharmacies or 503B outsourcing facilities?

1998 Dr. Gottlieb. I brought some slides with me, if the chairman
1999 would let me use them, of some of the things that we found. So,
2000 we can close on this, if that is okay. I don't know if we have
2001 them teed up.

2002 Thank you, Mr. Chairman.

2003 This is visible microbial contamination on a ceiling tile
2004 in a clean room.

2005 If we go to the next slide, this is a HEPA filter located
2006 immediately above an ISO5 workbench that was observed to have a
2007 stained surface. The stain was due to a drug product which had
2008 exploded due to excessive pressure when forcing non-sterile
2009 product through a sterilizing filter, a device used to force the

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2010 product sterilizing, in other words, a stainless steel caulking
2011 gun that was not sterilized.

2012 Next slide. This is a sleeve used in the aseptic glovebox
2013 for aseptic manipulation. You can see it is damaged where it is
2014 circled.

2015 Next slide. This is a toaster oven that was used to dry heat
2016 sterilize glassware. The oven wasn't capable, as we can probably
2017 presume, of reaching high enough temperature to be effective for
2018 that purpose.

2019 Next slide. This is a ceiling above the doorway to a clean
2020 room with exposed insulation. This was supposed to be a clean
2021 room that would store products manufactured.

2022 Next slide is a kitchen dishwasher that was actually being
2023 supplied with tap water and home detergent and used to clean
2024 equipment, equipment and the utensils that come in contact with
2025 products that were intended to be sterile.

2026 And they jumped my bug. This was a bug.

2027 But, you know, we also saw things like coffee filters being
2028 used to filter particulate matters. We find things that are
2029 deeply concerning. And these are sterile, these are facilities
2030 that are manufacturing sterile products, or at least intended to
2031 be sterile products.

2032 I appreciate the question.

2033 Mr. Green. Thank you.

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2034 Mr. Burgess. The Chair observes that debate on the Floor
2035 has proceeded to the point where Mr. McGovern is making some fairly
2036 significant gestures, which usually means he is concluding and
2037 we will be voting shortly. So, I will advise the committee that
2038 we will recess upon the votes that are called on the Floor.

2039 But we thought Ms. McMorris Rodgers was coming back, and she
2040 is. So, I will recognize her.

2041 Mrs. McMorris Rodgers. Thank you, Mr. Chairman.

2042 Mr. Burgess. But, again, I observe that the vote on the
2043 Floor is probably very close. Mr. McGovern is making smaller and
2044 smaller circles with his hands, and that usually means we are
2045 getting there.

2046 [Laughter.]

2047 Mrs. McMorris Rodgers. Okay. Very good. Okay.

2048 Well, Commissioner, thanks for being here.

2049 I wanted to ask about the 503As and the 503Bs, and just what
2050 the intent is moving forward as far as preserving them separately,
2051 or what your thoughts are.

2052 Dr. Gottlieb. Well, thank you, Congresswoman, for the
2053 question. On the 503A, are you talking about the bulks list or
2054 just the different facilities?

2055 Mrs. McMorris Rodgers. Well, I understand that you have
2056 issued some guidelines related to 503As, 503Bs, and I wanted just
2057 to understand better what you think the future is for the 503As.

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2058 Dr. Gottlieb. Well, I mean, the general question with
2059 respect to the 503As is we believe that the 503As, which is a
2060 traditional practice of pharmacy, should continue to flourish.
2061 We believe it provides an important product for patients, the
2062 practice of pharmacy being able to individualize products on the
2063 basis of a prescription for an individual patient.

2064 On the 503Bs, we do hope, and we always envisioned, that there
2065 would be more facilities converting into being outsourcing
2066 facilities. We also believe that more 503A facilities would opt
2067 to become 503B facilities. Now, in full disclosure, we have not
2068 seen the industry grow up the way we had hoped. We still believe
2069 it is early. And we intend to try to promulgate a set of policies
2070 that we believe that will, hopefully, provide a flexible
2071 regulatory framework based on risk that is going to allow more
2072 pharmacies to contemplate becoming 503B facilities. Because
2073 there is an argument to be made that, when a pharmacy can become
2074 a 503B facility and engage in larger-scale manufacturing, under
2075 GMP compliance standards, we are able to apply a level of oversight
2076 that ensures the sterility of the products that are being
2077 manufactured. That could, hopefully, provide for more patient
2078 access.

2079 But, with respect to the 503A facilities that were
2080 contemplated in the statute, and always enshrined in statute, that
2081 is the traditional practice of pharmacy that we believe should

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2082 be preserved and protected, and provides an important opportunity
2083 for patients to get products that are tailored to their unique
2084 clinical needs.

2085 Mrs. McMorris Rodgers. So, you anticipate that they will
2086 be preserved as you move forward, the 503A --

2087 Dr. Gottlieb. Well, they are. They are being preserved.
2088 The question becomes the scope of the activity and whether or not
2089 503A facilities can and should be engaging in larger-scale
2090 manufacturing, and manufacturing and distributing products. And
2091 we believe that DQSA contemplated a scheme where that kind of
2092 activity would move into the 503B facilities that would be subject
2093 to GMP standards, if you were engaging in manufacturing and
2094 wider-spread distribution.

2095 That is what brought us here. I mean, it was the fact of
2096 pharmacies like NECC engaging in manufacturing under the guise
2097 of a pharmacy license, not subject to standards that ensure the
2098 sterility of those products, that created the risks that brought
2099 Congress to contemplate this new framework.

2100 Mrs. McMorris Rodgers. Okay. Well, I look forward to
2101 talking further about this with you.

2102 Dr. Gottlieb. Thank you.

2103 Mr. Griffith. Will the gentlelady yield?

2104 Mrs. McMorris Rodgers. Yes. Yes, I would be happy to
2105 yield.

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2106 Mr. Griffith. And I would just ask, in relationship to 503A,
2107 because we were talking about it earlier, if that didn't
2108 contemplate office use, then why has FDA allowed it up until this
2109 point in time? Because that is existing law and was existing law
2110 before DQSA, and it was allowed.

2111 Dr. Gottlieb. Yes, I mean, it is a good question,
2112 Congressman. And I was at FDA over part of the time that we
2113 struggled with the 503A statute. As you know, after the Western
2114 States case vacated certain aspects of that law, FDA was on shaky
2115 legal ground with respect to trying to contain and implement that
2116 statute --

2117 Mr. Griffith. We know.

2118 Dr. Gottlieb. -- with the division in it.

2119 Mr. Griffith. I know, and, yes, that was, again, timid
2120 lawyering, because that just dealt with advertising. It didn't
2121 have anything to do with anything else, and it was not ruled, the
2122 question of severability was not ruled on by the Supreme Court.

2123 Dr. Gottlieb. Right. I think what the agency would have
2124 said at the time was that it had a difficult time bringing cases
2125 under that statute, and we also at the time faced a lot of pressure
2126 from Congress on the implementation of 503A. I think DQSA was
2127 not only a clarification of the statute and removed the offending
2128 provision, but was a clear declaration from Congress that you
2129 wanted the agency to be vigilant with respect to these --

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2130 Mr. Griffith. No question about being vigilant. Just we
2131 didn't anticipate eliminating something that had been in practice
2132 under the existing law that we left as the existing law.

2133 But, that being said, also, you showed the pictures of things
2134 you found as problems in compounding pharmacies, but you also
2135 found problems, which is why you do your job, in large
2136 manufacturers as well from time to time. Isn't that correct?

2137 Dr. Gottlieb. Absolutely right.

2138 Mr. Griffith. Thank you very much. I yield back.

2139 Mr. Burgess. The gentleman yields back.

2140 The Chair recognizes the gentleman from Texas for a unanimous
2141 consent request.

2142 Mr. Green. Mr. Chairman, I would also like to ask the
2143 Commissioner to submit those slides for the record.

2144 Mr. Burgess. Without objection, so ordered.

2145 [The information follows:]

2146

2147 ***** COMMITTEE INSERT 5*****

2148 Mr. Burgess. I do have one followup question that I feel
2149 compelled to ask. Because we are going to hear from a patient
2150 in the next panel, and Mr. Guthrie referenced -- I think it was
2151 Mr. Whitfield's constituent in several Congresses ago who came
2152 and talked to us about losing a spouse after the Exserohilum
2153 infection that they acquired.

2154 Does the agency have an opinion on when it is the duty of
2155 a physician or a surgery center or a hospital to inform a patient
2156 that they are receiving a medication from a compounding pharmacy
2157 as opposed to one of the other pharmacies?

2158 Dr. Gottlieb. I don't have a view on that, Congressman. I
2159 have seen survey data with respect to that, I think including data
2160 that was developed by Pew. So, I know you have a witness who can
2161 speak to that, the development of that data, on the next panel.

2162 As you know, there are labeling requirements for the products
2163 that are produced by the 503B facilities that provide warning
2164 information and certain disclosures, but not necessarily that it
2165 was a compounded product.

2166 Mr. Burgess. It doesn't escape me that the witness we had
2167 several Congresses ago, and likely the one we are going to hear
2168 from today, may very well tell us that they never had any idea
2169 what a compounding pharmacy was; they never heard of it before.
2170 And now, their lives have been seriously affected by --

2171 Dr. Gottlieb. Well, I would say that, here again, I think

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2172 this gets to the question of the prescription as a line of
2173 demarcation. Because if the prescription is the line of
2174 demarcation, if you are going into a 503A facility and getting
2175 a compounded product, you know that. If you are going into a
2176 doctor's office and you are getting a product from that doctor's
2177 office, and that was produced by a compounding pharmacy, not
2178 subject to sterility standards, you don't know that. That is why
2179 it is important, we believe, to have a mechanism in place to make
2180 sure that, when those products are being provided in that sort
2181 of de-identified way, because you no longer have that relationship
2182 to the pharmacist and understand where and how that product was
2183 manufactured, that there are standards applied for sterility to
2184 how that product was developed.

2185 Mr. Burgess. I also appreciate your comments that this is
2186 all about patient safety, and that is why we all want to get it
2187 right. We may not agree on everything on the dias here, one side
2188 or the other, but we do want to get it right. And we appreciate
2189 your efforts in trying to help us get that right.

2190 That will conclude the testimony from the first panel.

2191 Again, we are very close to a series of votes on the Floor.
2192 So, I am going to ask that we actually not take a break between
2193 panels. We will let Dr. Gottlieb gather his papers up and leave,
2194 and just take a second to put the nameplates out. But we probably
2195 better proceed directly into the second panel.

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2196 I call the subcommittee back to order.

2197 Once again, as we transition to our second panel of
2198 witnesses, I do want to thank all of our witnesses for being here
2199 and taking time to testify before the subcommittee. Each witness
2200 will have the opportunity to give an opening statement, followed
2201 by questions from members.

2202 Again, I will advise that we will recess when votes are called
2203 on the Floor.

2204 But today we are going to hear from Dr. George Williams,
2205 President-Elect of the American Academy of Ophthalmology; Dr.
2206 Bruce Brod, the Chairman of the Congressional Policy Committee
2207 for the American Academy of Dermatologists; Shawn Hodges, Vice
2208 President, International Academy of Compounding Pharmacists;
2209 Jacob Olson, the President and CEO of Skywalk Pharmacy, on behalf
2210 of the National Community Pharmacists Association; Jenn Adams,
2211 Senior Vice President, Clinical Product Solutions, PharMEDium
2212 Services; Molly Ventrelli, Vice President, Regulatory Affairs,
2213 Fresenius Kabi; Elizabeth Jungman, Director of Public Health of
2214 the Pew Charitable Trusts, and Nancy Dargan, a former patient of
2215 the New England Compounding Center.

2216 We appreciate all of you being here today.

2217 Dr. Williams, you are now recognized for 5 minutes for a
2218 summary of your opening statement.

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2219 STATEMENTS OF GEORGE WILLIAMS, PRESIDENT-ELECT, AMERICAN ACADEMY
2220 OF OPHTHALMOLOGY; BRUCE BROD, CHAIRMAN, CONGRESSIONAL POLICY
2221 COMMITTEE, AMERICAN ACADEMY OF DERMATOLOGISTS; SHAWN HODGES, VICE
2222 PRESIDENT, INTERNATIONAL ACADEMY OF COMPOUNDING PHARMACISTS;
2223 JACOB OLSON, PRESIDENT AND CEO, SKYWALK PHARMACY, ON BEHALF OF
2224 THE NATIONAL COMMUNITY PHARMACISTS ASSOCIATION; JENN ADAMS,
2225 SENIOR VICE PRESIDENT, CLINICAL PRODUCT SOLUTIONS, PHARMEDIUM
2226 SERVICES; MOLLY VENTRELLI, VICE PRESIDENT, REGULATORY AFFAIRS,
2227 FRESENIUS KABI; ELIZABETH JUNGMAN, DIRECTOR OF PUBLIC HEALTH, THE
2228 PEW CHARITABLE TRUSTS, AND NANCY DARGAN, FORMER PATIENT OF THE
2229 NEW ENGLAND COMPOUNDING CENTER

2230

2231 STATEMENT OF GEORGE WILLIAMS

2232 Dr. Williams. Chairman Burgess, Ranking Member Green, and
2233 members of --

2234 Mr. Burgess. And do be sure your microphone is on and pull
2235 it close.

2236 Dr. Williams. Is it working?

2237 Chairman Burgess, Ranking Member Green, and members of the
2238 committee, I am honored to be testifying to you on behalf of the
2239 American Academy of Ophthalmology on a topic critical to the
2240 practice of ophthalmology.

2241 My name is George Williams. I am a practicing retina
2242 specialist from Michigan. I am also the Immediate Past Secretary

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2243 of the American Academy of Ophthalmology; Secretary of Federal
2244 Affairs, and current President-Elect for the Academy.

2245 As the world's largest association of eye physicians and
2246 surgeons, the Academy seeks to protect sight and empower lives
2247 by setting standards for ophthalmic education, advocating for our
2248 patients and the public.

2249 Access to safe and effective compounded repackaged drugs is
2250 vitally important to the practice of ophthalmology. This is due
2251 in large part to the uniqueness of our specialty, as we utilize
2252 drugs in dosage forms that differ from other areas of medicine.
2253 Effective treatment often requires that drugs be compounded or
2254 repackaged in concentrations or doses that are tailored to a
2255 patient's specific needs and unusual route of administration to
2256 the eye. These drugs are used in the successful treatment of
2257 several ophthalmological treatments, including diseases that
2258 threaten sight such as age-related macular degeneration.

2259 Ophthalmology's treatment of patients facing
2260 sight-threatening diseases such as AMD requires access to drugs
2261 known as vascular endothelial growth factor inhibitors, or VEGF
2262 inhibitors. These include the FDA-approved anti-VEGF treatments
2263 ranibizumab and aflibercept, as well as repackaged bevacizumab,
2264 or Avastin. The Academy has long advocated for access to all
2265 three treatments, as individual patients may respond differently
2266 and have better outcomes with one treatment versus another.

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2267 Since the passage of the DQSA, the Academy's advocacy efforts
2268 have included focus on protecting access to repackaged Avastin.
2269 The Academy is aware of adverse event clusters associated with
2270 intravitreal injections of repackaged bevacizumab, including
2271 events in Georgia and Florida. Events like these, along with the
2272 passage of the DQSA, have led to the necessary changes at
2273 compounding pharmacies and improvements in the safety of this
2274 treatment.

2275 Because of our efforts since 2013 to track outcomes of
2276 patients who receive anti-VEGF therapies, we have been able to
2277 gather data on effectiveness and safety of these treatments. The
2278 American Academy of Ophthalmology utilized our IRIS registry,
2279 which is the nation's largest comprehensive eye disease clinical
2280 registry, to track adverse events associated with the use of these
2281 products from January of 2013 to June of 2016. These data clearly
2282 showed no statistically-significant difference in adverse events
2283 among different anti-VEGF agents, including repackaged Avastin.

2284 Today repackaged Avastin remains a safe and effective
2285 treatment option for patients facing sight-threatening disease,
2286 and Academy efforts to protect access are ongoing. The new
2287 guidance from FDA, which represented a step in the right
2288 direction, was recently finalized by the agency. The Academy
2289 will continue to engage with the agency, Congress, and compounding
2290 facilities to ensure patient access to repackaged bevacizumab.

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2291 The Academy is also concerned about continued access to other
2292 non-biologic compounds or drugs for office use. The FDA has
2293 issued final guidance on office use that we believe threatens
2294 access to compounded drugs for such use, requiring
2295 patient-specific prescriptions before a compounded drug can be
2296 distributed by a traditional compounding pharmacy. We are
2297 concerned that policy outlined in the final guidance forces
2298 practitioners to rely solely on outsourcing facilities to meet
2299 all of their needs for office-use drugs.

2300 I would like to share a few examples of how implementation
2301 of the DQSA is having some unintended consequences, is impacting
2302 access to compounded and repackaged drugs. This is why the
2303 Academy is supporting policy that ensures access to drugs for
2304 office space use, such H.R. 2871, the Preserving Patient Access
2305 to Compounded Medications Act, introduced by Congressman Morgan
2306 Griffith.

2307 I would like to discuss a patient from my state of Michigan.
2308 She is a 31-year-old lady who wears soft contact lenses and
2309 developed an infection in her eye. She was eventually determined
2310 to have a serious infection known as acanthamoeba keratitis. The
2311 standard treatment for this is the use of a drug called
2312 polyhexylmethyl biguanide. Essentially, this is pool cleaner.
2313 This was prescribed, but, unfortunately, it was not available in
2314 the state of Michigan. As a result, the patient's

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2315 ophthalmologist in Michigan was forced to contact doctors at the
2316 University of Illinois-Chicago and to obtain the drug from
2317 Chicago. However, Chicago was unable to provide the drug in
2318 Michigan, and the patient, suffering from severe eye pain, was
2319 forced to drive 225 miles from Michigan to Chicago in order to
2320 obtain this therapy. Fortunately, she responded well. But this
2321 is an example of the type of problems we have when patients cannot
2322 access immediately important therapies.

2323 The Academy has other examples of this involving the use of
2324 autologous serum drops that are given topically and have been used
2325 for more than three decades. These drugs are critical to the
2326 management of severe dry eye. However, due to compounding
2327 regulations, many compounding facilities have stopped producing
2328 these drops.

2329 In closing, ophthalmology strongly believes that compounded
2330 drugs must be produced safely and be subject to critically
2331 important testing. We do believe that regulatory policy in this
2332 arena can become restrictive and, in turn, negatively impact
2333 physicians' ability to properly and effectively treatment
2334 patients. It is important that, as implementation efforts move
2335 forward, the FDA strives to find a more balanced approach. We
2336 believe that increased direct engagement with the physician
2337 community is a strong path forward, and we look forward to future
2338 opportunities with FDA, Congress, and other stakeholders on these

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2339 important issues.

2340 Thank you.

2341 [The prepared statement of Dr. Williams follows:]

2342

2343 ***** INSERT 6*****

2344

Mr. Burgess. Thank you, Dr. Williams.

2345

Dr. Brod, 5 minutes for an opening statement, please.

2346 STATEMENT OF BRUCE BROD

2347

2348 Dr. Brod. Thank you, Chairman Burgess, Ranking Member
2349 Green, and members of the Health Subcommittee.

2350 I am Dr. Bruce Brod. I am pleased to share with you my
2351 perspective as a dermatologist, a view that is shared by the
2352 American Academy of Dermatology Association.

2353 Dermatologists rely heavily on compounded medications that
2354 are medically necessary and life-changing. We safely and
2355 effectively prepare and administer low-risk topical and
2356 intralesional compounded medications to a wide range of patients,
2357 including individuals presenting with special and emergent needs
2358 and persons suffering from rare diseases, including children.

2359 Current policy adversely affects the practice of medicine
2360 in two significant ways, the first being with respect to
2361 maintaining a small supply of office-use compounded medications
2362 for administration to patients in our offices. Dermatologists
2363 have historically obtained compounded medications from 503A
2364 compounding pharmacies for immediate use in the office without
2365 the need for a patient-specific prescription. However, current
2366 policy now restricts this. While we understand the FDA intended
2367 503B outsourcing facilities to be a meaningful resource for
2368 providing physicians with office-use stock, not all office-use
2369 compounded medications used by dermatologists are produced by

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2370 503Bs, including non-sterile topicals as well as sterile
2371 intralesional drugs used for injection in the skin.

2372 The FDA's website reflects a partial list of drugs that
2373 registered outsourcing facilities have reported producing,
2374 starting December 2016, but ending May 2017. So, the list is
2375 retrospective and it is incomplete, and it doesn't indicate if
2376 these drugs will be produced in the future. Furthermore, we have
2377 no indication that 503Bs will provide flexibility in the various
2378 concentrations that we use in our offices.

2379 The FDA lists only the facilities that are registered. Yet,
2380 it doesn't contain any contact information, real-time product
2381 availability information, or price listing. So, physician
2382 practices literally must go on a scavenger hunt for these needed
2383 compounds. In addition, dermatologists have reported that the
2384 outsourcing facilities have quoted prices that are
2385 cost-prohibitive.

2386 If a compounded drug is not available from an outsourcing
2387 facility, a patient now requires, first, a trip to the physician
2388 office for evaluation and diagnosis, then a trip to the pharmacy
2389 to obtain the prescription, and then, thirdly, a followup visit
2390 back to the physician to finally have the treatment administered.
2391 Those two additional steps impose new burdens on the patient,
2392 delayed treatment, and create inefficiencies in our practices.

2393 When compounded medications are handled outside of a

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2394 provider's control, there are also major safety concerns
2395 regarding proper storage, handling, and application. When the
2396 dermatologist cannot be sure how it has been stored between
2397 patient pickup at the pharmacy and administration in the office,
2398 it calls into question the integrity of the medication.

2399 An additional safety concern is the risk that patients may
2400 be tempted to self-administer the drugs prior to returning to the
2401 physician's office. Many of the powerful compounds in
2402 dermatology are used to destroy unwanted malignant and benign skin
2403 lesions. And so, if they are spilled on the skin by patients,
2404 they will cause scarring and disfigurement.

2405 The second way current policy adversely affects the practice
2406 of medicine pertains to dermatologists' preparation of low-risk
2407 sterile and non-sterile medications in the office setting.
2408 Because of the FDA's broad definition of compounding, many simple
2409 in-office preparations are considered compounding. Buffering
2410 lidocaine, for example, is a widely-used local anesthetic in
2411 dermatologic procedures. Without our ability to buffer
2412 lidocaine with sterile sodium bicarbonate, patients, including
2413 children, will endure painful injections of lidocaine. Using the
2414 buffered lidocaine allows us to perform very extensive skin cancer
2415 surgeries in an outpatient office setting without the risks and
2416 costs of sedation.

2417 Because the FDA considers reconstituting certain

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2418 FDA-approved neurotoxins with sterile saline to be compounding,
2419 the FDA's proposed guidelines imply that physician offices are
2420 compounding facilities, subject to the same equipment and process
2421 requirements as high-volume compounders. Many of those
2422 requirements are simply unworkable for dermatology offices, both
2423 structurally and financially.

2424 Accordingly, we are encouraged that the FDA mentions routine
2425 clinical practice and negligible patient risk in its 2018
2426 Compounding Policy Priorities Plan, which states that providers
2427 would not be subject to the same compliance policy in certain
2428 cases. The manner in which we routinely buffer and dilute our
2429 injectable medications in dermatology is really part of our normal
2430 practice of medicine.

2431 While we greatly appreciate the FDA and U.S. Pharmacopeia
2432 are working with medical specialties to explore an urgent-use
2433 exemption, we have real concerns that an exemption based on a
2434 restrictive timeframe will negatively affect patient access.
2435 The well-being of our patients is our primary concern and
2436 responsibility. On behalf of the American Academy of Dermatology
2437 Association, I want to thank you for holding this hearing, and
2438 I am happy to address any questions.

2439 [The prepared statement of Dr. Brod follows:]

2440

2441 ***** INSERT 7*****

2442

Mr. Burgess. Thank you, Dr. Brod.

2443

Mr. Hodges, you are recognized for 5 minutes, please.

2444 STATEMENT OF SHAWN HODGES

2445

2446 Mr. Hodges. Yes, sir. Yes, sir. Good afternoon,
2447 committee members.

2448 Mr. Chairman and members of the subcommittee, my name is
2449 Shawn Hodges, a pharmacist and owner of Innovation Compounding,
2450 a compounding-only pharmacy located in Kennesaw, Georgia, just
2451 outside of Atlanta. I also serve as the Vice President of the
2452 International Academy of Compounding Pharmacists, IACP, an
2453 organization that represents more than 4,000 pharmacists,
2454 technicians, students, and members of the compounding community
2455 who focus on the specialty of pharmacy compounding. I would like
2456 to express my gratitude and appreciate to the Health Subcommittee
2457 for taking the time to understand compounding pharmacy and patient
2458 access issues from a pharmacist's perspective with the
2459 implementation of DQSA.

2460 In 2012, a pharmacy owner who lost sight of his moral compass
2461 and violated his oath as a practicing pharmacist violated both
2462 state and federal laws and regulations related to quality and
2463 safety. As a result, more than 60 lives were lost and hundreds
2464 more fell ill, some to this day, nearly five-and-a-half years
2465 later. As compounders, our top priority is adhering to the
2466 highest-quality compounding standards to prevent something like
2467 this from happening again.

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2468 Since NECC, all regulatory bodies have made a concerted
2469 effort to improve the practice of pharmacy. In November of 2013,
2470 the DQSA was signed into law, somewhat clarifying the FDA's joint
2471 authority with the state boards of pharmacy, to monitor the
2472 quality of pharmacy compounding. State boards of pharmacy also
2473 updated pharmacy regulations and hired additional state
2474 inspectors to monitor and inspect compounding pharmacies. USP,
2475 the organization that sets the standards for governing
2476 compounding pharmacies, is revising its standards to continue to
2477 ensure best practices of pharmacy compounding, which can reduce
2478 the risk of harm to patients and compounding pharmacy employees.

2479 As DQSA is well into its fourth year, I would also like to
2480 share with the committee what the professional compounding
2481 pharmacy has experienced and provide suggestions on how all
2482 pharmacies, state boards, and the FDA can actually strengthen DQSA
2483 while protecting access to lifesaving compounded preparations.
2484 As I rely the suggestions of IACP and other key pharmacy
2485 stakeholders, please note that our overall goal is to encourage
2486 an open, transparent dialog with all stakeholders, public and
2487 private. We strive to work closely with FDA in developing an
2488 appropriate balance between regulating quality and safety without
2489 eliminating patient access.

2490 Pharmacies which are compliant and meet USP guidelines and
2491 state board of pharmacy rules fear that FDA overreach will impact

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2492 patient care. This fear has been substantiated by actions of FDA
2493 investigators. My pharmacy team experienced this firsthand in
2494 an FDA inspection that lasted for 11 days over a period of 4 months.

2495 It is important to acknowledge that the FDA investigations
2496 were fulfilling their assigned duties and expressed a keen
2497 interest in the quality of our preparations. For that, I had the
2498 utmost respect for them. However, many requests about our
2499 pharmacy had little to do with the quality of our compounded
2500 preparations, but were, rather, in how we operated our pharmacy
2501 practice that is regulated by the boards of pharmacy. Luckily,
2502 our pharmacy team employed attorneys who are knowledgeable of both
2503 state and federal pharmacy laws and regulations to advise FDA that
2504 they were inspecting outside the scope given to them under the
2505 law. Many of our fellow compounding pharmacists have had similar
2506 experiences.

2507 I would also like to share IACP's concerns as it relates to
2508 the memorandum of understanding between FDA and the states, which
2509 could limit patient access for preparations that are only
2510 available across state lines. Last week we were encouraged by
2511 Commissioner Gottlieb's 2108 Compounding Policy Priorities Plan
2512 that states he would rescind the current draft MOU and prepare
2513 a new draft for public comment. However, we still remain
2514 concerned that the FDA proposes to define distributing and
2515 dispensing as one and the same. As noted in all other federal

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2516 and state regulations, these are two distinct activities. If
2517 this is not corrected, the impact on patient access to medications
2518 will be detrimental, particularly for patients near state borders
2519 who rely on compounded medications from neighboring states.

2520 Another of our primary considerations for review is the role
2521 of office-use compounding. I regularly hear from prescribers who
2522 need compounded medications for office use that they cannot obtain
2523 from outsourcing facilities in small dosages necessary to
2524 expeditiously meet patients' needs. The fundamental concept of
2525 office use from 503A pharmacies offers solutions to prescribers
2526 who are faced with unique challenges, whether a dentist needs a
2527 fast-acting, liquid anti-anxiety drug on hand in case an autistic
2528 child may have a panic attack or a hospice nurse that suddenly
2529 needs a compounded nausea medication because she has
2530 terminally-ill patient who is not responding to a manufactured
2531 product. The purpose of office use is to support prescribers who
2532 otherwise do not have access to a GMP product.

2533 In closing, we at IACP want to be clear that our goal isn't
2534 to interfere with FDA's inspections on quality, but to ensure that
2535 FDA investigators who inspect compounding pharmacies are aware
2536 of and spec within the boundaries of FDCA. They also must have
2537 a working knowledge of USP standards and relevant state
2538 regulations. Likewise, we don't seek to weaken the DQSA in a way
2539 that will allow pharmacies to operate as drug manufacturers. Our

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2540 goal is to have an open and consistent dialog with Congress and
2541 the FDA to establish policies that more effectively balance
2542 patient safety with patient access, because patient access is a
2543 patient safety issue.

2544 We thank you for the opportunity to appear here today and
2545 provide our input, and we do look forward to continuing to work
2546 with you on these common goals.

2547 [The prepared statement of Mr. Hodges follows:]

2548

2549 ***** INSERT 8*****

2550 Mr. Burgess. Thank you, Mr. Hodges.

2551 Mr. Olson, you are recognized for 5 minutes. And because
2552 a vote has been called, we will take your testimony, and then,
2553 we will have to recess until after the votes. So, you may proceed.

2554 STATEMENT OF JACOB OLSON

2555

2556 Mr. Olson. Thank you. Thank you, Chairman Burgess,
2557 Ranking Member Green, and members of the subcommittee. Thank you
2558 for conducting this hearing on compounding.

2559 My name is Jake Olson, and I am the pharmacist and owner of
2560 Skywalk Pharmacy. We have four locations in the greater
2561 Milwaukee area, serving patients of Children's Hospital of
2562 Wisconsin and clinics. I am testifying on behalf of the National
2563 Community Pharmacists Association. NCPA represents America's
2564 community pharmacists, including the owners of more than 22,000
2565 independent community pharmacies that dispense nearly half of the
2566 nation's prescriptions.

2567 In 2003, I had the unique opportunity to open Skywalk
2568 Pharmacy as an independently-owned community pharmacy which would
2569 serve as the outpatient pharmacy for the Children's Hospital of
2570 Wisconsin, the first of its kind in the United States. My
2571 pharmacies specialize in treating pediatric patients with routine
2572 ear infections to cystic fibrosis, cancer, and organ transplants.
2573 I compound only non-sterile preparations and I am compliant with
2574 USP 795 standards. I am licensed only in Wisconsin. I do not
2575 ship compounded medications across state lines, and compounding
2576 comprises 20 percent of my business.

2577 Many of my pediatric patients have health conditions that

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2578 require medications that have not undergone FDA approval. In
2579 many cases drug manufacturers do not produce a
2580 commercially-available product in the necessary dosage form or
2581 strength for these patients' needs. Physicians call on me to help
2582 under these circumstances when compounding is the only option for
2583 their patients.

2584 I am here today as a healthcare provider and small business
2585 owner to present some of my experiences and those of my fellow
2586 independent pharmacists regarding the FDA's implementation of the
2587 Compounding Quality Act.

2588 First, it is imperative the state boards of pharmacy retain
2589 oversight of pharmacy compounding. I am not eligible to register
2590 as an outsourcing facility, nor would it make sense for me to do
2591 so. The dispensing of custom-made medications should continue
2592 to be regulated by the boards of pharmacy, as all other medical
2593 license profession practices are.

2594 Second, physician office-use compounding needs are not being
2595 met. We used to provide compounds for dentists to treat pediatric
2596 patients who would present with urgent issues. However, we
2597 stopped doing this in 2013 due to the uncertainty caused by DQSA
2598 and conflicting Wisconsin state law. Dentists still request this
2599 compounded medication to be on hand in the event that a patient
2600 needs this treatment. Because I am no longer providing dentists
2601 with this office-use compound, the dentist now has to close up

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2602 the tooth, have the patient leave, come down to my pharmacy, pick
2603 up a prescription, and then, return to the dentist. This cannot
2604 happen in the same day. So, the child will continue with an
2605 infected tooth until the dentist can reschedule an appointment.
2606 Most of these patients are innercity children with Medicaid.
2607 Transportation is a huge issue, and sometimes it will take a week
2608 or longer to get them to come back. All the while, the child is
2609 suffering.

2610 Third, not all office-use compounding needs can be met by
2611 outsourcing facilities. 503B outsourcing facilities provide an
2612 important function in meeting the needs of healthcare providers
2613 and patients. However, outsourcing facilities are not able to
2614 meet the entire office-use market, nor are they able to replace
2615 the role of the traditional compounding pharmacies.

2616 Because of the requirements placed on outsourcing facilities
2617 and the costs of complying with CGMP, they are not able to compound
2618 in small batches; thus, limiting the role they can play in meeting
2619 the immediate patient needs for compounds. By prohibiting 503A
2620 pharmacies to compound for office use, the FDA is severely
2621 limiting access.

2622 Fourth, FDA needs to end inspection reporting discrepancies
2623 between manufacturers and compounding pharmacies. I often hear
2624 from my fellow compounders who have been inspected by the FDA about
2625 the 483 reports that may be issued post-inspection and posted

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2626 publicly, like they were today, on FDA's website. I don't
2627 understand why these same reports are not also publicly posted
2628 for FDA-registered facilities. While FDA publicizes Form 483s
2629 and photographs from compounding pharmacy inspections, there is
2630 evidence of several of the same observations from CGMP
2631 manufacturers with no corresponding publicity. This treatment
2632 suggests there is intent by the FDA to sway the public and
2633 undermine the confidence that parents have in my ability to take
2634 care of their child's medications.

2635 Fifth, the FDA must make changes to the Pharmacy Compounding
2636 Advisory Committee and related activities. I am very concerned
2637 that not one of the voting members of the committee compounds for
2638 human use on a daily basis, considering the committee is making
2639 recommendations that can vastly impact the practice of
2640 compounding. The previous FDA PCAC had at least three
2641 pharmacists with current experience and expertise in compounding.
2642 The FDA should select, at minimum, one practicing human compounder
2643 on the committee as a voting member.

2644 Lastly, it is very confusing for me, as a compounder, to
2645 understand what I can or cannot compound with today because of
2646 some of the conflicting information.

2647 In summary, NCPA is committed to working with members of the
2648 Health Subcommittee, the FDA, and other stakeholders regarding
2649 these important matters for a balanced approach to ensuring

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2650 patient access to safe and effective compounded medications.

2651 Thank you.

2652 [The prepared statement of Mr. Olson follows:]

2653

2654 ***** INSERT 9*****

2655 Mr. Burgess. Thank you, Mr. Olson.

2656 And I apologize, we were only able to get through half the
2657 panel. We will get to the rest of you immediately after this
2658 series of votes. It will probably take us 30 minutes to complete
2659 that task.

2660 So, the committee stands in recess until immediately after
2661 the votes.

2662 [Recess.]

2663 Mr. Burgess. I think to be respectful of everyone's time,
2664 I am going to call the subcommittee back to order. We are
2665 expecting other members to show up almost immediately.

2666 But as we recessed for votes, we were about to hear from Jenn
2667 Adams, the Senior Vice President, Clinical Products Solutions
2668 from PharMEDium Services. So, Ms. Adams, you are recognized for
2669 5 minutes.

2670 STATEMENT OF JENN ADAMS

2671

2672 Ms. Adams. Thank you. Chairman Burgess, Ranking Member
2673 Green, and members of the subcommittee, thank you for the
2674 opportunity to participate in today's hearing.

2675 My name is Jenn Adams, and I am the President of PharMEDium
2676 Services. On behalf of PharMEDium, I want to thank you for
2677 holding this hearing on the implementation of the Compounding
2678 Quality Act, which Congress enacted as a part of the Drug Quality
2679 and Security Act of 2013.

2680 PharMEDium, which is a subsidiary of AmerisourceBergen,
2681 operates four 503B registered outsourcing facilities. I want to
2682 briefly describe, as we begin, what PharMEDium does, as our
2683 business models tracks exactly what Congress codified in the
2684 Compounding Quality Act. Our four facilities prepare
2685 ready-to-administer compounded sterile drugs for hospitals, so
2686 that they don't have to prepare these medications at a patient's
2687 bedside under conditions that could introduce more risks of
2688 contamination.

2689 Many sterile drugs, such as injectables, in their
2690 FDA-approved form are not manufactured in ready-to-use doses.
2691 Therefore, the drugs have to be prepared by diluting or admixing
2692 the FDA-approved drug with diluents or other components to achieve
2693 the appropriate dose for patient care. We prepare these sterile

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2694 drugs into customized preparations, as ordered by our hospital
2695 customers. And this is the primary need that outsourcing
2696 facilities fulfill. And PharMEDium exclusively compounds using
2697 only FDA-approved sterile drugs obtained from registered drug
2698 manufacturers. This practice fills a very different role than
2699 that of traditional pharmacy compounding, which involves filling
2700 an individual patient prescription as required by law.

2701 Based on our experience in serving the needs of hospitals
2702 and healthcare systems, outsourcing facilities anticipate the
2703 need for drug preparations. We compound those preparations on
2704 behalf of our customers, and then, our customers dispense the
2705 medications to their patients. The types of drug preparations
2706 that are compounded are, by definition, not available from
2707 manufacturers; therefore, requiring these more custom
2708 formulations to meet the clinical needs of patients.

2709 Both of these distinct types of compounding, by outsourcing
2710 facilities and also by traditional pharmacies, we believe are
2711 critical in ensuring that patients have access to safe compounded
2712 medications when needed.

2713 PharMEDium was, and remains, an active supporter of DQSA
2714 because we felt strongly that more oversight of our industry was
2715 needed. The premise of the DQSA is that outsourcing facilities
2716 are subject to FDA oversight and more stringent quality
2717 requirements. And as our industry shifts more toward

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2718 manufacturing quality standards, significant investment has been
2719 and is required in our facilities, personnel, and equipment to
2720 comply with these heightened standards. At PharMEDium our
2721 investment has, indeed, been quite significant, and the
2722 enhancements we have made have been challenging to implement, but
2723 we are confident that these improvements are in the best interest
2724 of patients and we are committed to continuing on this path in
2725 cooperation with the FDA.

2726 Unfortunately, the successful implementation of Section
2727 503B is under a separate threat; namely, from the misuse of bulk
2728 drug substances. I mentioned earlier that PharMEDium only
2729 compounds from FDA-approved drugs, as opposed to starting from
2730 bulk drug substances, which are sometimes referred to as bulk
2731 active pharmaceutical ingredients, or API powders.

2732 There are, indeed, circumstances in which it is sometimes
2733 necessary to compound from bulk drug substances, such as when an
2734 individual patient requires a dose that cannot be achieved when
2735 using the FDA-approved manufactured drug as a starting point.
2736 But using bulk powders and outsourcing facilities should be the
2737 rare exception versus the rule, as it requires using a version
2738 of the drug that has not gone through the FDA approval and,
2739 therefore, has not benefitted from all of the safeguards that are
2740 inherent to FDA's drug approval process, which are designed to
2741 mitigate the risks of contamination.

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2742 As a result, under the law, bulk powders are only to be used
2743 when clinically necessary and not simply substituted for the
2744 FDA-approved version of the drug. Nevertheless, right now we are
2745 witnessing rampant compounding from bulk drug substances in the
2746 marketplace, usually lacking any clinical justification, even for
2747 sterile drugs. This is particularly concerning because using
2748 bulk drug substances is much less expensive for the compounder;
2749 therefore, undercutting demand for the actual approved drugs and
2750 creating a loophole for compounders to circumvent the drug
2751 approval process.

2752 In light of these and other risks, we remain concerned about
2753 the rapid uptake of bulk drug substance powders in place of
2754 FDA-approved drugs. As we have learned from history, which
2755 demonstrated the tragic impact of poor compounding practice, FDA
2756 should make every effort to implement the DQSA in a manner that
2757 preserves patient access to important compounded medications and
2758 that eliminates opportunities to perform an end-run around clear
2759 restrictions of the law.

2760 While we commend FDA's overall efforts to implement DQSA,
2761 the agency has not tamped down on this rapidly growing abuse of
2762 bulks. Its release of an overly broad interim list of permissible
2763 drug bulk substances and its final guidance on what amounts to
2764 impermissible copies of approved drugs fail to call out these
2765 practices and will not curb these abuses. We appreciate,

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2766 however, that FDA announced that it would be releasing a separate
2767 draft guidance in March clarifying that bulk drug substances may
2768 only be used for compounding when there is a clinical need to
2769 compound drugs using these substances. FDA conformed that this
2770 restriction protects patient health and the drug approval
2771 process, for example, by helping to ensure that outsourcing
2772 facilities do not compound using a bulk drug substance when an
2773 FDA-approved version can be used to meet patient medical needs.

2774 While this acknowledgment is important, it is even more
2775 important that FDA follow this statement up with the promised
2776 guidance as soon as possible, revise the guidance on copies,
2777 communicate this message to providers who may not be aware of the
2778 undisclosed use of bulks, and to rigorously enforce these
2779 restrictions. In order to ensure that patients have a reliable
2780 and safe source of sterile compounded preparations, it is also
2781 important that FDA continue to move forward as quickly as possible
2782 in finalizing other 503B policies that will provide certainty and
2783 clarity to the outsourcing industry providers and patients. In
2784 particular, the lack of final GMP standards for outsourcing
2785 facilities has exacerbated ongoing confusion among state
2786 regulators, many of whom continue to impose expectations that
2787 differ from that of FDA's.

2788 Key congressional proponents champion the DQSA as clarifying
2789 the role of the states in regulating traditional compounding, and

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2790 outsourcing to be regulated at the federal level. That vision
2791 has not yet been fully realized.

2792 Again, thank you for the opportunity to contribute to this
2793 important dialog. I appreciate it, and I look forward to your
2794 questions.

2795 [The prepared statement of Ms. Adams follows:]

2796

2797 ***** INSERT 10*****

2798

Mr. Burgess. Thank you, Ms. Adams.

2799

Ms. Ventrelli, you are recognized for 5 minutes, please.

2800 STATEMENT OF MOLLY VENTRELLI

2801

2802 Ms. Ventrelli. Thank you. Chairman Burgess, Ranking
2803 Member Green, and members of the subcommittee, thank you for the
2804 invitation to testify today.

2805 My name is Molly Ventrelli, and I am Vice President of
2806 Regulatory Affairs for Fresenius Kabi USA. Fresenius Kabi is a
2807 global healthcare company specializing in lifesaving medicines
2808 and technologies for infusion, transfusion, and clinical
2809 nutrition. We manufacture most of these medicines in Illinois,
2810 New York, and North Carolina, and we employ more than 3,000 people
2811 in the U.S. Additionally, Fresenius Kabi operates 18 compounding
2812 centers around the world, and we are in the process of launching
2813 our first U.S.-based 503B compounding center in a suburb of
2814 Boston.

2815 We commend FDA's implementation of the DQSA, and we believe
2816 that FDA must continue to enforce the strong protections of the
2817 DQSA against illegal or improper compounding activity. Patient
2818 safety requires strict FDA oversight on outsourcing facility
2819 compounding by pharmacies that do not comply with FDA regulations
2820 and do not meet the highest standards for quality and CGMP.

2821 Drug compounding plays an important role in the delivery of
2822 health care by allowing a pharmacist, by a patient-specific
2823 prescription, to tailor a therapy for an individual's unique

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2824 needs. But it is critical to ensure the safety of patients
2825 receiving these compounded medications. Congress recognized
2826 this in drafting the DQSA and established the two regulatory
2827 structures, both 503A and 503B. Pharmacies that operate under
2828 503A are those that compound according to specific prescriptions
2829 unique to a patient under state board of pharmacy oversight. They
2830 do not compound large quantities in advance of a patient
2831 prescription.

2832 However, Congress also recognized that some hospitals and
2833 healthcare providers may need supplies of medications not made
2834 by pharmaceutical manufacturers or not made in a specific dosage
2835 form, combination, or strength that is medically required for
2836 patients. These products, which need to be on hand, represent
2837 unique safety concerns, as they are typically made in larger
2838 volumes. So, if they become contaminated or are produced
2839 incorrectly, more patients are exposed to harm. Congress
2840 required that these 503B facilities adhere to CGMP, rigorous
2841 requirements enforced by the FDA, with a full set of quality
2842 standards for the manufacturing, processing, packing, release,
2843 testing, and storage of pharmaceutical products.

2844 It is important to note that 503B outsourcing facility
2845 compounders may not make a drug that is essentially a copy of an
2846 approved medicine except under certain highly limited
2847 circumstances like drug shortages. One key reason Congress

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2848 included this was to preserve incentives for traditional
2849 manufacturers to continue to pursue FDA approval through the
2850 current NDA and ANDA review process. This protects patient
2851 safety and should be upheld.

2852 We support the FDA's efforts to ensure patient safety by
2853 timely inspecting 503B compounders and issuing compliance
2854 guidance. Fresenius Kabi is currently addressing this now at our
2855 site in Massachusetts.

2856 We also commend the FDA for its continued risk-based
2857 inspections of unregistered compounding pharmacies. FDA's
2858 enforcement of 503A is also important to ensure that facilities
2859 that are essentially acting as outsourcers by selling significant
2860 amounts of commercially unavailable compounded sterile drugs in
2861 the absence of patient prescriptions should register as 503B
2862 outsourcers. In the interest of public health, the safety and
2863 manufacturing standards of compounders should be held to rigorous
2864 standards to ensure patient safety.

2865 Additionally, to uphold patient safety, Congress sought to
2866 ensure that FDA-approved drugs would be used as source material
2867 by compounders whenever possible. Under the DQSA, compounders
2868 should not use bulk active pharmaceutical ingredients as an
2869 alternative to compounding from an FDA-approved medicine unless
2870 doing so would produce a clinical difference for an identified
2871 patient. Fresenius Kabi believes that there could be instances

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2872 where several 503B outsourcing compounders are doing exactly this
2873 in contravention of federal law. It is our strong recommendation
2874 that the committee support FDA's rigorous oversight of
2875 pharmaceutical compounding.

2876 Thank you for holding today's hearing, and I welcome any
2877 questions you may have. Thank you.

2878 [The prepared statement of Ms. Ventrelli follows:]

2879

2880 ***** INSERT 11*****

2881

Mr. Burgess. Thank you, Ms. Ventrelli.

2882

Ms. Jungman, you are recognized for 5 minutes, please.

2883 STATEMENT OF ELIZABETH JUNGMAN

2884

2885 Ms. Jungman. Good afternoon. I am Elizabeth Jungman,
2886 Director of Public Health Programs at the Pew Charitable Trusts.
2887 We are an independent, nonpartisan research and public policy
2888 organization with a longstanding focus on drug quality, including
2889 compounding. I want to thank you for holding this important
2890 hearing.

2891 This committee has a long history of working to protect
2892 Americans from the risk of substandard compounded drugs. Five
2893 years ago, even before we knew the full scope of the fungal
2894 meningitis outbreak, your oversight team investigated how the
2895 crisis began, and you worked with the Senate and across party lines
2896 to pass the DQSA. This legislation is making a difference.

2897 Today I will stress the importance of preserving it.
2898 Efforts to weaken the DQSA pose very real risks for patient safety.
2899 I will also share some new findings showing that DQSA is spurring
2900 better compounding oversight in the states.

2901 I was privileged to be among the Senate committee staff that
2902 helped develop the DQSA. We knew then the provisions would be
2903 met with resistance, but each round of negotiations started with
2904 a new count of illnesses and deaths, and it was a powerful
2905 motivator to push past that controversy and get the job done.

2906 The meningitis outbreak is, of course, not the only case of

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2907 harm. As we have heard today, just last year 43 people in Texas
2908 had contaminated antibiotics injected into their eyes and several
2909 suffered vision loss. Also, last year 41 patients received
2910 contaminated injections in a New Jersey clinic. They developed
2911 joint infections caused by microorganisms that should only be
2912 found in human mouths.

2913 Americans expect their government to play a major role in
2914 making food and drugs safe. Eighty-seven percent of Americans
2915 think that, according to a Pew Research Center survey.

2916 FDA evaluates the safety and effectiveness for most drugs
2917 and sets manufacturing quality standards, but compounded drugs
2918 are not subject to those protections, and, thus, should only be
2919 used when commercial alternatives won't work. There is a big
2920 difference between drugs prepared for a single patient who will
2921 use it immediately and drugs prepared in bulk quantities for use
2922 at some undetermined future date.

2923 Compounding for a single patient is a traditional part of
2924 pharmacy practice. The risks of dangerous contamination are
2925 relatively low and the impact for errors is contained. States
2926 oversee patient-specific compounding and mandate quality
2927 standards.

2928 But, if compounded drugs are going to be kept onhand,
2929 so-called office stock, the risks are greater. They are often
2930 stored for some period of time, increasing the chance that

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2931 contaminates like bacteria and fungus can grow. And since they
2932 are not tailored to specific patients, they products are
2933 frequently produced in bulk, multiplying the consequences of any
2934 error.

2935 That is why Congress created outsourcing facilities. In
2936 exchange for meeting appropriate manufacturing standards,
2937 outsourcing facilities can compound drugs without prescriptions.
2938 Congress has decided twice, first 20 years ago and again in 2013,
2939 that traditional compounding should require a patient-specific
2940 prescription. If compounders want to sell stock supplies, they
2941 must invest in the equipment, training, and specialized personnel
2942 necessary to mitigate the risk. That dividing line between stock
2943 supply and individual prescription creates accountability.

2944 This committee's investigation demonstrated the importance
2945 of clear and enforceable lines, so that facilities and their
2946 regulators know who is responsible for oversight and what rules
2947 apply. The prescription requirement is very clear. Either a
2948 patient's name is on the product or it is not.

2949 While FDA regulates outsourcing facilities, states are still
2950 the primary regulator of traditional pharmacies, and they play
2951 an important role in ensuring the safety of compounded drugs. In
2952 2014, Pew convened an advisory committee of pharmacy regulators,
2953 state pharmacy regulators, and other compounding experts to
2954 identify best practices for states. Next month, Pew, together

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2955 with the National Association of Boards of Pharmacy, will release
2956 a 50-state assessment.

2957 I am happy to say that most states now conform to best
2958 practices in two key areas. First, states are widely adopting
2959 quality standards that have been established by the USP, the
2960 United States Pharmacopeia. And second, states are aligning with
2961 federal law on the prescription requirement.

2962 However, there is more work to be done. Ideally, states
2963 should inspect compounding pharmacies every year, but our study
2964 showed that we haven't met this mark. That is why state and
2965 federal regulators must prioritize the most risky operations.

2966 To wrap up, since the DQSA became law, states have made
2967 important changes, and other stakeholders like outsourcing
2968 facilities have made significant investments, too. To avoid
2969 undermining that progress, Congress and the FDA must continue to
2970 protect, implement, and enforce the DQSA.

2971 Five years ago, this committee acted boldly to draw clear
2972 lines that protect patients from another tragedy. This hearing
2973 reminds us of why we need that law and what could happen if it
2974 is weakened.

2975 I welcome any questions.

2976 [The prepared statement of Ms. Jungman follows:]

2977

2978 ***** INSERT 12*****

2979

Mr. Burgess. Thank you, Ms. Jungman.

2980

Ms. Dargan, you are recognized for 5 minutes, please.

2981 STATEMENT OF NANCY DARGAN

2982

2983 Ms. Dargan. Thank you. Good afternoon, and thank you for
2984 the opportunity to be here today.

2985 My name is Nancy Dargan and I live in Brighton, Michigan.
2986 I am going to tell you how a contaminated compounded medication
2987 permanently harmed my health, putting a premature end to my career
2988 and ruining my family's finances and plans for our future.

2989 To begin my story, I have to travel back to early 2012. I
2990 was experiencing pain from arthritis in my back and hip, and my
2991 primary physician referred me to a pain clinic for periodic
2992 injections of a steroid called methylprednisolone, which is a
2993 compounded product.

2994 The shots gave me some relief and I continued my busy career,
2995 my life as a grant-writer, a business consultant. And everything
2996 changed that August. I had driven from my home in Michigan to
2997 West Virginia to meet with a new client and help them set up a
2998 nonprofit organization. During my stay I began to feel sick, but
2999 I didn't think very much of it at first. But the symptoms steadily
3000 worsened and I realized I had to cut my trip short.

3001 As I drove home, an excruciating burning sensation developed
3002 in my right hip spreading down to my knee. The pain became so
3003 unbearable that I had to use my left foot for gas and brakes. I
3004 arrived in Michigan completely unable to bear weight on my leg,

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3005 and my husband took me immediately to the hospital to figure out
3006 what was going on.

3007 The doctors ordered x-rays, a spinal tap, a biopsy, and
3008 several other tests and expressed that my condition was something
3009 they had not seen before. They worked to treat my pain, but,
3010 initially, had no clear diagnosis. So, they sent me home.

3011 It was there that I got a call from the pain clinic that had
3012 administered my steroid injections. They said I potentially
3013 received contaminated drugs and should go to the emergency room
3014 immediately.

3015 By this time, the hospital staff were realizing that my case
3016 was not an isolated incident. Other patients were showing up at
3017 the hospital with infections and pains similar to mine, and like
3018 several of them, I was ultimately diagnosed with a fungal
3019 infection.

3020 I underwent surgery and spent two weeks in the hospital. I
3021 was placed on a maximum dose of a drug called Voriconazole, a very
3022 powerful antifungal medicine with severe side effects that seemed
3023 nearly as bad as death itself. I took it four times a day for
3024 14 months, even waking in the middle of the night for doses.

3025 After I was discharged, my husband Mike became my caretaker,
3026 at great personal expense to him, both mentally and physically.
3027 His job was one of the worst a care partner can experience, dealing
3028 with the unknown effects of a major medical event. I can't tell

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3029 you how many times Mike would come into the room and I would be
3030 carrying on a conversation with my daughter, who had died in 1979.
3031 That was the result of hallucinations caused by the antifungal
3032 medication. I would call out for our pet, and I would get
3033 frustrated because he wouldn't respond, and we had had him put
3034 down the year before due to cancer.

3035 Through all this nightmare, Mike made sure that I made it
3036 to every doctor's appointment, even often three or four per week,
3037 on top of other tests, including blood draws every Friday. If
3038 something needed to be done, including our household chores, he
3039 did it. If something needed to be done around the house, he never
3040 left my side unless I was napping and he could get errands run.
3041 He was not only my caregiver, but my constant advocate.

3042 Of course, all of this has had a devastating impact on our
3043 lives and plans for the future. Financially, we have lost
3044 everything to this event. The hospital and doctor bills were
3045 astronomical. I lost my ability to maintain self-employment and,
3046 regrettably, had to close my business and refer my clients to
3047 others.

3048 We had partial ownership in a cabin left to my husband and
3049 his sister by his father, but had to sell our interest in this
3050 treasured family property which we enjoyed so much and which had
3051 such wonderful memories for my husband. I saw the grief in Mike's
3052 eyes every time we had to sell something he loved. The financial

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3053 toll has threatened our retirement and our independence as we grow
3054 older together.

3055 Today, five years after this tragedy began, I still have
3056 recurring symptoms and numerous side effects. I walk with a limp
3057 and cannot get an orthopedic surgeon to consider replacing my
3058 right hip because there are still fungal pockets on my bones. My
3059 pain levels are always elevated. My disease and treatment have
3060 made me vulnerable to opportunistic infections that have attacked
3061 my kidneys and my sinuses, and I still continue to suffer from
3062 short-term memory loss, and it is getting worse every year.

3063 Before this happened to me, I had never heard of drug
3064 compounding, and I never would have imagined coming to Washington
3065 to speak about it. But I feel obligated to do so. Sadly, there
3066 are many others who have endured as much suffering and more. I
3067 weep for the 60-plus families who lost their loved ones to this
3068 deadly and preventable outbreak and for the hundreds of patients
3069 who live every day with the lasting consequences of illnesses
3070 caused by contaminated compounded drugs. Many of these people
3071 are friends and neighbors who live in our community, and I am here
3072 to speak up for them, too. I don't want another soul to experience
3073 what we have.

3074 As a result of contaminated drugs and a failure to oversee
3075 them, I am now a person who will spend the rest of my days dealing
3076 with a complex illness. It wasn't easy for Mike and I to get here

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3077 today. We hope that by sharing our story we can help prevent this
3078 from happening to someone else or anyone else.

3079 Thank you for allowing me to take some of your time, and I
3080 welcome any questions you might have.

3081 [The prepared statement of Ms. Dargan follows:]

3082

3083 ***** INSERT 13*****

3084 Mr. Burgess. Thank you, Ms. Dargan. We appreciate your
3085 testimony, and appreciate all of you for spending so much time
3086 with us today.

3087 I am going to yield to Mr. Griffith 5 minutes for questions,
3088 since he was the Representative who was instrumental in moving
3089 this legislation along several years ago. So, Morgan, you are
3090 recognized for 5 minutes.

3091 Mr. Griffith. Thank you, Mr. Chairman. I appreciate it
3092 very much, and appreciate all of you being here.

3093 I think sometimes we are talking at cross-purposes because
3094 I don't think any of us want to see somebody like NECC coming back,
3095 because they were operating in a couple of dozen states, if I
3096 remember correctly, in my state and your state, Ms. Dargan --

3097 Ms. Dargan. California.

3098 Mr. Griffith. -- and California. They have been kicked
3099 out of Colorado. They were national manufacturers who were lying
3100 about what they were doing. They weren't your traditional small
3101 pharmacy that was doing even small batches.

3102 And so, what we have to do, as Ms. DeGette says, we have to
3103 try to find that balance, because we have situations that, in all
3104 fairness, I wasn't aware that one of the solutions to resolve the
3105 problem was that we were going to have folks going and picking
3106 up drugs. I forget who it was. I think a couple folks were
3107 talking about the dentist. Mr. Olson? And I think somebody,

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3108 maybe Dr. Brod mentioned it, too, that they are having the patients
3109 have to go to pick up the drug from the pharmacist because of the
3110 new interpretation on 503A. I think we all think 503B and the
3111 new stuff is good stuff. It is a question of that balance.

3112 And so, if you could, first, Mr. Olson, and then, Dr. Brod,
3113 just tell me quickly about you and your testimony, but what other
3114 situations besides the dentist who has to send somebody in and,
3115 then, a child has to go through or an adult has to go through pain
3116 for a day or two, until the dentist can get them back in?

3117 Mr. Olson. Thank you for the question, Congressman.

3118 The dentist is the most critical one to my office. We have
3119 other dental products that we had provided in the past. But I
3120 think the other situation that we have is we are having to teach
3121 parents to do this themselves at home, instead of me providing
3122 it now. So, it is not necessarily an office-use situation, but
3123 because I am not able to compound it -- for example, insulin
3124 dilutions, we are having to teach parents to dilute their own
3125 insulin at home. We are having to teach patients to draw up their
3126 own medications at home because we are not allowed to perform that
3127 in our pharmacy. And we are just unsure, if we do that, whether
3128 we will be violating anything.

3129 Mr. Griffith. Dr. Brod, you had some other examples?

3130 Dr. Brod. Yes, several instances. So, we use cantharidin
3131 quite a bit. It is not commercially available. So, we are

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3132 relying upon getting it from a compounding pharmacy. It is used
3133 to treat predominantly children and, also, genital warts, too.

3134 So, you can envision a situation where a child comes in.
3135 They are a little scared to begin with. We recommend cantharidin.
3136 It is painless. Other treatments that we have, such as freezing
3137 or burning, to get rid of warts and molluscum, common skin
3138 infections, are very painful and intimidating.

3139 The parent took off of work. The child is out of school.
3140 We say, "You need a patient-specific prescription." The 503Bs,
3141 these are small batches, so we are having trouble getting them
3142 at any reasonable cost. So, the parent, then, has to go to the
3143 pharmacy, schedule another appointment back into the office.

3144 The other problem, too, is we treat a lot of genital warts
3145 which carry oncogenic viruses. Patients with that don't want to
3146 come in in the first place. A lot of the other treatment
3147 alternatives, especially in patients with skin of color, can cause
3148 dyspigmentation and scarring. Things like cantharidin or
3149 podophyllin are really good options. And diminishing access
3150 creating inefficiencies I think is actually a public health issue.

3151 Mr. Griffith. Do you find that some people, when they find
3152 out they have got to go to the pharmacist and, then, make another
3153 appointment, that they just don't do the treatment at all?

3154 Dr. Brod. Yes. Sometimes they don't do the treatment at
3155 all; they don't come for followup visits, yes.

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3156 Mr. Griffith. Does anybody disagree that we all think that
3157 the 503B program as it was originally intended for those medium
3158 to larger folks is a good thing? Anybody disagree with that?

3159 [No response.]

3160 So, we have got to find that balance. Dr. Williams, do you
3161 have examples of where that balance is askew right now?

3162 Dr. Williams. I do, I believe. One of the most devastating
3163 conditions that can occur in your eye is an acute bacterial
3164 infection. This can either be on the surface of the eye, as I
3165 discussed with that patient with a corneal problem, or in the --

3166 Mr. Griffith. I am running out of time. So, if I could get
3167 you to cut to the chase?

3168 Dr. Williams. The answer to your question is, yes, we need
3169 office-based access to specific antibiotics that are not
3170 available through the 503B mechanism.

3171 Mr. Griffith. And you don't need a big batch? You just need
3172 a couple of small batches, isn't that correct, from time to time?

3173 Dr. Williams. I just need enough to have on the shelf, so
3174 when that one patient a week comes in, I can take care of him.

3175 Mr. Griffith. And I worry about my rural areas and my folks
3176 who have a problem, suddenly an emergency late at night or on the
3177 weekend, and there is no compounding pharmacy readily available
3178 in that small, rural community. Is that a concern for your
3179 doctors as well?

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3180 Dr. Williams. Absolutely. That is one of the most common
3181 scenarios that we hear.

3182 Mr. Griffith. That is what I am hearing, too.

3183 I appreciate all your testimony. I think everybody had some
3184 valid points. I figure we have got to figure out a way. Our job
3185 is to help work with the FDA and find that proper balance.

3186 And with that, Mr. Chairman, I yield back.

3187 Mr. Burgess. Thank you, Mr. Griffith.

3188 I am going to proceed with my 5 minutes for questions. Mr.
3189 Green, I will come to him next. I was going to give him time to
3190 collect his thoughts since he just rushed in here.

3191 Dr. Williams, several references have been made to an
3192 ophthalmic preparation that was injected after cataract surgery.
3193 Now a patient comes in for cataract surgery in an outpatient
3194 facility. They are coming in with the expectation that they are
3195 either going to need drops or injection after the surgery, is that
3196 correct?

3197 Dr. Williams. That is correct.

3198 Mr. Burgess. So, in that instance, could they not come in
3199 with the prescription already in hand or having picked it up
3200 themselves at a pharmacy? What would prevent that from being the
3201 way this would be administered?

3202 Dr. Williams. So, for an elective procedure such as
3203 cataract surgery, that would be a possibility. The drug that the

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3204 specific episode, it is still not exactly clear what happened.
3205 It does not appear to be a contamination in the sense of a microbial
3206 or infectious cause. It seems to be that there was a toxicity
3207 involved when the two drugs were mixed. And so, it is still not
3208 entirely clear exactly what happened. But, even if those
3209 patients had had a prescription and brought that in, it probably
3210 would not have changed the outcome in this particular case.

3211 Mr. Burgess. Correct. The compounds would have been the
3212 same and the doses and the route of administration would have been
3213 the same, and the outcome you would predict would be the same.
3214 So, I think that is a point well-taken. Just having a
3215 prescription does not necessarily protect you in all instances
3216 from an untoward event.

3217 In the case of the methylprednisolone acetate -- and I do
3218 remember that so vividly from our hearings a couple of years ago
3219 -- so, here you have got a compound that has to be
3220 preservative-free because it is going into the epidural space and
3221 you don't want to damage a nerve with a preservative. And, of
3222 course, being a steroid, it reduces the body's ability to fight
3223 infection. So, it is like everything culminated in these cases
3224 to really create literally one of the worst things that I can
3225 recall having ever seen.

3226 In addition to all the sympathy I have for everyone else,
3227 the sympathy for the emergency room doctors -- I know we had a

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3228 patient here in the previous hearing, and it was so difficult for
3229 the attending physicians in the emergency room to really get a
3230 grasp of what was going on, similar to other events that have
3231 happened in this country. When there was anthrax in the post
3232 office here in suburban Washington, the same thing, the emergency
3233 room doctors, seeing those patients out of context, it made it
3234 very, very difficult for them.

3235 Ms. Adams, you referenced the bulk active pharmaceutical
3236 ingredients. Can you give us an idea of which bulk pharmaceutical
3237 ingredients you are talking about?

3238 Ms. Adams. Yes, I can. Thank you.

3239 So, when we look at the list, as an example, of the 200
3240 permissible substances in Category I for bulk compounding right
3241 now, as we cross-reference that list, we feel that almost half
3242 of them have an FDA-approved vial that could be used rather than
3243 bulk substances. So, it is a long list that we think needs much
3244 revision.

3245 Mr. Burgess. Okay.

3246 Ms. Adams. And I think important to note, revising the list
3247 is something that for sure needs to happen. But, in addition to
3248 that -- that is not a holistic approach -- we also think that,
3249 really, to address the issue beyond just that list of 200
3250 substances, the essentially copy needs to be revised to
3251 differentiate between compounding that starts from FDA-approved

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3252 vials and compounding that starts from bulk substances.

3253 Mr. Burgess. And are you assisting the agency in revising
3254 that list?

3255 Ms. Adams. We are. We have got a good dialog going with
3256 the agency. We have got an opinion, which we have documented for
3257 them, and we are happy to continue to serve as a resource in that
3258 regard.

3259 Mr. Burgess. Very well.

3260 Mr. Olson, again, thank you for being here for the people
3261 that you represent. Let me just ask you, on the FDA's draft
3262 memorandum of understanding, they decided to rescind the original
3263 draft and they are going through significant revisions. States
3264 are going to be required at some point, though, to sign onto this
3265 memorandum of understanding, is that correct?

3266 Mr. Olson. Yes, Congressman, that is my understanding.

3267 Mr. Burgess. And what will be the consequences if a state
3268 decided we are not going to sign onto that memorandum of
3269 understanding? How would that leave you?

3270 Mr. Olson. It would leave us very conflicted as to what we
3271 are supposed to do. Because if we abide by our state laws, that
3272 is what we should be abiding by. But in my situation I am only
3273 licensed in Wisconsin, so I wouldn't have to worry about the
3274 situation specifically. But I would think it would put
3275 pharmacies in bordering towns or bordering areas in a precarious

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3276 position to figure out, well, wait, if the state I am in signed
3277 it, but the state I am shipping into didn't, then where does that
3278 leave me, or vice versa. Even though, to be fair, most of the
3279 time if you are shipping into another state, you have to be
3280 licensed in that other state as well. So, there is a state license
3281 that you would have in both states. It would just be the
3282 conflicting memorandum of understanding about whether you can
3283 ship and how much you can ship into that state.

3284 Mr. Burgess. Thank you.

3285 And, Dr. Brod, just as an observation, years ago I remember
3286 discovering that a little bit of bicarbonate in a vial of lidocaine
3287 could make a tremendous difference as to what your patients
3288 thought about you. And I didn't realize I was compounding when
3289 I was doing that. I just thought I was being a nice guy. But
3290 in your testimony you reference that as an episode of compounding,
3291 is that correct?

3292 Dr. Brod. A tremendous difference. And in speaking with
3293 colleagues who haven't been able to buffer in the office, they
3294 say that the patients note a distinctive difference. I mean, we
3295 are very reliant on it. We perform extensive surgeries, but we
3296 do it in the outpatient setting, Mohs surgery with reconstruction.
3297 Having the bicarb to buffer the lidocaine, so that injections in
3298 multiple areas of the face are tolerable, it really allows us to
3299 do surgery outpatient instead of going into a surgical facility

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3300 with sedation and those types of things. So, it is a world of
3301 difference and our patients really appreciate it very much.

3302 Mr. Burgess. Let me just echo, before I yield to Mr. Green,
3303 let me just echo the comments of Mr. Griffith again. We
3304 appreciate so much you all being here. We recognize that there
3305 are some issues that we are going to have to work through, and
3306 we appreciate your help in getting there.

3307 Mr. Green, you are recognized for 5 minutes, please.

3308 Mr. Green. Thank you, Mr. Chairman.

3309 I apologize to the panel about being late, but I had a medical
3310 that I couldn't do. I couldn't have any of my great staff deal
3311 with that.

3312 But I want to thank you for being here. And you know that
3313 Congressman Griffith and Congressman DeGette and the chairman,
3314 we want to fix it because we want to make sure the system works.
3315 And that is what we did after the tragedies in Massachusetts with
3316 65 people dying. But we appreciate you all being here and giving
3317 your stands on it, so we can actually work through and see what
3318 the solutions will be.

3319 Ms. Jungman, I know the Pew Charitable Trust has done a lot
3320 of research on compounded drugs and was actively engaged in this
3321 issue before the DQSA was signed into law and since. I think it
3322 would be helpful to take a step back and get an understanding of
3323 why this law was necessary and how we can support its

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3324 implementation in a manner that strikes the right balance between
3325 access and safety.

3326 Ms. Jungman. I would be delighted to answer that question,
3327 and thank you.

3328 So, as you know, the history of compounding has a long and
3329 complicated legal history, right? It has been a part of
3330 traditional pharmacy practice for as long as pharmacy has existed.
3331 But over time businesses grew up; they were compounding at a larger
3332 scale. And Congress first tried to tackle that in the nineties,
3333 met some legal challenges that Dr. Gottlieb referred to. And NECC
3334 I think really brought to the forefront of everyone's mind the
3335 scale of the patient risk that was there.

3336 We have done a lot of work trying to capture the adverse
3337 events that have happened in all sorts of facilities from
3338 compounding pharmacies, but there is really not a comprehensive
3339 way to know what the risks, what the scale of the impact is.

3340 And so, what the DQSA does is draw really clear lines that
3341 are designed to ensure that patients have access to the highest
3342 quality product that meets their clinical need. So, if you can
3343 use an FDA-approved product, that is great. If you can't use an
3344 FDA-approved product, then you want a product that is made under
3345 appropriate quality standards. And so, there is a balance there
3346 that is about both ensuring that the quality standards are
3347 appropriate, but that the lines are really clear, so that everyone

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3348 knows which side of the line they have to be on.

3349 Mr. Green. I was a state legislator in Texas and we worked
3350 with our pharmacy board and trusted them. I know, typically, we
3351 have these national legislative groups that have standard pieces
3352 of legislation from state to state. So, we do have some kind of
3353 commonality between Texas and Louisiana, or whatever. But is
3354 there anything like that, so we wouldn't have such 50 different?
3355 Is there any agency that does that, and say, "This is the standard
3356 way you pharmacy boards deal with it."?

3357 Ms. Jungman. The National Association of Boards of Pharmacy
3358 does have a model law that does talk about some of these issues.
3359 There is, of course, still state variation. But the research that
3360 we will publish in about two weeks, not quite in time for this
3361 hearing, will show that states are really beginning to align with,
3362 really kind of come into compliance with each other and in line
3363 with DQSA.

3364 Mr. Green. What is the history of responsibility between
3365 the state boards of pharmacy and the FDA? And how did DQSA change
3366 that defining line?

3367 Ms. Jungman. At the time that the NECC outbreak happened
3368 there was a lot of confusion. And I think we saw that in the
3369 hearings that happened at that time, where there was a lack of
3370 clarity about who was supposed to be taking charge of these
3371 institutions. And so, the DQSA really stressed accountability

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3372 and clear lines for that reason. So, it was, of course, about
3373 improving the safety of the products, but it was also about making
3374 sure that everyone knew who was, to use the phrase that kept being
3375 used at the time, "on the flagpole". Which regulatory agency was
3376 in charge of any type of activity?

3377 And so, the Congress at the time -- and you gentlemen know
3378 this better than anyone -- considered a lot of different ways of
3379 drawing those lines. Could you do it based on volume? Could you
3380 do it based on geographic reach? But, ultimately, the
3381 prescription requirement was the line that was clear and
3382 enforceable, and that was considered to be really important for
3383 ensuring that the right quality standards were applied.

3384 Mr. Green. When we had the hearings earlier on the tragedy
3385 in Massachusetts, I remember we had FDA and the Massachusetts
3386 Pharmaceutical Board, and they looked at each other. Here we were
3387 sitting up here and saying, somebody has got to be minding the
3388 store, and that is what we are looking for.

3389 States are critical partners in the effort to ensure patient
3390 access to safe compounded drugs. And I understand Pew will soon
3391 release a report with our National Association of Boards of
3392 Pharmacy which assesses best practices that are more achievable
3393 by the states. Hopefully, we can have that coordination. Again,
3394 we just want somebody to make sure, whether it is the state level
3395 or across border lines, the FDA, somebody needs to be minding the

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3396 store to make sure we don't have an incident like we did in
3397 Massachusetts, well, literally countrywide, but it originated
3398 there.

3399 Thank you.

3400 Ms. Jungman. Thank you.

3401 Mr. Guthrie. [presiding] Thank you.

3402 And I will now recognize myself for 5 minutes for questions.

3403 Dr. Williams, your testimony has been about the critical need
3404 for office use of compounded drugs. How do we ensure office use
3405 is allowed while protecting patient safety?

3406 Dr. Williams. Well, I think that is the critical issue we
3407 have been discussing all day. We do not think that the
3408 patient-specific prescription contributes to safety in any way.
3409 It would allow us to track the use of drugs perhaps. But, for
3410 the incidents where timely treatment is critical -- and as I
3411 mentioned earlier, infections of the eye, even a delay of an hour
3412 or two will have adverse effects. So, we need to be able to have
3413 these drugs available in office. We can just pull them off the
3414 shelf. And it is just absolutely critical.

3415 I alluded earlier to the pool cleaner for this type of
3416 infection. And it sounds crazy that we would use a pool cleaner
3417 for an infection in the eye, but I can assure you, if you had that
3418 infection, you would want immediate access to that treatment.

3419 Mr. Guthrie. Thank you very much.

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3420 Ms. Adams, some compounded drugs for ophthalmology are being
3421 done only by a single facility. Do you know why this is and was this
3422 the case before DQSA?

3423 Ms. Adams. Thank you.

3424 I don't have specific knowledge of where ophthalmology drugs
3425 are compounded and in what scale. PharMEDium is strictly
3426 sterile-to-sterile compounding in our 503B facilities. And as
3427 we stand right now, we do not serve the ophthalmology patient
3428 population. So, I don't have specific knowledge of that.

3429 Mr. Guthrie. Would you know anything about that, Dr.
3430 Williams? Is it done by a single facility and why is that the
3431 case? Was it the case before DQSA?

3432 Dr. Williams. So, before the DQSA, it was done by a single
3433 facility, so-called traditional or 503As. There are many
3434 ophthalmic drugs that are available through 503Bs, and we
3435 encourage our members to use those. But it is these relatively
3436 rare conditions, but, yet, very potentially catastrophic, where
3437 we need immediate access. And simply writing a prescription and,
3438 then, having the patient have to go get it, if, in fact, they can
3439 get it -- these are drugs that are not typically manufactured or
3440 compounded at a high rate. So, for a rural population, it could
3441 be literally hundreds of miles, as I stated in my statement.

3442 Mr. Guthrie. Yes, absolutely. Thank you very much.

3443 I am going to yield the time, my remaining time, to Mr.

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3444 Griffith of Virginia.

3445 Mr. Griffith. Mr. Hodges, I am going to ask you a question.
3446 It is getting down a little deeper in the weeds, and we still want
3447 to reach a balance. But the committee has heard, much to their
3448 chagrin, all about my family's allergy issues. And some
3449 pharmacies specialize in serving patients with specific needs,
3450 such as a drug without a particular dye or ingredient for those
3451 patients who do have allergies to those particulars. And they
3452 do it because they specialize. They do it in multiple states.

3453 If the shipment of a patient-specific compounded
3454 prescription is limited by the memorandum of understanding, will
3455 patients be able to get all of these medications from local
3456 pharmacies?

3457 Mr. Hodges. Thank you, sir.

3458 Simply put, no, they will not. Not all pharmacies make all
3459 products for every type of patient population. So, for instance,
3460 we engage in allergy immunotherapy. There is only a handful of
3461 pharmacies in the country that offer that. And so, it is
3462 particularly a concern for us that we cannot meet these patients'
3463 needs because we are not able to provide it, in fear of the MOU,
3464 if it is implemented.

3465 And so, what we want to do is work closely with the FDA. We
3466 have some ideas about what we can do to ensure the quality and
3467 access. We have ideas. But we are looking for a sit-down with

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3468 the Commissioner. We have requested this year and years prior
3469 we have sent letters, and we are not getting a response. And so,
3470 what we would like to do is ask that the Commissioner have a
3471 sit-down with us. We have some ideas on what we can do.

3472 But, to answer your question, it would be a problem if the
3473 MOU went into effect, especially for patients that live across
3474 state borders.

3475 Mr. Griffith. All right. I appreciate that.

3476 I will tell you that Commissioner Gottlieb, of all the folks
3477 that we have dealt with at that level, is probably the most
3478 responsive that the committee has found. And so, we will work
3479 towards that. But he is very responsive, tries to listen, tries
3480 to pay attention. And so, it is a good working relationship.
3481 Hopefully, together we can find a balance to the issues that have
3482 been raised by today's hearing.

3483 I appreciate all of you very much.

3484 And I yield back, Mr. Chairman.

3485 Mr. Guthrie. Thank you. The gentleman yields back, and I
3486 yield back my time.

3487 Seeing that there are no further members wishing to ask
3488 questions, I would like to thank all of our witnesses for being
3489 here today.

3490 I would like to submit the statements from the following for
3491 the record: American Society of Health System Pharmacists;

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3492 American College of Mohs Surgery; Avella; Outsourcing Facilities
3493 Association; American Society of Cataract and Refractive Surgery;
3494 National Association of Chain Drug Stores; American Pharmacists
3495 Association; a joint statement from the American Academy of
3496 Allergy, Asthma & Immunology and the American College of Allergy,
3497 Asthma and Immunology.

3498 [The prepared statements follow:]

3499

3500 ***** COMMITTEE INSERT 14*****

3501 Mr. Guthrie. Pursuant to committee rules, I remind members
3502 they have 10 days to submit additional questions for the record,
3503 and I ask that the witnesses submit their response within 10
3504 business days upon receipt of the questions.

3505 Without objection, the subcommittee is adjourned.

3506 [Whereupon, at 2:43 p.m., the subcommittee was adjourned.]

3507