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1 {York Stenographic Services, Inc.}

2 RPTS MEYERS

3 HIF087.140

4 EXAMINING THE CURRENT STATE OF COSMETICS

5 TUESDAY, MARCH 27, 2012

6 House of Representatives,

7 Subcommittee on Health

8 Committee on Energy and Commerce

9 Washington, D.C.

10 The Subcommittee met, pursuant to call, at 10:15 a.m.,
11 in Room 2322 of the Rayburn House Office Building, Hon. Joe
12 Pitts [Chairman of the Subcommittee] presiding.

13 Members present: Representatives Pitts, Shimkus,
14 Blackburn, Gingrey, Latta, Lance, Guthrie, Barton, Pallone,
15 Towns, Schakowsky, Markey and Waxman (ex officio).

16 Staff present: Clay Alspach, Counsel, Health; Debee
17 Keller, Press Secretary; Ryan Long, Chief Counsel, Health;
18 Carly McWilliams, Legislative Clerk; Andrew Powaleny, Deputy

19 Press Secretary; Heidi Stirrup, Health Policy Coordinator;
20 Phil Barnett, Democratic Staff Director; Alli Corr,
21 Democratic Policy Analyst; Eric Flamm, FDA Detailee;
22 Elizabeth Letter, Democratic Assistant Press Secretary; Karen
23 Nelson, Democratic Deputy Committee Staff Director for
24 Health; and Rachel Sher, Democratic Senior Counsel.

|
25 Mr. {Pitts.} This subcommittee will come to order. The
26 chair recognizes himself for 5 minutes for an opening
27 statement.

28 Cosmetics are regulated by FDA under the Federal Food,
29 Drug, and Cosmetic Act, FFDCa, of 1938. The FFDCa forbids
30 the introduction of adulterated or misbranded cosmetics into
31 interstate commerce and provides for seizure, criminal
32 penalties and other enforcement authorities for violations of
33 the Act.

34 The Fair Packaging and Labeling Act, the FPLA, also
35 requires cosmetics to carry an ingredient declaration to help
36 consumers make informed purchasing decisions.

37 Unlike other products regulated by FDA, however, such as
38 drugs, medical devices and biologics, most cosmetic products
39 and ingredients are not subject to FDA premarket approval.
40 Instead, cosmetic manufacturers are largely responsible for
41 substantiating the safety of their products and ingredients
42 before they go to market.

43 Currently, cosmetic facilities can register with FDA on
44 a voluntary basis, but FDA cannot compel them to do so.
45 While FDA has the authority under FFDCa to enter and inspect
46 cosmetic manufacturing facilities, the industry does not pay
47 user fees for this purpose.

48 According to a June 2010 study by
49 PriceWaterhouseCoopers, the personal care or cosmetics
50 industry is responsible for 2.8 million jobs in the United
51 States, and small businesses create the vast majority of
52 these positions.

53 For the past several years, the industry and members of
54 both parties have been reviewing FDA's regulatory authority
55 over these products. One issue under review is the need for
56 a national uniform standard for cosmetic products and
57 preemption of State legislation.

58 I want to welcome each of our witnesses today, and I
59 hope you can share your perspectives on several matters,
60 including what deficiencies, if any, you currently see in
61 FDA's regulatory authority over cosmetics; what new
62 authorities, if any, do you believe FDA needs in this area;
63 and if new authorities are needed, what will be the impact on
64 small businesses across the country?

65 [The prepared statement of Mr. Pitts follows:]

66 ***** COMMITTEE INSERT *****

|
67 Mr. {Pitts.} I would yield the balance of my time to
68 Mr. Lance.

69 Mr. {Lance.} Thank you very much, Mr. Chairman.

70 The personal care product industry employs over 2.8
71 million Americans including over 176,000 in the State of New
72 Jersey, the State where I am from. Their products generate
73 over \$30 billion in sales annually including a trade surplus
74 of \$5 billion in the last reported year, 2006.

75 As the chairman has said, personal care products have
76 been regulated by the FDA since 1938 with the enactment of
77 the Federal Food, Drug and Cosmetics Act and that the law
78 prohibits the introduction of adulterated or misbranded
79 cosmetics into interstate commerce and provides for seizure,
80 criminal penalties and other enforcement authorities for
81 violations of the Act. Additionally, the Fair Packaging and
82 Labeling Act requires an ingredient declaration for cosmetics
83 so consumers might make informed purchasing decisions. These
84 products are among the safest regulated by the FDA, and the
85 agency has strong authority to regulate cosmetics. There is
86 also a panel for cosmetic ingredient review, which was
87 established in 1976 with the support of the FDA and the
88 Consumer Federation of America. This panel is dedicated to a
89 thorough and continuing review of cosmetic ingredient safety

90 and is both independent and nonprofit and helps ensure the
91 safety of cosmetics.

92 Despite these standards, there does not exist a national
93 standard for ingredients in cosmetic and personal care
94 products. I believe a uniform standard for cosmetic
95 ingredients would serve to enhance public health so long as
96 it is based on sound science and rigorous safety standards.
97 In doing so, we would ensure that the interstate flow of
98 personal care products would not be disrupted by differing
99 State standards. We need preemption in this area.

100 I look forward to hearing from the panels as we discuss
101 this important issue, and Mr. Chairman, I yield back the
102 balance of my time.

103 [The prepared statement of Mr. Lance follows:]

104 ***** COMMITTEE INSERT *****

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105 Mr. {Pitts.} The chair thanks the gentleman and
106 recognizes the ranking member of the Subcommittee on Health,
107 Mr. Pallone, for 5 minutes for an opening statement.

108 Mr. {Pallone.} Thank you, Chairman Pitts. I appreciate
109 your willingness to hold today's hearing on the current state
110 of cosmetic regulation. In fact, I welcome it because our
111 subcommittee has had limited opportunity to examine cosmetics
112 and their use in any substantive manner.

113 Cosmetics like other products regulated by the FDA are
114 used extensively throughout the United States by all types of
115 people, men, women and children of all ages. According to
116 the Personal Care Products Council, every day millions of
117 consumers around the world rely on personal care products
118 from moisturizers, lipsticks and fragrances to sunscreens,
119 soaps and toothpaste. These products have become an ordinary
120 and in most instances habitual part to our lifestyles. Each
121 of us in this room likely woke up today and used up to a
122 dozen cosmetic products before arriving at work, which we
123 will repeat day after day for the rest of our lives. From
124 simply shampooing our hair to using complex-formula lotions
125 that claim to improve the appearance of our wrinkles,
126 cosmetics are a part of our lives.

127 Meanwhile, these products are in such demand that there

128 are entire retail stores dedicated to their sales so it is no
129 surprise to me when I hear that the industry generates more
130 than \$250 billion in annual retail sales. However, what was
131 surprising to hear was that the FDA has little, if any,
132 authority over these everyday products and they certainly
133 have little ability to ensure that the products are safe for
134 the American consumers' use.

135 Now, no moisturizing lotion is going to kill me if I rub
136 it on my skin, hopefully, but it could create a debilitating
137 rash or have a longer-term health effect as a result of
138 everyday multiple use. So these products are not high risk
139 but they are by no means risk-free. So that is why I joined
140 with my colleague and friend, Mr. Dingell, to introduce the
141 Cosmetic Safety Enhancement Act of 2012, which is modeled
142 after the Food Safety Modernization Act, to help address the
143 lack of authority at the FDA to regulate cosmetics or
144 actively ensure that cosmetic products are safe, and I
145 believe it is important that consumers have a level of
146 certainty about the products they are buying and using, and
147 that if anything alarming were to come to light about one of
148 these products, FDA would have the capability to respond
149 accordingly.

150 Specifically, I am concerned that the FDA has no
151 knowledge of the domestic and foreign facilities operating in

152 the marketplace that are manufacturing cosmetic products.
153 Currently, FDA runs a voluntary program but that is of course
154 incomplete. Our bill would require an annual registration
155 for all companies along with a fee to help maintain that
156 activity. The bill also gives FDA a number of new
157 authorities to put in place, a comprehensive oversight
158 program within the agency. It includes an annual listing of
159 a company's products, demonstration by the company of a
160 cosmetic product's safety, serious adverse-event reporting
161 requirements, Good Manufacturing Practices for cosmetic
162 facilities, and FDA recall authority. I hope that our bill
163 can serve as a starting point to discussions moving forward
164 as we look to address any further cosmetic regulations.

165 Now, I know there are other approaches to regulating
166 cosmetics, but what is clear from all perspectives is that
167 FDA doesn't have the authority it needs to properly monitor
168 an industry that touches nearly every American consumer, and
169 I believe it is time that Congress fix that problem. I hope
170 that my colleagues on both sides of the aisle will continue
171 to work with me in a productive manner to produce a fair,
172 balanced and, most importantly, practical product that we can
173 all support.

174 And again, I want to thank the witnesses that are
175 joining us today. I look forward to continuing to work with

176 all of them and the stakeholders to ensure we have a strong
177 system in place to regulate and monitor the safety of our
178 cosmetics.

179 [The prepared statement of Mr. Pallone follows:]

180 ***** COMMITTEE INSERT *****

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181 Mr. {Pallone.} I would like to yield the remainder of
182 my time to Congresswoman Schakowsky, who has also been a
183 leader on this issue.

184 Ms. {Schakowsky.} Thank you very much for yielding, Mr.
185 Pallone.

186 The fact is this: Cosmetics contain ingredients that
187 can cause cancer, mutate cellular structure and cause
188 reproductive and developmental harm. Industry claims that
189 these ingredients are present at such low doses that they
190 aren't a problem, but men, women and children are exposed
191 every day to dozens or hundreds of ingredients in their
192 shampoos, cologne, makeup, lotions and other products. We
193 have to consider the cumulative effect of exposure.

194 Any bill this committee considers needs to include as
195 the Schakowsky-Markey-Baldwin Safe Cosmetic Act does the
196 following elements: one, strong safety standards that ban
197 carcinogens, mutagens and reproductive toxins; two, full
198 ingredient disclosure and labeling--consumers simply have a
199 right to know what is in their products; and three, mandatory
200 recall authority for the FDA. There are certainly other
201 important elements but I wanted to mention those. I think
202 today's testimony will underscore the need for these
203 provisions as well as the complexity of this industry and the

204 need for thorough consideration of any legislation making
205 changes to cosmetics regulations, and I yield back to Mr.
206 Pallone.

207 [The prepared statement of Mr. Schakowsky follows:]

208 ***** COMMITTEE INSERT *****

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209 Mr. {Pitts.} And Mr. Pallone yields back. The chair
210 thanks the gentleman and now recognizes the chair emeritus of
211 the full committee, Mr. Barton, for 5 minutes for an opening
212 statement.

213 Mr. {Barton.} Thank you, Chairman Pitts.

214 If you want to know the value of cosmetics, look no
215 further than myself. I have a 6-year-old son, and he told me
216 the other day that I was more wrinkly than former President
217 Bush. We had seen President Bush, and he said Daddy, you are
218 more wrinkly. Yet when I am on TV after I have been made up
219 by the makeup artists at Fox or CNN or C-SPAN or one of the
220 local television stations, he always tells me how good I
221 look. I am a walking testimony to the value of cosmetics.

222 This is an important hearing, not because of the
223 controversial aspect of it but because of the potential
224 mischief that could occur from it. I would caution my
225 friends on the Republican side of the aisle to be careful
226 what we ask for. We just heard Congressman Lance's comments
227 that we need a uniform standard, and I know that he says that
228 with great sincerity, but we also just heard Congresswoman
229 Schakowsky talk about a list of items that must be included
230 in any legislation. We have an industry that is a \$50
231 billion to \$60 billion-a-year business, and if there are

232 health problems that are occurring because of that business,
233 I don't know what they are. I have not heard of any health
234 issues that resulted from the application of cosmetics, and
235 when I read what the industry practices are today and what
236 the various voluntary groups are that work with the FDA, it
237 would seem to me that we have got a system that is working.

238 What seems to be driving this train is that some States
239 are beginning to adopt State regulatory issues that make it
240 difficult for the industries that sell, the businesses that
241 sell, the companies that sell across State lines and operate
242 in some of those States. I would think that the way to
243 address that would be to work with each of the State
244 legislatures rather than to have a national standard because
245 make no mistake, if we give the FDA new authority, they are
246 going to use it, and if we give the FDA user fee authority,
247 they are going to expand upon it. I mean, it is almost a law
248 of nature that if you give a federal agency more authority,
249 they use it and expand it, and if you give them more revenue,
250 they consume it and then come back for more. At this stage,
251 it seems to be somewhat benign but the longer we go, the
252 further we go down the trail, the more cumbersome can be. I f
253 you look at the user fee issue for medical devices that is
254 currently before either the subcommittee or the full
255 committee, the amount of user fees they are requesting has

256 doubled from what it was in the last reauthorization period.

257 So Mr. Chairman, I am very pleased that you are doing
258 the hearing. We have an industry that is competitive
259 internationally, that is accepted domestically, that creates
260 tens of thousands if not hundreds of thousands of jobs. One
261 of the biggest in the world is located not in my district but
262 near my district, Mary Kay Cosmetics, and I see those little
263 pink cars everywhere I go from the women, primarily women,
264 that are self-employed and have created thriving, independent
265 businesses with their entrepreneurship and their hard work.

266 So if it is not broke, don't fix it. We certainly can
267 have hearings and develop a record, but just as when I was a
268 younger Congressman, I was campaigning in an area that was
269 not known to be supportive of Republicans, and I knocked on
270 this man's door and I said I am Joe Barton, I am running for
271 Congress, will you vote for me, and he said are you a
272 Republican or a Democrat, and I said I am a Republican. He
273 said I am a Democrat, and he said are you a Dallas Cowboy fan
274 or a Houston Oilers fan--that is how long ago it was--and I
275 said well, I am a Cowboy fan. He said I am an Oiler fan.
276 And finally he said are you a Texas Aggie or a Texas
277 Longhorn, and I said I am a Texas Aggie, and he said I am a
278 Texas Longhorn. So I said well, will you vote for me, and he
279 said, son, I wouldn't vote for you if you were the only one

280 on the ballot. So I went back to the car and my aide said
281 how do we put that voter down, and I said undecided.

282 So Mr. Chairman, put me down as undecided, but I am
283 going to listen with an open mind, and if we can get an
284 agreement that doesn't give too much authority to the FDA, I
285 am a possible. With that, I yield back, Mr. Chairman.

286 [The prepared statement of Mr. Barton follows:]

287 ***** COMMITTEE INSERT *****

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288 Mr. {Pitts.} The chair thanks the gentleman and
289 recognizes the ranking member of the full committee, Mr.
290 Waxman, for 5 minutes for an opening statement.

291 Mr. {Waxman.} Thank you very much, Mr. Chairman.

292 We are all very familiar with cosmetic products. In
293 fact, most Americans use cosmetic products multiple times
294 every day. We apply lotions to our skin, we wash our hair,
295 when we have it, using shampoos, and we brush our teeth using
296 toothpaste.

297 But most Americans probably do not realize just how
298 little oversight the FDA, which is charged with ensuring the
299 safety of these products, actually has exercised over them.
300 Cosmetics companies are not required to register their
301 facilities or let FDA know they even exist. Cosmetic
302 companies are not required to report cosmetic-related
303 injuries to the FDA or to let FDA know what ingredients are
304 in their products. FDA doesn't even have the ability to
305 recall these products if they are found to be unsafe. To
306 illustrate just how small FDA's role in cosmetics oversight
307 truly is, it is worth noting that FDA's cosmetics program is
308 staffed by just 53 people, only 14 of whom focus primarily on
309 cosmetics, compared to the well over 3,000 staff that make up
310 FDA's drug review program.

311 When it comes to cosmetics, we are essentially in a
312 buyers beware mode. For the most part, this may not be a
313 problem, and because of this fact, many argue that there is
314 no need for comprehensive regulation of cosmetics. Cosmetics
315 are not ingested like foods or drugs or implanted like
316 medical devices. Yet we know there are some cosmetics that
317 contain harmful ingredients. Some lipsticks were found to
318 contain lead, a known reproductive toxin. Certain hair
319 products have been shown to contain formaldehyde, a known
320 carcinogen. Even some baby shampoos were found to have
321 carcinogens in them.

322 There can be a distinction between ingesting a
323 carcinogen and applying it to our skin. But what we do not
324 know is what effect repeated, long-term exposure to these
325 chemicals on our skin might have. We know that some toxins,
326 such as the mercury recently found in a number of face
327 creams, are readily absorbed through the skin.

328 We should all be united in a goal of ensuring that the
329 cosmetics we use, often on a daily basis, are safe. The
330 difficulty will be in coming to an agreement on how to do
331 this. Although there are many issues we need to resolve, I
332 would hope we could all agree that some basic concepts should
333 be embodied in any cosmetics program. Cosmetics companies
334 should be required to register with the FDA, comply with good

335 cosmetics manufacturing practices, demonstrate the safety of
336 their products, provide adequate information to consumers
337 about the ingredients in their products, and report
338 cosmetics-related injuries to FDA. FDA should have the
339 authority to recall unsafe cosmetics, and FDA should have
340 adequate resources to oversee the cosmetics marketplace,
341 which, in this budget climate, means industry should be
342 required to chip in by paying fees.

343 Most important, States should be free to supplement
344 whatever federal program we put in place so they can protect
345 their own citizens from unsafe cosmetics. California, for
346 example, has a safe cosmetics law that requires manufacturers
347 to notify the State public health authorities if their
348 products are known to contain ingredients that could cause
349 cancer, birth defects, or reproductive harm. California has
350 a very reasonable and balanced law that explicitly protects
351 from public disclosure protected trade secret information.
352 It is the kind of State initiative that we ought to keep in
353 place, especially if California has a strong law and the
354 federal government will have a weak one. That is not a case
355 for preemption, that is a case for letting States also
356 operate in this sphere.

357 As with many of the other proposals we have considered
358 in the context of user fee reauthorizations, the issue of

359 cosmetics reform is an important one that we need to address
360 on a bipartisan basis. If we can't do this in time to add
361 cosmetic provisions to the fast-moving user fee bill, we
362 should consider cosmetic reform separately. I would strongly
363 oppose the addition of a cosmetics bill to the user fee
364 package if we are not able to come to full agreement on its
365 parameters.

366 I want to close by saying how glad I am that we have Dr.
367 Michael DiBartolomeis here today to talk about the success of
368 the California program and what we can learn from it.

369 Thank you, Mr. Chairman.

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

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372 Mr. {Pitts.} The chair thanks the gentleman.

373 We have two panels this morning. We will call our first
374 witness to the witness table. Our first panel will have just
375 one witness, Mr. Michael Landa, Director of the Center for
376 Food Safety and Applied Nutrition at the FDA. We are happy
377 to have you with us today, Mr. Landa, and you are recognized
378 for 5 minutes, if you can summarize your testimony. Your
379 written testimony will be entered into the record.

|
380 ^STATEMENT OF MICHAEL LANDA, J.D., DIRECTOR, CENTER FOR FOOD
381 SAFETY AND APPLIED NUTRITION (CFSAN), U.S. FOOD AND DRUG
382 ADMINISTRATION

383 } Mr. {Landa.} Thank you. Good morning, Mr. Chairman and
384 members of the committee. I am Michael Landa, Director of
385 the Center for Food Safety and Applied Nutrition at the Food
386 and Drug Administration. I am pleased to be here today to
387 discuss FDA's oversight of cosmetics.

388 Every day across the country, Americans use a wide
389 variety of cosmetic products including shampoos, perfumes,
390 hair colors and makeup. These consumers expect their
391 cosmetics and the wide variety of individual ingredients in
392 these products to be safe. FDA plays a critical role in
393 ensuring that the Nation's cosmetics are among the safest in
394 the world.

395 In my testimony today, I will describe FDA's current
396 authorities and activities to oversee the safety of
397 cosmetics, the challenges we face due to changes in the
398 industry and the increasingly global marketplace, and the new
399 authorities the Administration is seeking to strengthen FDA's
400 regulatory oversight of cosmetics.

401 Cosmetic firms are responsible for substantiating the

402 safety of their products and ingredients before marketing.
403 However, they are not required to submit safety
404 substantiation data to the agency. In general, except for
405 color additives and those ingredients which are prohibited or
406 restricted from use in cosmetics by regulation, a
407 manufacturer may use any ingredient in a cosmetic, provided
408 the ingredient does not adulterate the finished cosmetic and
409 the finished cosmetic is properly labeled. If manufacturers
410 do not remove dangerous products from the market once a
411 safety concern emerges, the agency can pursue enforcement
412 actions against violative products or against firms or
413 individuals who violate the law.

414 Regulations are in place that specify the labeling
415 requirements for cosmetics. These requirements include, for
416 example, the name and place of business of the manufacturer,
417 packer or distributor, material facts about the product and
418 directions for safe use, if they are needed, and a list of
419 ingredients. Cosmetic product labels are not required to
420 provide information on how consumers or health care
421 professionals can report adverse events, and such reporting
422 is not required. However, FDA has long encouraged cosmetics
423 manufacturers and distributors to report adverse events on a
424 voluntary basis.

425 FDA also encourages companies to register their

426 establishments through the Voluntary Cosmetic Registration
427 Program and file cosmetic product ingredient statements with
428 the agency. However, there is no requirement in the statute
429 for firms to do either. The agency established this program
430 and the cosmetic product ingredient statement program to gain
431 more information about cosmetics that are being manufactured
432 and marketed to consumers in this country. This information
433 enhances FDA's ability to identify potentially unsafe
434 ingredients and finished products and to provide safety
435 information to consumers. However, we estimate that only
436 one-third of cosmetics manufacturers voluntarily file
437 cosmetic product ingredient statements for their products
438 with the agency.

439 I would now like to discuss some of the challenges we
440 have been facing. During the past several years, Americans
441 have seen a dramatic increase in the number and types of
442 cosmetic ingredients in products on the market. Over 8
443 billion personal care products are sold annually in the
444 United States. Cosmetic products and ingredients are also
445 entering the country from a growing number of other
446 countries. From fiscal year 2004 to fiscal year 2010, the
447 number of cosmetics imports has nearly doubled.

448 To help address this challenge, FDA and its counterparts
449 in the European Union, Canada and Japan established a forum

450 in 2007 to exchange ideas and better align practices for
451 maintaining global consumer protections in the cosmetics
452 arena. The forum, known as the International Cooperation on
453 Cosmetics Regulation, meets annually to discuss topics of
454 mutual interest in which cooperation may be possible. The
455 FDA is holding a public meeting on May 15 in advance of the
456 annual meeting in July to solicit information from interested
457 parties.

458 In addition to the challenges posed by an increasingly
459 global marketplace, the cosmetic industry is rapidly
460 undergoing significant changes as the technologies used in
461 manufacturing become increasingly sophisticated and the
462 ingredients more complex. For example, the use of
463 nanotechnology may result in cosmetic products or ingredients
464 with different chemical or physical properties than their
465 counterparts that do not contain nanomaterials.

466 In response to these challenges and to ensure adequate
467 oversight of cosmetics, the fiscal year 2013 President's
468 budget request includes new legislative authority for FDA to
469 require domestic and foreign cosmetics manufacturers to
470 register with the agency and pay an annual registration fee.
471 The user fees would support FDA's cosmetics program and are
472 estimated to generate \$19 million in new resources. The
473 product ingredient and facility information submitted with

474 registration would expand FDA's information about the
475 industry and better enable it to develop necessary guidance
476 and safety standards. It would also enable the agency to
477 identify and address research gaps, for example, about the
478 safety of novel ingredients. Specifically, the agency would
479 conduct the following activities with the new user fee
480 resources: establish and maintain a mandatory cosmetic
481 registration program; acquire, analyze, and apply scientific
482 data and information from a variety of sources to set U.S.
483 cosmetics safety standards; maintain a strong U.S. presence
484 in international standard-setting efforts; provide education,
485 outreach, and training to industry and consumers, and refine
486 inspection and sampling of domestic imported products and
487 apply risk-based approaches to postmarket monitoring of
488 domestic and imported products. Overall, the new authority
489 for registration and user fees would strengthen FDA's ability
490 to protect American consumers from potentially unsafe
491 cosmetic products or ingredients.

492 In conclusion, FDA is committed to ensuring the safety
493 of cosmetics used by consumers across the United States. The
494 agency will continue to work closely with all its partners on
495 a wide variety of issues important to ensuring cosmetic
496 safety. As Congress considers potential steps to address
497 these issues, we look forward to working with you.

498 Thank you for the opportunity to discuss FDA's
499 activities to ensure the safety of cosmetics, and I would be
500 happy to answer any questions you may have.

501 [The prepared statement of Mr. Landa follows:]

502 ***** INSERT 1 *****

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503 Mr. {Pitts.} The chair thanks the gentleman, and I will
504 begin the questioning and recognize myself for that purpose.

505 First, on Cosmetic Ingredient Review, I understand that
506 the Cosmetic Ingredient Review is an important part of
507 ensuring cosmetic safety and that industry participates in
508 the CIR along with consumer groups and FDA. Can you describe
509 briefly the composition and activities of the Cosmetic
510 Ingredient Review panel and what is FDA's role in the CIR?

511 Mr. {Landa.} FDA is a participant. It does not vote.
512 The membership is principally supplied by industry. It is a
513 wide range of expertise in various disciplines, and reviews
514 ingredients as they are brought to the attention of the CIR
515 for possible safety problems, brought to CIR's attention
516 either by FDA or by industry or by FDA.

517 Mr. {Pitts.} Have you ever questioned the objectivity
518 of the Cosmetic Ingredient Review panel? Have there been
519 instances where the FDA has disagreed with a CIR
520 recommendation?

521 Mr. {Landa.} I'm not aware of any such instances. I
522 think the question one might ask about the CIR is that
523 because it consists of members from industry, one might ask
524 about potential conflicts of interest, for example, the
525 potential for bias or prejudice.

526 Mr. {Pitts.} Now, I saw the President's budget request
527 for \$19 billion in cosmetic user fees. Hasn't the agency
528 already received a substantial increase in appropriations in
529 recent years and why do you need those user fees?

530 Mr. {Landa.} The agency has received a significant
531 increase over the last several years but it still finds
532 itself with a total of about 50 full-time equivalents to
533 regulate a very large and growing industry. We have little
534 more than a dozen employees who are devoted full time to
535 cosmetics regulation. There are other employees in the
536 field, for example, who do cosmetics inspections along with
537 engaging in other activities. There are employees who do
538 research but not on cosmetics alone. It is a rather small
539 program in light of the size of the industry.

540 Mr. {Pitts.} Now, how would small businesses be taken
541 into account in regard to these fees?

542 Mr. {Landa.} Well, I think the precise sort of nature
543 of the fees, whether it would be based on size of the
544 company, gross revenue would have to be negotiated, certainly
545 preferably with industry and to a successful conclusion. The
546 size of the fees could vary, for example, according to the
547 size of a company or gross revenues. One could also consider
548 the possibility of an exclusion altogether for companies
549 below a second size or waiver provisions. I think it would

550 be important to be flexible in that regard.

551 Mr. {Pitts.} You are asking for new authority in the
552 cosmetic area. Give us a little brief background on what
553 authority FDA currently has and what new authorities you are
554 asking for.

555 Mr. {Landa.} FDA's current authority is principally
556 post market. The premarket authority is limited to color
557 additives. It is color additives used in this case, in
558 cosmetics. We have the same authority for color additives
559 used, say, in foods or drugs, but in this case, for color
560 additives used in cosmetics. Premarket approval of those
561 color additives is required. We have the authority to ban
562 ingredients when we reach a finding that they are not safe.
563 That is authority we exercise through rulemaking. We have
564 the standard enforcement authorities that have been in the
565 Act since 1938 like seizure against product that is
566 misbranded is adulterated, injunction authority to halt
567 shipments of products that are adulterated or misbranded, and
568 there are criminal penalties under the statute for having
569 committed a violation by, for example, shipping in interstate
570 commerce and adulterated or misbranded cosmetics.

571 Mr. {Pitts.} And what new authorities are you seeking
572 and why are seeking them?

573 Mr. {Landa.} The request is for mandatory registration

574 for firms domestic and foreign because now there is no
575 requirement for firms to register with us or for them to tell
576 us about their products or about their ingredients. The
577 request also, of course, is for user fees.

578 Mr. {Pitts.} All right. My time is expired. I yield
579 to the ranking member 5 minutes for questions.

580 Mr. {Pallone.} Thank you, Mr. Chairman. You asked some
581 of the questions I was going to ask, so I just crossed them
582 out but there a few things I still wanted to kind of get more
583 clarification on.

584 Mr. Landa, in your back and forth with the chairman, you
585 talked about the Cosmetics Ingredient Review panel, or CIR.
586 My understanding is that the reviews the CIR conducts and any
587 conclusions it draws are not part of any official FDA
588 activity or findings and some have proposed a regulatory
589 scheme that would have CIR findings on the safety of
590 ingredients become accepted and enforceable by the FDA unless
591 the FDA makes a different determination through a process
592 that includes public notice. Many of us have some real
593 concerns about that model, so I wanted to ask, would the FDA
594 be comfortable with this concept of having the findings of
595 the CIR be binding on the FDA?

596 Mr. {Landa.} As you note, they are not now binding on
597 the agency.

598 Mr. {Pallone.} I know they are not.

599 Mr. {Landa.} I think making them binding would raise a
600 number of questions. As I indicated earlier, one is that the
601 CIR is composed of individuals, experts, to be sure, who are
602 employees of the industry. So I think there is always a
603 question about conflict of interest, objectivity, bias,
604 prejudice, that sort of thing. I think having private sector
605 determinations be binding on the FDA would be an
606 unprecedented approach to regulation. I think finally, there
607 is probably a question, I certainly haven't explored it, but
608 a question to be asked about whether that type of delegation
609 is even lawful, is constitutional.

610 Mr. {Pallone.} Well, I don't think it is a good
611 approach to put the FDA stamp of approval on what are
612 essentially industry findings about the safety of their own
613 products, so I agree with you.

614 Then my second area, again, the chairman went into it a
615 little bit, in your testimony, you mentioned that FDA
616 encourages cosmetic companies to voluntarily report adverse
617 events to the FDA and it encourages voluntary registration.
618 You also mentioned that the President's fiscal year 2013
619 budget calls for establishment of mandatory registration and
620 fees that would cover the registration and more analysis
621 based on, among other things, adverse-event reporting. It

622 seems to me that if the FDA were to collect fees and expend
623 resources on these efforts that we would make to make sure
624 that they were leveraged to full capacity in ensuring the
625 safety of cosmetic products, and I think at a minimum, we
626 would want to consider making serious adverse-event reporting
627 mandatory, giving the FDA mandatory recall authority and
628 giving the agency more authority to understand review the
629 safety of cosmetic ingredients. So do you agree that these
630 authorities and activities would be important to creating a
631 more effective safety system for cosmetics?

632 Mr. {Landa.} Well, of course, the President's request
633 here is for mandatory registration legislation and for user
634 fees. The Administration has not taken a position on any
635 other authorities. I do think it would be useful to consider
636 the value of mandatory adverse-reaction reporting and
637 valuable to consider making explicit the establishing of
638 current Good Manufacturing Practice requirements for
639 cosmetics. We believe we have that authority but it always
640 helps to make it more explicit. And there are probably other
641 authorities that would useful to consider and certainly the
642 agency would be happy to work with the committee on that.

643 Mr. {Pallone.} All right. Thanks. I am just trying to
644 get a little specific. I know the chairman asked about a
645 small business exemption. You know, Mr. Dingell and I had

646 that in the Food Safety Modernization Act. We had small food
647 processes that made most of their sales directly to consumers
648 and have less than \$500,000 annual sales were exempted from
649 some of the requirements of the Act. Do you believe a
650 similar small business exemption would be necessary? Do you
651 want to comment on that a little more about what kind of--

652 Mr. {Landa.} Perhaps I was unclear. When I was
653 responding to the question, I meant to respond to it in the
654 context of user fees and to say that in the context of
655 developing a structure for user fees, one could tie them to
656 the number of employees, gross revenues, have different fees
657 depending on size. One could also consider exclusions
658 altogether for businesses below a certain size as well as I
659 think waivers. But my comments were addressed to the effect
660 of user fees on small business.

661 Mr. {Pallone.} So you wouldn't argue for an exemption
662 from other requirements other than user fees?

663 Mr. {Landa.} Again, the Administration hasn't taken a
664 position on any of these requirements so I don't really have
665 anything to add beyond my observation that I was focused on
666 user fees.

667 Mr. {Pallone.} All right. Thank you.

668 Thank you, Mr. Chairman.

669 Mr. {Pitts.} The chair thanks the gentleman and

670 recognizes the chair emeritus of the full committee, Mr.
671 Barton, for 5 minutes for questions.

672 Mr. {Barton.} Thank you, Mr. Chairman. I am just going
673 to ask one or two questions and yield the balance of my time
674 to Congresswoman Blackburn.

675 Mr. Waxman in his opening statement seemed almost
676 insulted that there were only 53 people at the FDA that dealt
677 with cosmetics. I don't think that is necessarily a bad
678 thing if things are working pretty well. More regulators
679 doesn't automatically make for a better America.

680 Where is the fire at the FDA that we have to have these
681 authorities and these user fees? What is the huge problem
682 here that all of a sudden we need to enact some sort of
683 additional federal authority?

684 Mr. {Landa.} Let me make two observations. The first
685 is that in the most recent year for which we have information
686 from a voluntary system, there are several hundred reports of
687 problems and I think more than a hundred instances of some
688 harm, and that is a voluntary system which I think by
689 definition does not capture the universe. The second point I
690 would make, though, is the request here is for mandatory
691 registration that would encompass facilities, products and
692 ingredients from which we learn about the universe. It is
693 pretty clear at the moment we don't really know how many

694 facilities there are, how many products there are, how many
695 ingredients.

696 Mr. {Barton.} Well, wouldn't some sort of an increased
697 disclosure pretty well handle it? I mean, I cannot imagine
698 any consumer in America that would knowingly purchase a
699 cosmetic that had a real health issue. I mean, all it takes
700 is one Facebook or one Twitter message and that product is
701 deader than a doornail. I mean, why increase the regulatory
702 burden if in fact you said hundreds, where there are 300
703 million consumers in America. You know, I guess there are
704 probably people that abuse aspirin, take too many aspirin.
705 We don't take aspirin off the market because of that.

706 Mr. {Landa.} The hundreds we are talking about, the
707 several hundred I mentioned is in a voluntary system which
708 surely does not reflect the total number of complaints. I
709 think this is an area in which it is hard to imagine that
710 label disclosure alone would provide adequate protection.
711 People are, it seems to me, unlikely or may well be unlikely
712 to know just from reading a label--

713 Mr. {Barton.} I am going to yield to Ms. Blackburn
714 because I promised her some time, and it is only 2 minutes
715 left, but I don't see a problem here. I really don't. And
716 if you need another \$19 million, do a little internal soul
717 searching and find \$19 million in savings out of the hundreds

718 of millions, if not billions, of dollars that the budget of
719 the FDA is.

720 With that, I am going to yield the balance of my time to
721 Congresswoman Blackburn.

722 Mrs. {Blackburn.} And I thank the gentleman.

723 Mr. Landa, I want to talk to you about one specific
724 product. I have been on this issue now for a while, and we
725 have got some cosmetic companies that are out there. They
726 are marketing products with the active pharmaceutical
727 ingredients that are used in Latisse, and we have written
728 letters, we have tried to get an answer. We would love to
729 get these products off the market because they have an active
730 pharmaceutical ingredient. So what else beyond warning
731 letters can the FDA do to prevent these companies from
732 marketing pharmaceutical products as cosmetics and why do you
733 think the FDA might be so hesitant to take some action on
734 these cases?

735 Mr. {Landa.} Well, if a product--a product can be both
736 a cosmetic and a drug, and if it is a drug, by virtue of the
737 uses, its intended uses to cure, treat, mitigate disease, for
738 example, it is subject to the drug requirements of the Act,
739 typically the New Drug requirements of the Act, meaning that--
740 -

741 Mrs. {Blackburn.} But the FDA doesn't seem to be taking

742 any action, even though this has been brought to their
743 attention and followed forward on.

744 Mr. {Landa.} Could you give me the name of the product?

745 Mrs. {Blackburn.} Latisse, and I will be happy to give
746 you additional information. I think that our issue is this.
747 You requested funding, so in 2005 the Office of Cosmetics and
748 Colors had been reduced to \$3.5 million and 10 FTEs to
749 oversee \$11 billion of products sold annually. In 2007, it
750 went to \$10 million. And then we responded, and FDA's
751 cosmetic activities were funded in 2012 at \$11.7 million with
752 20-plus FTE positions. The concern is this: in order to
753 keep the marketplace safe, in order to provide confidence to
754 the millions of American women that use cosmetic products and
755 also use some products that have active pharmaceutical
756 ingredients in them like Latisse, what we want to do is make
757 certain that you all are doing the work and carrying forward
758 on this workload.

759 So my time is up, and we will give you the appropriate
760 information so that you can give us a written and detailed
761 response, and I yield back.

762 Mr. {Landa.} I will do that. Thank you.

763 Mr. {Pitts.} The chair thanks the gentlelady and
764 recognizes the gentlelady from Illinois, Ms. Schakowsky, for
765 5 minutes for questions.

766 Ms. {Schakowsky.} Thank you, Mr. Chairman, and thank
767 you, Director Landa, and I want to associate myself with the
768 remarks and the questioning, the line of questioning of
769 Congresswoman Blackburn that we need to follow up when
770 questions are raised about the safety of products.

771 How many cosmetic companies are there?

772 Mr. {Landa.} We don't have a complete list.

773 Ms. {Schakowsky.} And how many chemical ingredients are
774 used to formulate cosmetics?

775 Mr. {Landa.} We don't have a complete list.

776 Ms. {Schakowsky.} And how many chemical ingredients
777 have been banned for use in cosmetics in the United States?

778 Mr. {Landa.} I think the number is about a dozen.

779 Ms. {Schakowsky.} Actually, I believe it is 10. And
780 how many chemical ingredients have been banned for use in
781 cosmetics in the European Union?

782 Mr. {Landa.} I don't know.

783 Ms. {Schakowsky.} That is over 1,200, and you talked
784 about how we are working with the European Union to deal with
785 this issue. So you might want to look at what they are
786 doing.

787 In its 37-year history, the industry-funded Cosmetic
788 Ingredient Review panel has reviewed just 11 percent of the
789 10,500 cosmetic ingredients cataloged by FDA. According to a

790 2004 study by the Environmental Working Group, the 89 percent
791 of ingredients that remain unassessed are used in more than
792 99 percent of all cosmetic and personal care products on the
793 market used by pregnant women, children and the elderly. So
794 what kind of premarket testing and safety substantiation is
795 required by the FDA of cosmetic ingredients before they are
796 allowed to go into cosmetic products?

797 Mr. {Landa.} The statute, setting aside color
798 additives, which I mentioned earlier, there is no premarket
799 approval requirement that applies to cosmetics. Companies
800 are responsible for ensuring that the products they market
801 are safe. We certainly encourage them to do testing that is
802 both adequate and appropriate to the task but they are not
803 required to submit the results of testing to us.

804 Ms. {Schakowsky.} And even of the 10 ingredients that
805 have been banned, is there postmarket testing? Does the FDA
806 check and see if these ingredients are showing up?

807 Mr. {Landa.} We do some monitoring. So for example, we
808 have found mercury in products offered for import and have
809 prohibited their importation.

810 Ms. {Schakowsky.} So when you check, you have actually
811 found those ingredients appearing?

812 Mr. {Landa.} From time to time, yes.

813 Ms. {Schakowsky.} I wanted to in part respond to

814 Chairman Emeritus Barton, that everything is just fine. I
815 wanted to just read a portion of a letter from a Jennifer
816 Arce, a salon worker. She said ``I have loved every minute
817 of my career as a stylist until a product called Brazilian
818 Blowout completely changed my life as I knew it. The FDA has
819 found hair smoothing products including Brazilian Blowout
820 contain between 8.7 and 10.4 percent of the carcinogen
821 formaldehyde but these products have been labeled as
822 formaldehyde-free.'' First of all, let me just ask you this.
823 If they are labeled as formaldehyde-free, even though they
824 have formaldehyde, what authority do you have to deal with
825 that?

826 Mr. {Landa.} Such a product would be misbranded, and in
827 fact, we wrote--issued a warning letter to a company
828 marketing such a product--

829 Ms. {Schakowsky.} Bu the FDA--

830 Mr. {Landa.} --citing both safety grounds and the
831 labeling issue you have just alluded to.

832 Ms. {Schakowsky.} Right. But she goes to say ``The FDA
833 does not have mandatory recall authority and could not recall
834 these products, leaving salon workers and consumers at
835 risk.'' Is that true?

836 Mr. {Landa.} It is correct that we do not have
837 mandatory recall authority.

838 Ms. {Schakowsky.} So here is what she says, though,
839 ``that when clients' hair is blow dried, flat ironed, curled
840 or is processed under the hood dryer, the fumes that come out
841 of her hair upon heating make me and several of my coworkers
842 symptomatic all over again. Instantly, I get a sore throat,
843 dry mouth, difficulty breathing, dehydrated, a migraine,
844 cough. My tongue gets completely numb, burning and watering
845 eyes, blurred vision, burning lungs. I now get scabs on the
846 inside of my nose. I become almost bedridden from how raw my
847 throat becomes.'' She goes on about the inhalers that she
848 has to use. ``I am getting sicker and sicker with every
849 exposure. It is taking me longer to recover each time. I
850 have never had any type of respiratory problem nor have I
851 ever used an inhaler before my Brazilian Blowout exposure.''

852 It just seems to me that when we have the average
853 consumer using ten personal care products, we use them on our
854 children, men use them as well, that we need to give the FDA
855 more authority, and I would yield back. But Mr. Chairman, if
856 I could ask for unanimous consent to put some documents in
857 the record?

858 Mr. {Pitts.} Without objection, so ordered.

859 Ms. {Schakowsky.} Thank you.

860 [The information follows:]

861 ***** COMMITTEE INSERT *****

|
862 Mr. {Pitts.} The chair thanks the gentlelady and now
863 recognizes the gentleman from Ohio, Mr. Latta, for 5 minutes
864 for questions.

865 Mr. {Latta.} Thank you, Mr. Chairman, and Mr. Landa,
866 thanks very much for being here today. I would like to just
867 ask a couple questions this morning.

868 The first is, I think that Chairman Emeritus Barton kind
869 of asked a little bit on, how many--I think you said there
870 were several hundred reported instances every year of
871 products that--

872 Mr. {Landa.} Several hundred in fiscal year 2011, the
873 most recent for which we have information.

874 Mr. {Latta.} And that is what would be reported to FDA?

875 Mr. {Landa.} Yes.

876 Mr. {Latta.} Is there any idea how many that are
877 reported in the news? Do you follow that at all?

878 Mr. {Landa.} Not in a way that would permit
879 compilation.

880 Mr. {Latta.} And the next question is, as I was looking
881 at your testimony on page 6 when you are talking about how
882 many cosmetics have been imported from fiscal year 2004 to
883 2010, it has nearly doubled from a million to about 1.9
884 million imports. Of those that are imported, do you see a

885 change in those, that those are ones that might have more
886 problems being reported? Do you check those?

887 Mr. {Landa.} We do some monitoring. Obviously with
888 numbers like that, the agency cannot even eyeball, much less
889 do much testing.

890 Mr. {Latta.} When you say monitoring, what do you do?
891 Do you have, like, selected products that you just kind of
892 randomly take, bring in and check, or how do you do that?

893 Mr. {Landa.} We will look for products of certain type.
894 We will look for certain types of ingredients. I mean, one
895 example, there was a problem several years ago with face
896 paint, a product from China. It was the kind of product that
897 Boy and Girl Scouts would use at various parties. And so
898 that is an example of a type of product we keep an eye out
899 for, there having been a problem with it once.

900 Mr. {Latta.} Okay. And then also in the testimony, you
901 also pointed out a little bit later that the United States,
902 the European Union, Canada and Japan are all kind of in a
903 consortium--would that be best way to say it--looking at
904 products?

905 Mr. {Landa.} And ways of dealing with the industry.
906 So, for example, there is an agreement on looking at a
907 certain international standard or a set of principles for
908 current Good Manufacturer Practice regulations. We are

909 trying to reach agreement on ways of reducing animal testing.

910 Mr. {Latta.} Do other countries adhere to that that
911 aren't part of that consortium?

912 Mr. {Landa.} I think it varies.

913 Mr. {Latta.} Are there some countries, again, going
914 back to the importation, are there some counties that are
915 making cosmetics that you would say would be having more
916 problems than others?

917 Mr. {Landa.} I think in some cases, we know more about
918 manufacturing so we probably know about manufacturing, for
919 example, in western Europe than we do in China or India.

920 Mr. {Latta.} Okay. Again, when these--I guess that
921 kind of goes back to the earlier question about looking at
922 the products that are coming in that are imported. Are those
923 countries then looked at with a keener eye than others?

924 Mr. {Landa.} We try to do that.

925 Mr. {Latta.} Any idea how many of those imports come
926 from those countries that aren't part of Japan, European
927 Union, Canada, United States?

928 Mr. {Landa.} I don't know. I can see--if you like, I
929 can see if we can get a handle on that.

930 Mr. {Latta.} Okay. And then also, when you are talking
931 about the Voluntary Cosmetic Registration Program, you say
932 that you have currently got about 1,600 domestic and foreign

933 registered cosmetic establishments. What percentage would
934 that be of overall then that would be out there? Is it a
935 very, very small percentage or a large percentage?

936 Mr. {Landa.} I don't think it is very, very small, but
937 I think the answer is, we don't really know. I mean, I don't
938 think it is 2 percent but I don't think we know that it is 35
939 or 28 or 17.

940 Mr. {Latta.} Mr. Chairman, that concludes my
941 questioning. I yield back.

942 Mr. {Pitts.} The chair thanks the gentleman and
943 recognizes the gentleman from New York, Mr. Towns, for 5
944 minutes for questions.

945 Mr. {Towns.} Thank you very much, Mr. Chairman.

946 Let me thank you, Mr. Landa, for being here to testify
947 today. I want to follow up on the question that was sort of
948 raised by Congresswoman Blackburn. I would like for you to
949 just let me know exactly what can the FDA do to protect
950 consumers in cases where the agency knows that there is a
951 misbranding. What can you do?

952 Mr. {Landa.} Working through the Department of Justice,
953 we can effect a seizure of such a product. Also, again,
954 working through the Department of Justice, we can obtain an
955 injunction to prohibit manufacture and shipment of the
956 product. There is also--under the Federal Food, Drug and

957 Cosmetic Act, there are criminal penalties so that is another
958 remedy available.

959 Mr. {Towns.} So in the event that you are now able to
960 get the user fees, you know, what difference would it make?

961 Mr. {Landa.} I think user fees would help us set safety
962 standards, say, for microbiological safety. To the extent we
963 found it necessary, it would enable us to focus on ingredient
964 safety. I think it would help us establish current Good
965 Manufacturing Practice regulations. The process is
966 difficult. It would enable us to have more investigators in
967 the field doing inspections of cosmetic facilities. The fees
968 would enable us to do training, to do education, to do
969 outreach and to perhaps strengthen the voluntary reporting
970 system. And just a word about training. In some ways, for
971 sort of the easy part of this, ``easy'' in quotes, is
972 establishing the standards. The hard part is securing
973 compliance, which requires training of investigators but also
974 outreach to industry and training and technical assistance
975 because the idea is that you want to bring everyone along to
976 comply. It is not practical to seek to obtain compliance
977 simply by using the standard enforcement tools.

978 Mr. {Towns.} Just assume that you get the user fees as
979 you request. Would you also ask for recall authority?

980 Mr. {Landa.} The Administration has not taken a

981 position on that. I think the question there is, what one
982 might want to do is look at the utility of that kind of
983 authority in other contexts, I mean, before making a judgment
984 about its utility in this context.

985 Mr. {Towns.} Mr. Chairman, on that note, I yield back.

986 Mr. {Pitts.} The chair thanks the gentleman and
987 recognizes the gentleman from New Jersey, Mr. Lance, for 5
988 minutes for questions.

989 Mr. {Lance.} Thank you, Mr. Chairman, and thank you for
990 being with us, Mr. Landa.

991 Congresswoman Blackburn began the discussion, and I
992 would like to continue it, regarding the Latisse example,
993 originally used, as I understand it, for glaucoma and more
994 recently for enhancement of eyelashes. We know that the
995 pharmaceutical company--I believe it is Allergan--did the
996 right thing. It submitted its product for appropriate
997 approval with clinical testing data through the FDA's drug
998 approval pathway despite its being costlier and resulting in
999 the products taking longer to reach market. Are you
1000 concerned that if the FDA does not adequately prevent the
1001 illegal marketing of pharmaceuticals as cosmetics, we will be
1002 creating an incentive for companies simply to bring new
1003 products to market as cosmetics, avoiding the costs and
1004 delays associated with the drug approval pathway?

1005 Mr. {Landa.} I think that is a possibility, yes.
1006 Obviously, it is much more expensive to bring a product to
1007 market as a drug. It entails going through the New Drug
1008 Approval process. And I should have said earlier, we will
1009 get back to you about the question that Ms. Blackburn asked.
1010 But Latisse, now that I am remembering, is marketed as a drug
1011 and not as a cosmetic.

1012 Mr. {Lance.} Correct. And those companies doing the
1013 right thing are at a market disadvantage with those companies
1014 not doing the right thing, many of them from abroad.

1015 Mr. {Landa.} If they are marketing as a cosmetic a
1016 product that is truly a drug, that is correct.

1017 Mr. {Lance.} Yes.

1018 Mr. {Landa.} Claims can make a difference, so depending
1019 on the nature of the claims, a product may be a cosmetic
1020 alone and not a cosmetic and a drug.

1021 Mr. {Lance.} Well, thank you. I hope to continue to
1022 work with you on this issue. I think we need an even playing
1023 field, especially for the companies that are doing the right
1024 thing, American companies, in my judgment, and others are not
1025 doing the right thing.

1026 You mentioned an increase in products that are marketed
1027 as cosmetics but list ingredients that are themselves drugs
1028 or would normally cause the product to be classified as a

1029 drug. How does the agency handle products that do not list
1030 the ingredients in question or modify claims in such a way to
1031 mask the inclusion of an active pharmaceutical ingredient?

1032 Mr. {Landa.} Well, if the ingredient is of the type you
1033 have described is not listed, then the product is misbranded.

1034 Mr. {Lance.} Yes.

1035 Mr. {Landa.} The listing of that sort of an ingredient
1036 is required.

1037 Mr. {Lance.} And do you take enforcement action in that
1038 case?

1039 Mr. {Landa.} We certainly can, ranging from a warning
1040 letter at the administrative letter to the types of actions I
1041 described earlier, seizure and--

1042 Mr. {Lance.} Are we not more likely to continue to see
1043 an increase in these types of products if the FDA allows
1044 products to be illegally marketed in this manner?

1045 Mr. {Landa.} I think if companies look at a market and
1046 see that there is an opportunity that the government is not
1047 attending to, they are more likely to continue focusing on
1048 that market.

1049 Mr. {Lance.} Thank you. I think that is certainly
1050 accurate and obvious, and I hope to work with the FDA in a
1051 way that makes sure that we all play by the same rules on an
1052 even playing field. I do not believe that is the case now,

1053 and I respectfully suggest that the FDA needs to do a better
1054 job in this area, and I look forward to working with you and
1055 certainly with other members of the subcommittee on this
1056 important issue.

1057 Thank you, Mr. Chairman, and I yield back the balance of
1058 my time.

1059 Mr. {Pitts.} The chair thanks the gentleman and
1060 recognizes the gentleman from Illinois, Mr. Shimkus, for 5
1061 minutes for questions.

1062 Mr. {Shimkus.} Thank you, Mr. Chairman.

1063 I have to be honest with you. I am not a cosmetic
1064 expert, and I am not going to try to be one, but I do know
1065 that, you know, in downtown, even in rural America and Main
1066 Street America, you have beauticians and in the malls you
1067 still have a kind of vast array of consumer goods and
1068 economic activity in this sector. I think in your opening
1069 testimony, you talked about \$60 billion in sales per year.
1070 Do we know how that is broken down as to large versus small
1071 businesses and the number of jobs that are in this sector?

1072 Mr. {Landa.} I think that information is knowable but I
1073 do not know it.

1074 Mr. {Shimkus.} Of course, you know, it is the constant
1075 debate about the balance, and as we want to protect consumer
1076 safety, we want to also make sure that we are not providing a

1077 great disincentive to some of these very small businesses
1078 that really rely on the cosmetic sector in their own
1079 families' welfare. I mean, it is a very vibrant aspect of
1080 our economy.

1081 So let me go to a debate on the whole safety of this
1082 cosmetic debate, and I guess one of my concerns was that when
1083 we talk about the scientific evidence, when the scientific
1084 evidence suggests that a certain tolerance level be set for a
1085 constituent to ensure safety, then the scientific evidence
1086 would suggest that the tolerance level is appropriate for all
1087 areas of the country to ensure safety. That is a question.
1088 If you have scientific evidence, that should be--that should
1089 apply across the board regardless if you are in--let us pick
1090 a State like California versus a state like Illinois. Would
1091 you agree that really the scientific evidence should be the
1092 base and that should move decision making on the regulatory
1093 regime?

1094 Mr. {Landa.} Yes. The only caveat is that sometimes
1095 the scientific evidence and experts' opinions of it aren't
1096 completely clear or there isn't a complete consensus. So
1097 there may be a view that level X is sufficient to provide
1098 protection, and there may be another view based on the same
1099 data that level Y, which is lower or higher than level X, is
1100 sufficient to provide adequate protection.

1101 Mr. {Shimkus.} And I appreciate that, but I mean, that
1102 is why it is science and methodology and the scientific
1103 method versus opinion. The concern is allowing opinion to
1104 rule or overrule what is a scientific consensus, and I know
1105 you are going to be careful not to upset the apple cart here
1106 but I am just making that point, you know, establishing that,
1107 because not just in this sector but we see that in other
1108 sectors of the federal government as the Energy and Commerce
1109 Committee and the Health Subcommittee. I mean, we
1110 eventually--people eventually come to us and say please help
1111 us get to a scientific point in the debate so that there is
1112 one standard versus 50 different standards. I think the
1113 other thing that drives me a little bit crazy is when large
1114 States might be able to extort the private sector based upon
1115 their view of what the scientific evidence might be and
1116 really change market dynamics on products, goods and
1117 services.

1118 Mr. {Landa.} The only point I was trying to make about
1119 data is that different and equally qualified experts applying
1120 the same criteria can look at the same data set and reach
1121 different conclusions about a level that is intended to be
1122 protected.

1123 Mr. {Shimkus.} And I am not going to disagree with
1124 that. I am just going to say in an international market and

1125 an interstate commerce clause having a single standard
1126 eventually nationally you have to make a decision and that
1127 decision ought to arrive across. You did confirm--excuse me,
1128 Mr. Chairman, let me just go on--that the current FDA law
1129 requires manufacturers to substantiate the safety of their
1130 products before marketing. You did make that statement
1131 earlier?

1132 Mr. {Landa.} Yes. The law in effect places on
1133 companies the burden to market products that are safe and to
1134 not market products that are not safe.

1135 Mr. {Shimkus.} Thank you.

1136 Mr. {Pitts.} The chair thanks the gentleman. That
1137 completes the questionnaire for the subcommittee members. We
1138 have a member of the full committee here who would like to
1139 ask questions. Without objection, the chair recognizes the
1140 gentleman, Mr. Markey from Massachusetts, for 5 minutes for
1141 questions.

1142 Mr. {Markey.} Thank you, Mr. Chairman, very much.

1143 Most people assume that their favorite beauty and bath
1144 products have been approved by the FDA before they hit the
1145 shelves but looks can be deceiving. The products that are
1146 labeled purifying, cleansing or safe and gentle for baby are
1147 among the least regulated consumer products on the market.
1148 And when you talk about cosmetics, we are talking about men

1149 as well. We are talking about their shaving cream, their
1150 shampoo, their deodorants, their after shave, all the way
1151 down the list. This is the modern world we live in.

1152 So more than 12,000 unique chemical ingredients are used
1153 in personal care products. Many of these have been linked to
1154 cancer, infertility, behavioral problems in children and
1155 other chronic conditions. The majority of these have never
1156 been assessed for safety in cosmetic products by any
1157 independent or government body.

1158 The only federal agency that has jurisdiction over
1159 cosmetic products, the FDA, currently operates with their
1160 hands tied. The cosmetics department within FDA operates
1161 with only a handful of employees and lacks a significant
1162 authority to address these concerns.

1163 Representative Schakowsky and Representative Baldwin and
1164 I introduced a bill in the last Congress and then again in
1165 this Congress, and we spent the Congress before that doing
1166 the research and putting the concept together to regulate
1167 this area, and I look forward to working with my colleagues
1168 in order to ensure the safety of all personal care products.

1169 Mr. Landa, does the FDA have the authority to ensure
1170 that products like bubble bath or baby lotion are free from
1171 toxic chemicals like formaldehyde before they hit the
1172 shelves?

1173 Mr. {Landa.} The agency does not have premarket
1174 approval authority for cosmetics, as I mentioned earlier.
1175 Our premarket approval authority extends only to color
1176 additives used in cosmetics.

1177 Mr. {Markey.} Thank you. If the FDA believed that the
1178 level of formaldehyde found in a baby bubble bath was
1179 harmful, could it require a recall of that product from
1180 market shelves?

1181 Mr. {Landa.} It could not under current law.

1182 Mr. {Markey.} In the 1800s, arsenic was sold by
1183 pharmacists everywhere as a soap to rid the skin of liver
1184 spots, blotches, wrinkles and other signs of aging. It turns
1185 out, you never have to worry about aging if you rub arsenic
1186 on your face every day because arsenic helps you avoid the
1187 aging process altogether. If a company decided to include
1188 arsenic in 2012 as a component of a face cream, would they
1189 even have to notify the FDA first?

1190 Mr. {Landa.} It would not.

1191 Mr. {Markey.} It would not?

1192 Mr. {Landa.} Correct. There is no premarket
1193 notification requirement.

1194 Mr. {Markey.} There is no premarket notification to the
1195 FDA that a company would include arsenic in a face product.
1196 Now, if the arsenic was used as a component of a fragrance

1197 mixture, would the company be required to list arsenic on the
1198 product label?

1199 Mr. {Landa.} As a component of a fragrance, it would
1200 not.

1201 Mr. {Markey.} It would not. So that would come, I
1202 think, as a shock to most people because, you know, we are in
1203 a consumer society today where everyone assumes that on the
1204 box of cereal or any other product which they are going to
1205 use for their family that they can turn the box around and
1206 check it out, see what is in it, but arsenic is just not
1207 something that would have to be listed because the FDA does
1208 not have the authority to require that to be disclosed to the
1209 public, and I think therein lies the problem. Give the
1210 public the information they need, and once they do, boom, you
1211 are going to see the changes that are needed. As well, the
1212 FDA should be able to do what it takes in order to protect
1213 the public in this sector.

1214 So from my perspective, I think, you know, whether it be
1215 the male or the female in the family, whether it be the baby
1216 in the family, that everyone has a right to be protected,
1217 everyone has a right to know what could happen to them
1218 because of exposure to these chemicals.

1219 I thank you, Mr. Chairman, for the courtesy of being
1220 allowed to ask these questions.

1221 Mr. {Pitts.} The chair thanks the gentleman.

1222 That concludes our questioning for the first panel. The
1223 chair would like to thank Mr. Landa for your testimony, your
1224 answering of questions, and if we have any follow-up
1225 questions, we will send them to you and ask you to respond.

1226 Mr. {Landa.} Thank you, Mr. Chairman.

1227 Mr. {Pitts.} Thank you.

1228 We will call our second panel to the witness table at
1229 this time, and I would like to thank all of them for agreeing
1230 to testify before the subcommittee today, and I would like to
1231 quickly introduce our expert panel. First, Dr. Halyna
1232 Breslawec is the Chief Scientist and Executive Vice President
1233 for Science for The Personal Care Products Council. Mr.
1234 Peter Barton Hutt is Senior Counsel at the Washington, D.C.,
1235 law firm of Covington & Burling, and a lecturer on food and
1236 drug law at Harvard Law School. Ms. Curran Dandurand is the
1237 Chief Executive Officer, Co-founder and Co-owner of Jack
1238 Black LLC. Ms. Deborah May is the President of Wholesale
1239 Supplies Plus in Broadview Heights, Ohio. And Dr. Michael
1240 DiBartolomeis is the Chief of the Occupational Lead Poisoning
1241 Prevention Program and California Safe Cosmetics Program for
1242 California's Department of Public Health.

1243 Again, thank you all for coming. We have your prepared
1244 statements, which will be made a part of the record. We ask

1245 that you summarize your opening statements in 5 minutes. Dr.
1246 Breslawec, we will begin with you. You are recognized for 5
1247 minutes to summarize your testimony.

|

1248 ^STATEMENTS OF HALYNA BRESLAWEC, PH.D., CHIEF SCIENTIST AND
1249 EXECUTIVE VICE PRESIDENT FOR SCIENCE, THE PERSONAL CARE
1250 PRODUCTS COUNCIL; PETER BARTON HUTT, J.D., SENIOR COUNSEL,
1251 COVINGTON & BURLING, LLP; CURRAN DANDURAND, CO-FOUNDER AND
1252 CHIEF EXECUTIVE OFFICER, JACK BLACK SKINCARE; DEBORAH MAY,
1253 PRESIDENT AND CHIEF EXECUTIVE OFFICER, WHOLESALE SUPPLIES
1254 PLUS; AND MICHAEL J. DIBARTOLOMEIS, PH.D., C.I.H., CHIEF,
1255 OCCUPATIONAL LEAD POISONING PREVENTION PROGRAM AND CALIFORNIA
1256 SAFE COSMETICS PROGRAM, CALIFORNIA DEPARTMENT OF PUBLIC
1257 HEALTH

|

1258 ^STATEMENT OF HALYNA BRESLAWEC

1259 } Ms. {Breslawec.} Chairman Pitts, Ranking Member Pallone
1260 and distinguished members of the committee, thank you for the
1261 opportunity to testify before you on behalf of The Personal
1262 Care Products Council. My name is Halyna Breslawec. I hold
1263 a Ph.D. in medicinal chemistry and am the Chief Scientist and
1264 Executive Vice President for Science for The Personal Care
1265 Products Council, the trade association representing more
1266 than 600 member companies that manufacture, distribute and
1267 supply the vast majority of finished personal care products
1268 marketed in the United States.

1269 Prior to joining the council, I spent 14 years at the
1270 U.S. Food and Drug Administration, worked in the private
1271 sector as a medical device consultant, and served as the
1272 Deputy Director of the Cosmetic Ingredient Review, CIR.

1273 Cosmetics are among the safest category of products
1274 regulated by FDA. The safety of our consumers and their
1275 families is always the number one priority for our industry.
1276 Careful and thorough scientific research and development are
1277 the most important aspects of cosmetic formulation and the
1278 foundation for everything that we do. The cosmetics industry
1279 invests more than \$3.6 billion each year on research and
1280 development and to ensure product safety. Companies conduct
1281 thorough product safety evaluations using the same science-
1282 based approaches embedded in FDA, EPA and other regulatory
1283 agencies around the world. Numerous health questions are
1284 addressed including but not limited to the potential for
1285 cancer, reproductive harm and allergy. A complete safety
1286 assessment also accounts for who uses the products, how they
1287 are used and how often they are used over a lifetime.

1288 The foundation of science-based safety assessment is
1289 that any ingredient has a safe range and an unsafe range,
1290 whether it is water or a vitamin or a newly discovered
1291 compound. An ingredient's safe range is defined through many
1292 studies. In formulating cosmetics, companies choose

1293 ingredients that can be used well within their safe range and
1294 avoid ingredients that cannot be used safely. Once a product
1295 is in use, companies continue to monitor consumer experience
1296 in the marketplace.

1297 Our industry also supports independent programs to
1298 review product and ingredient safety. The most significant
1299 example is the Cosmetic Ingredient Review, or CIR, which was
1300 established in 1976 with support from the FDA and the
1301 Consumer Federation of America. Today, CIR is the only
1302 scientific program in the world dedicated to a systematic,
1303 thorough and continuous review of cosmetic ingredient safety
1304 in a public forum. The CIR expert panel is an independent
1305 body of world-renowned physicians and scientists, most of
1306 whom are affiliated with academic institutions, who assess
1307 cosmetic ingredient safety data in an open and public manner.
1308 The FDA, Consumer Federation of America and the council are
1309 non-voting members of CIR. CIR has reviewed the safety of
1310 more than 2,400 cosmetic ingredients, some of them
1311 specifically at the request of FDA.

1312 Consumers, scientific and medical groups nominate the
1313 expert panels who must meet strict conflict of interest
1314 standards. The expert panel members are not industry
1315 employees. CIR maintains a completely transparent process.
1316 All meetings and safety data are open to the members of the

1317 public, who can raise issues for consideration by the CIR
1318 panel. Their findings are published in the peer-reviewed
1319 journal, the International Journal of Toxicology.

1320 We strongly recommend that FDA incorporate the CIR into
1321 its cosmetic regulatory process by formally recognizing its
1322 findings. Science and safety are the cornerstones of the
1323 cosmetic industry and collectively we must remain steadfast
1324 in our commitment to safety.

1325 I would like take off my science hat for a minute and
1326 say a few words about the enormous contributions our industry
1327 has in making the U.S. economy stronger, especially how the
1328 cosmetic industry plays a unique role in empowering American
1329 women both as consumers and professionals. Women make up 66
1330 percent of our industry's workforce and hold more than half
1331 of the management positions. Our member companies offer
1332 women strong entrepreneurial opportunities that offer
1333 personal growth and economic freedom.

1334 Chairman Pitts, Ranking Member Pallone, distinguished
1335 members of the committee, the cosmetic industry puts consumer
1336 safety first and we will continue to proactively work to
1337 ensure the products we manufacture contribute to the well-
1338 being of American consumers. Thank you.

1339 [The prepared statement of Ms. Breslawec follows:]

1340 ***** INSERT 2 *****

|
1341 Mr. {Pitts.} The chair thanks the gentlelady and
1342 recognizes Mr. Hutt for 5 minutes for an opening statement.

|
1343 ^STATEMENT OF PETER BARTON HUTT

1344 } Mr. {Hutt.} Mr. Chairman, Ranking Member Pallone and
1345 members of the committee, I am Peter Barton Hutt. I am
1346 Senior Counsel in the Washington, D.C., law firm of Covington
1347 & Burling, and a lecturer on food and drug law at Harvard Law
1348 School, where I have taught a full course on food and drug
1349 law for the past 19 years. During 1971 to 1975, I served as
1350 Chief Counsel for the Food and Drug Administration.

1351 Thank you for the opportunity to appear before you today
1352 on behalf of The Personal Care Products Council, the trade
1353 association representing the cosmetic industry in the United
1354 States and globally.

1355 First, let me briefly describe the council and the
1356 United States cosmetic industry. The council represents not
1357 only well-known United States and global brands but the
1358 majority of the members have 50 or fewer employees. Over 90
1359 percent of all cosmetic companies in our country are small
1360 businesses that have 50 or fewer employees. We are here
1361 today to discuss future FDA regulation of this cosmetic
1362 industry. I would like to make three points.

1363 First, the Federal Food, Drug and Cosmetic Act of 1938
1364 creates a strong framework for FDA regulation of cosmetics.

1365 Under this law, it is a crime to market an unsafe or
1366 mislabeled cosmetic. Cosmetic companies are required to
1367 substantiate the safety not only of their products but also
1368 their individual ingredients before being marketed to the
1369 public.

1370 My second point is that the basic statutory provisions
1371 that govern FDA regulatory authority today were put in place
1372 in 1938. Since 1938, FDA and the cosmetic industry have
1373 worked together to keep pace with changing technology by
1374 promulgation of creative regulations and the establishment of
1375 new regulatory programs. But even though FDA has repeatedly
1376 stated that cosmetics are the safest products they regulate,
1377 it is time to bring FDA's statutory authority up to date.

1378 My third point is that we believe that Congress can
1379 address these developments by making simple but important
1380 changes in FDA's statutory authority over cosmetics. We
1381 offer the following seven principles to guide this effort,
1382 and we support enactment of legislation that includes all of
1383 them.

1384 First, enacting into law the existing FDA programs for
1385 registration of manufacturing establishments and listing of
1386 cosmetic products. Second, requiring submission of reports
1387 on adverse reactions that are both serious and unexpected.
1388 Third, mandating FDA regulations establishing good

1389 manufacturing practices for cosmetics. Fourth, establishing
1390 programs to require FDA to review and determine whether
1391 controversial cosmetic ingredients and constituents are or
1392 are not safe, followed by strong FDA enforcement. Fifth,
1393 requiring FDA review of all Cosmetic Ingredient Review
1394 determinations on cosmetic ingredient safety and either
1395 acceptance or rejection of those determinations, again
1396 followed by strong FDA enforcement. Sixth, FDA establishment
1397 of a national cosmetic regulatory databank for use by
1398 everyone in the country. And seventh, an unambiguous
1399 Congressional determination that, as modernized, the revised
1400 statute will apply uniformly through the country.

1401 Concerns about safety of cosmetic ingredients must be
1402 addressed as rapidly as possible by FDA science. Congress
1403 should define a clear path for anyone to request that FDA
1404 review the safety of a cosmetic ingredient or constituent.
1405 We believe this will allow concerns about cosmetic
1406 ingredients and their constituents to be resolved
1407 expeditiously by the appropriate federal agency, the experts
1408 in the field, the Food and Drug Administration, rather than
1409 by 50 disparate State agencies.

1410 Under recently enacted laws, cosmetic companies must now
1411 submit ingredient reports to four different States, and there
1412 are copycat legislation efforts pending in additional States

1413 as well. None of these laws is consistent with the others.

1414 It is extremely important for the protection of the
1415 public and the vitality of this industry that FDA establish
1416 national standards on safety so that they apply in every
1417 State. It is impossible to formulate innovative products if
1418 different safety standards apply in different States. That
1419 is why national uniformity of these regulatory changes is
1420 critical to our support of this legislation.

1421 Mr. Chairman, Mr. Pallone, members of the committee,
1422 thank you again, and we look forward to working with you.

1423 [The prepared statement of Mr. Hutt follows:]

1424 ***** INSERT 3 *****

|
1425 Mr. {Pitts.} The chair thanks the gentleman and now
1426 recognizes Ms. Dandurand for 5 minutes for an opening
1427 statement.

|
1428 ^STATEMENT OF CURRAN DANDURAND

1429 } Ms. {Dandurand.} Good morning, Chairman Pitts and
1430 Ranking Member Pallone. My name is Curran Dandurand, and I
1431 am the CEO of Jack Black LLC, a company I founded 12 years
1432 ago with my husband and my colleague, Emily Dalton. We
1433 founded the company with our combined life savings and a
1434 vision of a market segment that we believed was underserved.
1435 Our company develops and markets quality personal care
1436 products for men under the brand name Jack Black.

1437 When we started, it was just the three of us operating
1438 out of my homes. We now employ 39 people plus another 30
1439 part-timers and we have office distribution and warehouse
1440 facilities.

1441 Jack Black is sold in all 50 states and in international
1442 markets and virtually all of our products and packaging are
1443 manufactured here in the United States.

1444 I am here today as a small business owner. When we
1445 started our business, there were only a small number of
1446 companies that marketed a full line of personal care products
1447 for men. Today, and in part due to our own success, this has
1448 dramatically changed and there are many more brands in the
1449 category. Some of these brands are being marketed by large,

1450 very powerful multinational companies with significant
1451 advertising and marketing resources.

1452 For smaller companies like ours that don't have these
1453 resources, the key to our growth is product innovation. New
1454 product innovation is the lifeblood of our business and
1455 drives our success.

1456 Product safety is the cornerstone of our brand
1457 philosophy. The first step in our product innovation process
1458 is to conduct an extensive ingredient review of the proposed
1459 new formula, and we confirm that the individual ingredients
1460 are safe and the combination of the ingredients is safe. The
1461 next step is to test the new formulation using the human
1462 repeat insult patch test, or HRIPT, and this ensures that the
1463 formula is non-irritating and non-allergenic. Once the
1464 product has passed the HRIPT, then we proceed to consumer
1465 panel testing to confirm product performance and consumer
1466 acceptance.

1467 The other key concern in the product development process
1468 is making certain that our products can be produced within
1469 our cost parameters and that they are fully compliant with
1470 the laws of all jurisdictions.

1471 Currently, within the United States, there has been a
1472 movement to create separate State requirements. These
1473 regulations would be separate and apart from and inconsistent

1474 with the federal standards established by FDA. Having to be
1475 knowledgeable about and comply with potentially 50 different
1476 standards on labeling, ingredient safety and registration
1477 requirements would be burdensome and impossible for a small
1478 company like hours, even successful ones.

1479 Smaller companies simply do not have the resources to
1480 develop and maintain separate inventories to meet the
1481 different State laws, and we cannot afford to have the
1482 regulatory staff needed to monitor and meet the registration
1483 requirements contained in some of the proposed State
1484 legislation. Compliance with separate State laws would
1485 trigger an avalanche of costs as companies have to make
1486 labeling and packaging changes, formulation changes, undergo
1487 new testing for each and every unique State requirement. I
1488 can tell you, if this had been the regulatory landscape 12
1489 years ago when I started Jack Black, we would have had a very
1490 difficult time getting out of the starting gate, much less
1491 become successful, and our company and product line would
1492 probably not exist today.

1493 It is absolutely clear that myriad diverse State
1494 regulations would substantially increase the cost of
1495 producing and distributing personal care products with a
1496 disproportionate impact on smaller companies. Consequences
1497 for small business owners would be disastrous. Many would

1498 have to stop doing business in States where they cannot
1499 afford to comply. Others would go out of business
1500 altogether. For those that remain in the market, they will
1501 have to pass along significant price increases to their
1502 consumers to cover the higher costs of doing business. The
1503 end result is significant additional costs to small business
1504 plus jobs and revenue losses for the economy, but without any
1505 corresponding consumer benefit or improvements in product
1506 safety.

1507 The science does not change from State to State.
1508 Therefore, it does not make sense for varying State
1509 regulations regarding cosmetic safety standards. For the
1510 benefit of all stakeholders, consumers, personal care
1511 marketers as well as regulators, there is a need for one
1512 consistent national standard which protects consumer health
1513 and safety and provides clear direction and certainty for the
1514 regulated companies and the regulators.

1515 Do I need to stop?

1516 Mr. {Pitts.} Are you finished?

1517 Ms. {Dandurand.} I have, like, two more sentences.

1518 Mr. {Pitts.} Go ahead. You may finish.

1519 Ms. {Dandurand.} This would mean transparency in all
1520 health and safety decisions and a single forum where all can
1521 participate. We support the modernization of FDA laws that

1522 creates a national standard for cosmetics. I believe this
1523 will best protect the health and safety of our consumers and
1524 provide a strong foundation for growth and success of our
1525 small entrepreneurial companies that create jobs here in the
1526 United States.

1527 Thank you very much for the opportunity to appear before
1528 you.

1529 [The prepared statement of Ms. Dandurand follows:]

1530 ***** INSERT 4 *****

|
1531 Mr. {Pitts.} The chair thanks the gentlelady and now
1532 recognizes Ms. May for 5 minutes for an opening statement.

|
1533 ^STATEMENT OF DEBORAH MAY

1534 } Ms. {May.} Good morning, Chairman Pitts, Ranking Member
1535 Pallone and members of the Subcommittee on Health. Thank you
1536 for this opportunity today. My name is Deborah May and I am
1537 President of Wholesale Supplies Plus in Broadview Heights,
1538 Ohio. I am honored to offer my testimony on behalf of the
1539 members of the handcrafted soap and cosmetic industry.

1540 Sixteen years ago, I was working as a registered nurse
1541 in the ICU at the Cleveland Clinic. On August 1, 1996, I
1542 gave birth to my second daughter, who was eventually
1543 diagnosed as being cortically blind and having severe autism.
1544 In the months that followed, I lost my job because of my
1545 daughter's around-the-clock medical needs. Our bills became
1546 overwhelming. My husband, a Catholic high school teacher,
1547 and I were drowning in debt. Our secure, predictable,
1548 middle-class life was gone. I sought support through online
1549 forums with other mothers facing similar challenges. Through
1550 one exchange, I was introduced to the art of making handmade
1551 soaps and cosmetics. I was amazed at how easy it was to make
1552 high-quality small batches of products for my family and
1553 friends.

1554 I registered for a local high school craft show and sold

1555 out. My first wholesale account was from a craft show
1556 customer whose brother owned a shop in California. He was
1557 delighted I would make 10 bars of a custom soap in any
1558 combination of scent and color and fill that order within 48
1559 hours. At home, I built my business and it worked. I loved
1560 what I was doing, and most important, it saved my family from
1561 foreclosure and allowed us to pay overwhelming medical bills.

1562 In 1999, I founded the company Wholesale Supplies Plus.
1563 My goal was to teach others how to make their own handcrafted
1564 cosmetics and provide supplies in very small quantities that
1565 start-up businesses could afford to purchase. Today,
1566 Wholesale Supplies Plus has 100,000 unique customers buying
1567 from us in the United States. We will exceed \$10 million in
1568 sales this year and have 35 employees.

1569 In a recent collaboration of data sharing, it was
1570 concluded that there are over 200,000 businesses hand
1571 producing cosmetics in the United States today. Ninety-five
1572 percent of these are women-owned businesses and average
1573 between one and three employees. That translates to between
1574 200,000 and 600,000 jobs in the United States today.

1575 The handmade cosmetic industry supports the Congress's
1576 efforts to ensure safe cosmetics. We believe our products
1577 are the safest on the market. We personally inspect each
1578 ingredient and have our hands in every part of the

1579 manufacturing process. Most ingredients we use are food
1580 grade and can be found at grocery stores. We support the
1581 principles of giving the FDA recall authority. We support
1582 the principles of mandatory adverse-event reporting for
1583 serious reactions that cause loss of life. We support the
1584 closing of labeling loopholes such as current incidental
1585 ingredient exclusions that are used to hide things such as
1586 preservatives from the consumer. We support small business
1587 exemptions for facility registration. These exemptions would
1588 allow individuals to make products for themselves, their
1589 friends, their family without the fear of breaking federal
1590 laws. Small business exemptions will encourage
1591 entrepreneurial growth and create local jobs. We support
1592 small business exemptions for fees. Fees are a barrier for
1593 entering into our market and will shut down all but a few of
1594 the 200,000 companies now producing handmade cosmetics and
1595 soap in our industry.

1596 We do not support reporting to the FDA individual
1597 product batches including ingredient suppliers used in that
1598 batch. Under the considered provision, it presumes truckload
1599 purchases of ingredients. That is not the case with our
1600 small businesses. We frequently buy small quantities of
1601 ingredients several times a week. Requiring us to report to
1602 the FDA each time we change supplies only serves to give

1603 large corporations a greater market advantage over small
1604 businesses. Quite simply, for every report a large
1605 corporation files, a handmade producer may need to file up to
1606 5,000 reports a month. Small businesses cannot afford to
1607 manage such a mandate, and frankly, it does nothing to
1608 improve the safety of cosmetics.

1609 I am not here seeking exemptions for Wholesale Supplies
1610 Plus. I am here so that the 200,000 small businesses making
1611 handcrafted cosmetics have the same opportunity to grow and
1612 become the next success story like Burt Bee's, like Mary Kay
1613 Cosmetics and even James Gamble of Proctor and Gamble, all of
1614 whom started as handcrafted microbusinesses. As Ronald
1615 Reagan said during his first inaugural address, government
1616 can and must provide opportunity, not smother it, foster
1617 productivity, not stifle it.

1618 On behalf of the handcrafted soap and cosmetic industry,
1619 I hope for the opportunity to work with this subcommittee on
1620 legislation as it moves forward. Testifying today has been
1621 my honor and privilege. Thank you.

1622 [The prepared statement of Ms. May follows:]

1623 ***** INSERT 5 *****

|
1624 Mr. {Pitts.} The chair thanks the gentlelady and now
1625 recognizes Dr. DiBartolomeis for 5 minutes for an opening
1626 statement.

|
1627 ^STATEMENT OF MICHAEL J. DIBARTOLOMEIS

1628 } Mr. {DiBartolomeis.} Good morning, Mr. Chairman and
1629 distinguished members of the Energy and Commerce Health
1630 Subcommittee.

1631 My name is Dr. Michael DiBartolomeis and I am a
1632 toxicologist and Chief of the Safe Cosmetics Program, which
1633 was established in the California Department of Public Health
1634 in 2006. In this role, I have heard concerns from many
1635 consumers and professionals in the personal care industry
1636 about cosmetic products and the negative health effects they
1637 may have on susceptible persons for lack of information
1638 available on their ingredients, the number of chemicals and
1639 formulations in them that have not undergone toxicity
1640 testing, the unknown health impacts for long-term low-dose
1641 exposure to individual chemicals or chemical mixtures, and
1642 insufficient consumer and workplace safety standards and
1643 enforcement.

1644 We use cosmetics from infancy through our senior years
1645 on a daily basis. Women use an average of 15 cosmetic
1646 products per day, and daily usage may be as high as 50
1647 products. Exposure to chemicals in cosmetics can occur from
1648 breathing vapors or particles, inadvertent swallowing and by

1649 application to the skin and eyes.

1650 The cosmetics provision within the Federal Food, Drug
1651 and Cosmetic Act was written over 70 years ago. Since that
1652 time, the cosmetics industry has grown to be a multibillion-
1653 dollar industry with products being marketed worldwide and
1654 sold not only in retail stores but by individuals working out
1655 of their homes and over the Internet.

1656 While the industry has changed, the provisions of
1657 federal law for regulating cosmetics have not. As a result,
1658 the burden falls on government to show harm before a cosmetic
1659 can be removed from the market. No premarket safety testing
1660 is required. Manufacturers have almost no incentive to test
1661 products for their potential to cause serious latent harm
1662 such as cancer. Cosmetic labels are not required to disclose
1663 some ingredients, and there are no requirements to disclose
1664 them to the federal government. And chemicals that can cause
1665 cancer, reproductive and/or developmental harm are
1666 consistently ending up in cosmetic products.

1667 The California Safe Cosmetics Act of 2005 requires
1668 manufacturers to disclose to the State all intentionally
1669 added chemical ingredients in their products that cause these
1670 adverse effects regardless of concentration. The Act also
1671 requires manufacturers to submit any additional information
1672 on their products as deemed necessary by the program to

1673 conduct its investigations. The FDA does not have comparable
1674 authority.

1675 Although the Act does not set safety standards or
1676 product bans, it responds to public concerns by empowering
1677 consumers to avoid the most toxic chemicals, thereby
1678 promoting product reformulation. By the end of last year,
1679 over 17,000 cosmetic products were reported to the program by
1680 700 unique companies as containing one or more reportable
1681 chemical ingredients. In total, 24,664 hazardous ingredients
1682 were reported in these products represented by 96 different
1683 chemicals.

1684 The data collected by the Safe Cosmetics Program are
1685 used to target health investigations, laboratory analyses and
1686 issue health advisories. For example, in March 2010, the
1687 program started receiving phone calls from hairstylists and
1688 clients complaining about the health effects of using a hair-
1689 straightening product called Brazilian Blowout. Complaints
1690 included burning eyes, nose, throat and scalp, hair loss,
1691 asthma episodes, skin blisters and other effects consistent
1692 with formaldehyde, a known human carcinogen. However, this
1693 product was advertised as formaldehyde-free. What happened
1694 over the next 22 months is too long of a story for me to tell
1695 here. However, the end result is informative. On January
1696 30, 2012, California announced a settlement with the makers

1697 of Brazilian Blowout requiring that they warn consumers about
1698 the dangers of using their product and stop marketing their
1699 product as formaldehyde-free. It was the first government
1700 enforceable action in the United States to address the
1701 exposure to formaldehyde associated with these products.
1702 Although the sale of this product in California violated five
1703 separate State laws and resulted in numerous acute injuries,
1704 these products are still being used in salons across the
1705 United States. In contrast, six countries have recalled the
1706 use of formaldehyde-based straighteners.

1707 On March 6, 2012, the New York Times reported that the
1708 makers of Brazilian Blowout agreed to settle a class-action
1709 suit for \$4.5 million. The CEO said the settlement will be
1710 paid by its insurance company, and was quoted as saying ``We
1711 get to sell our product forever without reformulation. That
1712 is the acquittal we have been waiting for.''

1713 Over the past 6 years, I have contemplated the
1714 challenges related to evaluating cosmetic product safety, and
1715 I have arrived at five elements which I believe would help in
1716 protecting public health. Number one, remove the burden to
1717 prove from government having to demonstrate harm by instead
1718 requiring manufacturers to document product safety through
1719 premarket testing of new cosmetics using a tiered battery of
1720 toxicity tests. Two, ensure that toxicity testing and safety

1721 data and other key information are available to government
1722 agencies and consumers. Number three, improve cosmetic
1723 labeling so that all chemical ingredients including
1724 fragrances, colors and flavors and those in professional-
1725 grade products are disclosed to consumers. Number four,
1726 establish safety standards for cosmetics and issue prompt
1727 mandatory recalls when they are found to be unsafe,
1728 adulterated or misbranded. And five, if a standing science
1729 advisory committee for cosmetic safety is thought to be
1730 valuable, require that it be wholly independent rather than
1731 industry sponsored and that its members have no conflicts of
1732 interest.

1733 I don't know how many cases like Brazilian Blowout
1734 exist. However, the fact is, cosmetics that contain known
1735 human carcinogens or chemicals that impair human reproduction
1736 or development or are toxic to the endocrine system are
1737 marketed and sold without adequate safety testing because the
1738 existing law allows it. This is a very serious public health
1739 problem which we could prevent because there are some very
1740 workable solutions to consider.

1741 I want to thank the committee for inviting me, and I
1742 would be happy to answer your questions.

1743 [The prepared statement of Mr. DiBartolomeis follows:]

1744 ***** INSERT 6 *****

|
1745 Mr. {Pitts.} The chair thanks the gentleman, and we
1746 will now begin questioning and recognize myself for 5 minutes
1747 for that purpose.

1748 Dr. Breslawec, Ms. Schakowsky indicated that the
1749 Cosmetic Ingredient Review panel has reviewed over 1,000
1750 ingredients. Dr. Landa on the last panel stated that he was
1751 not aware of a single instance where the FDA has disagreed
1752 with a CIR recommendation. Are you aware of an instance
1753 where the FDA has disagreed with a CIR recommendation?

1754 Ms. {Breslawec.} No, I am not.

1755 Mr. {Pitts.} Mr. Hutt, in your long experience, are you
1756 aware of any? The same question.

1757 Mr. {Hutt.} As you know and as Mr. Landa mentioned, FDA
1758 participates in every single deliberation of the Cosmetic
1759 Ingredient Review expert panel. We are unaware of any
1760 instance where the panel did not listen closely to FDA or
1761 where FDA disagreed with the panel recommendation.

1762 Mr. {Pitts.} Let me continue with you, Mr. Hutt. Have
1763 States tried to ban cosmetics and their ingredients? And
1764 speak as to why a national uniformity of cosmetic regulation
1765 is important.

1766 Mr. {Hutt.} I am not aware that States have taken
1767 action against cosmetic ingredients to ban them. I have just

1768 listened to the testimony from Dr. DiBartolomeis--I hope I
1769 get that right--that the State there was unable to come up
1770 with sufficient evidence to ban the Brazilian Blowout
1771 product. In contrast, when the Cosmetic Ingredient Review
1772 took a look at the request of FDA of the safety of that
1773 product, and I would like to turn to Dr. Breslawec to discuss
1774 this in greater detail, but what happened was, the Cosmetic
1775 Ingredient Review panel recommended a ban of the product for
1776 use in hair straightening. So here is a good example where
1777 the voluntary self-regulation is much more stringent,
1778 certainly than the State of California and perhaps even then
1779 the Food and Drug Administration.

1780 Mr. {Pitts.} Dr. Breslawec, would you care to comment?

1781 Ms. {Breslawec.} Yes, I would love to elaborate on
1782 that. The Food and Drug Administration approached the
1783 Cosmetic Ingredient Review having heard of adverse effects
1784 resulting from hair straighteners that claimed not to contain
1785 formaldehyde. The Cosmetic Ingredient Review panel accepted
1786 the request for review, and completed a review within a year,
1787 which is very, very short period of time. There was a very
1788 robust discussion about the safety of hair straighteners,
1789 whether formaldehyde was actually in the straighteners
1790 because a lot of them were labeled as formaldehyde-free when
1791 in fact they contained methylene glycol, which essentially is

1792 formaldehyde in liquid form. Following a very robust
1793 discussion, the CIR panel of experts determined that
1794 formaldehyde and methylene glycol in hair straighteners was
1795 not safe, and as a result of that--and The Personal Care
1796 Products Council agreed with their determination and
1797 supported their determination.

1798 Mr. {Pitts.} Ms. Dandurand, Ms. May, your stories were
1799 inspiring and compelling. I would like to ask both of you,
1800 should the cosmetics regulations be updated, in your opinion?

1801 Ms. {Dandurand.} Well, as I said in my opening remarks,
1802 I think we need a national standard, and I think I am in
1803 favor of registration of the facilities and providing the FDA
1804 with our ingredients so they do have a database. I would be
1805 supportive of both of those.

1806 Mr. {Pitts.} Ms. May?

1807 Ms. {May.} I think as witness testimony today,
1808 cosmetics are safe in the United States, are the safest
1809 products that the FDA regulates. My fear is that as
1810 legislation moves forward, there will be unintended
1811 consequences to small businesses and an economic impact.

1812 Mr. {Pitts.} And we don't have long, but Dr.
1813 DiBartolomeis, do you want to add to that your opinion on
1814 regulation being updated?

1815 Mr. {DiBartolomeis.} Actually, what I would like to do

1816 is just clarify something. I did not testify that the
1817 California Department of Public Health didn't have evidence
1818 to show that Brazilian Blowout wasn't harmful and shouldn't
1819 be removed from the market. We just lacked the authority to
1820 actually recall a product and remove it from the market.

1821 Mr. {Pitts.} Mr. Hutt, was the product seized? What
1822 was the follow-up?

1823 Mr. {Hutt.} The product was not seized. The resolution
1824 in California was simply to put information on the label and
1825 in the beauty salons. The State of California does have what
1826 is called a baby food and drug law statute. It is called the
1827 Sherman Act in California. It does permit for taking
1828 cosmetic products that are adulterated off the market, but
1829 California did not choose to use that authority. They do
1830 have the authority.

1831 Mr. {Pitts.} Thank you. My time is up.

1832 The chair recognizes the ranking member of the full
1833 committee, Mr. Waxman, for 5 minutes.

1834 Mr. {Waxman.} Thank you very much, Mr. Chairman. Thank
1835 you, Mr. Pallone, for allowing me to go before you in asking
1836 questions.

1837 Dr. DiBartolomeis, thank you very much for being here
1838 today. It should go without saying that the fact you are
1839 here demonstrates just how important it is to California that

1840 its law be preserved. As I understand it, the California
1841 Safe Cosmetics Act of 2005 contains a number of provisions
1842 that would seem to be essential to any system designed to
1843 ensure the safety of cosmetics in our country. First and
1844 foremost, the California law requires companies to disclose
1845 to the State if the ingredients in their products could cause
1846 cancer, reproductive harm or birth defects, and the law at
1847 the same time still protects trade secret information, so
1848 this is a very reasonable approach. The Sherman law in
1849 California is a law that I voted for when I was in the State
1850 legislature, and it again showed that California was ahead of
1851 the rest of the country. But there are limits on what you
1852 can do, even in the California law, and you talked about that
1853 earlier.

1854 In your testimony, you mentioned 700 companies have
1855 complied with the reporting requirements in California. Do
1856 you have a sense of whether this system has been onerous for
1857 companies? Do you get information from both large and small
1858 companies?

1859 Mr. {DiBartolomeis.} We do. The actual limit is \$1
1860 million of aggregate sales--

1861 Mr. {Waxman.} Is your microphone on?

1862 Mr. {DiBartolomeis.} Oh, I think it is now. Sorry. So
1863 the aggregate sales of \$1 million is a cutoff, so any company

1864 smaller than that would not have to report. We actually have
1865 help lines, we have an email that people can email us. In
1866 our reporting system, we have comments and an area where
1867 people can comment. We receive calls all the time. We work
1868 with manufacturers to report, and we have never received any
1869 comments that the reporting was too onerous for them to do.

1870 Mr. {Waxman.} You mentioned some staggering numbers in
1871 your testimony. Over 24,000 hazardous ingredients have been
1872 reported to the State. In one of the claims that we have
1873 repeatedly heard is that cosmetics do not present significant
1874 risk to consumers because they are not ingested. As a
1875 toxicologist in charge of the California cosmetics program,
1876 can you give us some sense for how much comfort we should
1877 take from the claims that the cosmetics are inherently safe
1878 because they are not ingested? It would be helpful if you
1879 could use examples of ingredients found in cosmetics to help
1880 us understand this issue better.

1881 Mr. {DiBartolomeis.} Well, the two that have been
1882 brought up here today, not just by me but others, Brazilian
1883 Blowout is something you breathe, so it is not something
1884 that--you are applying it but you are actually breathing
1885 formaldehyde that comes out from using this chemical and
1886 using this formulation. We have heard about mercury in face
1887 creams. That is something that you are rubbing on your skin.

1888 The mercury sinks in, and we actually have frank mercury
1889 toxicity in mothers and kids who have been exposed to these
1890 products. You could add nail polishes and nail polish
1891 removers to that. You are breathing in toluene vapors. You
1892 are getting exposed to phthalates and possibly even
1893 formaldehyde. So those are three examples right there that
1894 are not just from skin but other sources of exposure.

1895 Mr. {Waxman.} The industry legislation proposal would
1896 require national uniformity in cosmetics oversight, and of
1897 course, national uniformity is a nice way of saying that
1898 Congress will override and preempt State laws. As a general
1899 matter, I think preemption is a bad idea. However, there are
1900 instances in which preemption can make sense, particularly
1901 when the federal law is strong and there are multiple State
1902 laws with different requirements. Your testimony describes
1903 five elements that would in your view be important to have in
1904 a strong cosmetics regulatory program, and my understanding
1905 is that none of these elements is reflected in the industry
1906 proposal

1907 If a federal system were to be put in place that does
1908 not contain these elements, would you be concerned about that
1909 system preempting a law like California's? Do States need to
1910 preserve their ability to apply more stringent standards
1911 regarding information disclosure and safety determination of

1912 cosmetics and ingredients?

1913 Mr. {DiBartolomeis.} Well, the short answer is yes, I
1914 would be concerned. You know, disclosure and being able to--
1915 authorizing the State to get more information from cosmetic
1916 manufacturers and then conducting health investigations are
1917 pretty strong requirements and mandates, but actually, I
1918 don't even think those go far enough, to be honest with you.
1919 So I would be concerned if the federal law were actually less
1920 stringent.

1921 Mr. {Waxman.} Thank you.

1922 Ms. May, I want to thank you for coming to speak to us
1923 today. Your story is certainly very touching and inspiring.
1924 You mentioned in your testimony that you support banning
1925 unsafe ingredients, giving FDA recall authority and requiring
1926 reporting of adverse events and serious reactions in
1927 connection with cosmetic products. I know that I share the
1928 belief with many of my colleagues that these are important
1929 powers for the FDA to have. Can you elaborate on why it is
1930 important that the FDA have these powers?

1931 Ms. {May.} We feel that the FDA should have the
1932 authorities to substantiate all cosmetic ingredient safety
1933 studies, that they are the impartial entity to evaluate any
1934 studies that are brought that are of concern. We support
1935 only safe ingredients in cosmetics, and we feel an impartial

1936 group of people through the FDA only to substantiate that is
1937 the best system.

1938 Mr. {Waxman.} Thank you.

1939 Thank you, Mr. Chairman.

1940 Mr. {Pitts.} The chair thanks the gentleman and now
1941 recognizes Dr. Gingrey for 5 minutes for questions.

1942 Dr. {Gingrey.} Mr. Chairman, thank you, and I apologize
1943 to the panelists for walking in late, but we had a concurrent
1944 subcommittee hearing downstairs, and it is impossible to be
1945 in two places at one time.

1946 Let me start off by just asking a very straightforward,
1947 simple, softball question to each one of you, and I will
1948 start--and how do you pronounce your name, Doctor?

1949 Ms. {Breslawec.} Breslawec.

1950 Dr. {Gingrey.} Thank you. We will start with you and
1951 then go down the panel. Do you believe that decisions on the
1952 safety of cosmetic products should be based off of science or
1953 politics?

1954 Ms. {Breslawec.} Science.

1955 Dr. {Gingrey.} Mr. Hutt, you are up.

1956 Mr. {Hutt.} You are asking me the science?

1957 Dr. {Gingrey.} Absolutely.

1958 Mr. {Hutt.} I believe very strongly that it should be
1959 based on science. In my 4 years as Chief Counsel of FDA, we

1960 always based our decisions on the best science that was
1961 available.

1962 Ms. {Dandurand.} Science.

1963 Ms. {May.} Science.

1964 Mr. {DiBartolomeis.} When adequate studies are
1965 available and have been done and disclosed and the
1966 information is--the scientific information is done according
1967 to standards, I would have to say the science is the most
1968 important decision-making factor, but there are times when
1969 you actually don't have that information and pretty much for
1970 almost all cosmetic products for long-term effects, that is
1971 the situation.

1972 Dr. {Gingrey.} Are you suggesting then that politics
1973 plays a role?

1974 Mr. {DiBartolomeis.} No, but there have to be--
1975 something else enters into the decision-making process. It
1976 can't be just the science because you don't have the science.

1977 Dr. {Gingrey.} Well, I thank all of you for your
1978 forthrightness in responding to that question.

1979 Let me turn to Mr. Hutt in regard to these series of
1980 questions. Have States tried to ban cosmetics and their
1981 ingredients?

1982 Mr. {Hutt.} States have in a few instances set
1983 standards for particular ingredients, for example, mercury,

1984 that sometimes appears in cosmetics. I am unaware of any
1985 specific cosmetics other than the Brazilian Blowout that we
1986 have discussed previously where a cosmetic has been attempted
1987 to be banned, but as we heard just a few moments ago, the
1988 State did not even ask for a ban, even though they could have
1989 under their law.

1990 Dr. {Gingrey.} Let me ask you this, if you think is
1991 true. Why is national uniformity of cosmetic regulation
1992 important? Do you think that it is important, and why?

1993 Mr. {Hutt.} It is extremely important. The cosmetic
1994 industry in the United States is a national industry. It is
1995 not a local industry. Even the smallest of cosmetic
1996 companies does not limit their product to one State. They
1997 are shipped all over the country, indeed, all over the world.
1998 And if we have different requirements in different States, we
1999 are going to have just massive confusion in our country. It
2000 would be like in the automobile industry, suppose we didn't
2001 have a national standard for automobile safety. You would
2002 have to stop at every border and get approval to go into the
2003 next State. The same is true for cosmetics.

2004 Dr. {Gingrey.} Let me address this question--and I
2005 thank you, Mr. Hutt--to Ms. Dandurand. I saw that the
2006 President's budget requested \$19 billion in cosmetic user
2007 fees. Do you think the FDA needs these user fees? I was

2008 under the impression that in the last several years the FDA
2009 budget in regard to cosmetic oversight has increased
2010 substantially. So an additional \$19 billion in cosmetic user
2011 fees, your thoughts on that? And any other members of the
2012 panel might want to comment as well.

2013 Ms. {Dandurand.} Well, I am not in favor of user fees.
2014 I really don't want to absorb any additional costs to my
2015 small business at this time, and I am not clear on what the
2016 benefit to my business would be for that user fee.

2017 Dr. {Gingrey.} You are clear what the--

2018 Ms. {Dandurand.} I am not clear.

2019 Dr. {Gingrey.} --lack of benefits might be in regard to
2020 your bottom line?

2021 Ms. {Dandurand.} Correct.

2022 Dr. {Gingrey.} Anyone else? Ms. May, please.

2023 Ms. {May.} I am not sure with the volumes of paperwork
2024 and the number of employees that the FDA is going to need to
2025 hire to handle the provisions of the bill, that \$19 million
2026 is even going to be enough. They are talking about
2027 registering every product, every bottle of lotion.

2028 Dr. {Gingrey.} And by the way, thank you for correcting
2029 me.

2030 Ms. {May.} Did I correct you?

2031 Dr. {Gingrey.} That was a million versus a billion.

2032 There is a difference there, even in Congress.

2033 Ms. {May.} Even--if a company has to register every
2034 single bottle of lotion, every formula, our industry in the
2035 handcrafted soap and cosmetic industry, we may have a
2036 customer that comes to us and a child has a nut allergy and
2037 they ask us to change out the oil in a lotion so that their
2038 child doesn't have an allergic reaction, we would need to
2039 pause, stop, notify the FDA of a change. If we change a
2040 fragrance oil, we change any additive, we would need to re-
2041 register that product every time with the FDA. That is up to
2042 1,000 at minimum, 5,000 reports a month one small business
2043 will need to file. I don't know how the FDA is going to
2044 manage all of that paperwork and oversee that.

2045 Dr. {Gingrey.} Well, I am going to have to stop right
2046 there because I am already a minute over the time, but thank
2047 you, Mr. Chairman, for your indulgence, and thank you,
2048 panelists.

2049 Mr. {Pitts.} The chair thanks the gentleman and
2050 recognizes the ranking member, Mr. Pallone, for 5 minutes for
2051 questions.

2052 Mr. {Pallone.} Thank you, Mr. Chairman.

2053 I wanted to start with Ms. May, and thank you for
2054 speaking to us today, and your story was certainly very
2055 touching and inspiring. I note that in your current

2056 business, you are a supplier to small cosmetic manufacturers,
2057 and some of the proposals we have seen include provisions
2058 that require manufacturers to keep or provide information to
2059 substantiate the safety of their ingredients and products.
2060 Could you just tell us whether you think this would be an
2061 important requirement to have in a new law?

2062 Ms. {May.} I believe the FDA should substantiate the
2063 safety of all cosmetic ingredients.

2064 Mr. {Pallone.} Okay, but what I am asking is whether
2065 they would require manufacturers to keep or provide
2066 information to substantiate the safety.

2067 Ms. {May.} Under the current FDA provisions, an
2068 ingredient is actually called a cosmetic. So I think it is
2069 important to recognize the difference between an ingredient
2070 manufacture and somebody blending ingredients together at an
2071 approved level. I feel all ingredient manufacturers if they
2072 are marketing to the cosmetic industry and telling us that
2073 something should be used at a certain percent, at a certain
2074 temperature, at a certain pH, they should substantiate that
2075 claim. That is how our industry is using those ingredients.

2076 Mr. {Pallone.} Okay. Thanks.

2077 Let me go to Dr. DiBartolomeis. You mentioned in your
2078 testimony the importance of mandatory recall authority to
2079 remove cosmetics that have been found to be unsafe,

2080 adulterated or misbranded, and I couldn't agree with you
2081 more, and I have a proposal that would give the FDA this
2082 authority to issue mandatory recalls. It seems to me that
2083 the Brazilian Blowout case, which has been mentioned by many
2084 people including Ms. Schakowsky, would be a good candidate
2085 for the use of this mandatory recall authority, and you
2086 mention in your testimony there have been efforts to call
2087 attention to the dangers of these kinds of products but they
2088 are still being used throughout the United States, and yet
2089 six countries have recalled products like that. So can you
2090 describe in more detail the types of dangers California saw
2091 associated with these products and whether you think recall
2092 authority would have been helpful to California in its
2093 efforts?

2094 Mr. {DiBartolomeis.} Right. Well, first of all, the
2095 cosmetics program is not regulatory so we ourselves don't
2096 have the authority to remove a product from the market. It
2097 would have to be our parallel food and drug branch, you know,
2098 FDA equivalent. As far as I know, they were in the process
2099 of moving down that road but they for whatever reason have
2100 not completed that step. So if there was a mandatory recall
2101 authority, whether it is at the federal or at the State
2102 level, this product would have been removed before it even
2103 had to go to court, and it was ridiculous that we had to

2104 spend almost 2 years going to court, and all we got was a
2105 warning label and a slap on the wrist and then a manufacturer
2106 saying great, we just got relieved of any responsibility.

2107 Mr. {Pallone.} So obviously you would like to see the
2108 FDA have that as well as--

2109 Mr. {DiBartolomeis.} Well, I think that that is an
2110 important feature of any legislation.

2111 Mr. {Pallone.} Now, I know that--I just want to ask you
2112 about these other things that I have talked about in my
2113 legislation, but they are not on your list, I guess, of the
2114 five basic elements for a cosmetic regulatory program that
2115 you outlined, and I want you to just go through them and tell
2116 me whether you agree that it would be important to have them.
2117 So do you think it would be important to have mandatory
2118 registration, first of all?

2119 Mr. {DiBartolomeis.} I am actually not even clear
2120 exactly what that would be. I haven't read any of the
2121 federal legislation so I would need a little more
2122 information. But, you know, we have mandatory reporting, and
2123 if that is the equivalent, then I think that is part of the
2124 disclosure aspect and I think that that is very important.

2125 Mr. {Pallone.} What about the adverse-event reporting?

2126 Mr. {DiBartolomeis.} You know, that an interesting--

2127 Mr. {Pallone.} It sounds like you have adverse-event

2128 reporting but not mandatory registration. Is that accurate,
2129 or not?

2130 Mr. {DiBartolomeis.} For which? I am sorry.

2131 Mr. {Pallone.} In other words, I am getting the
2132 impression that you have in California what I call adverse-
2133 event reporting but not mandatory registration.

2134 Mr. {DiBartolomeis.} The cosmetics program doesn't have
2135 either of those two things.

2136 Mr. {Pallone.} Oh, you don't?

2137 Mr. {DiBartolomeis.} But it may be actually in parallel
2138 to--if the Food and Drug Administration has some kind of, you
2139 know, event reporting, it probably does exist in the Sherman
2140 law as well. I am just not that familiar.

2141 Mr. {Pallone.} Well, let me just ask you, I mean, I am
2142 just trying to get a handle on the registration, the adverse-
2143 event reporting, Good Manufacturing Practices, if you want to
2144 just comment on those, because I know they weren't listed in
2145 your five basic elements.

2146 Mr. {DiBartolomeis.} I was told to keep it to five.
2147 So, you know, Good Manufacturing Practices are comparable, I
2148 think, in a way to doing toxicity testing according to
2149 standards and so any time you have standards that are going
2150 to be met by all the manufacturers as well as by, you know,
2151 other entities that are going to be reviewing them, I think

2152 that is a good thing to do. If we had a mandatory event
2153 reporting, you know, an adverse-event reporting system in
2154 place for Brazilian Blowout, for example, it would not have
2155 had to come to our program first. I mean, there would have
2156 been some system in place. I have two staff and a budget of
2157 \$280,000 to run this program, so \$19 million sounds really
2158 good to me, and, you know, to actually have us responding to
2159 phone calls and then calling the Department of Justice and
2160 starting this process just seems pretty inefficient. There
2161 should be a better way and there should be a much more
2162 succinct and really quick way to do this process.

2163 Mr. {Pallone.} Okay. Thanks a lot.

2164 Mr. {DiBartolomeis.} Sure.

2165 Mr. {Pallone.} Thank you, Mr. Chairman.

2166 Mr. {Pitts.} The chair thanks the gentleman and now
2167 recognizes the gentlelady from Illinois, Ms. Schakowsky, for
2168 5 minutes for questions.

2169 Ms. {Schakowsky.} Thank you.

2170 Mr. Hutt, the European Union has banned or restricted
2171 the use of over 1,200 chemicals linked to cancer,
2172 reproductive and developmental harm from cosmetics. So just
2173 yes or no, does The Personal Care Products Council support a
2174 similar ban or restriction here in the United States on
2175 carcinogens, mutagens and reproductive toxins?

2176 Mr. {Hutt.} No, because those aren't used in the United
2177 States.

2178 Ms. {Schakowsky.} Well, Mr. DiBartolomeis, would that
2179 be the result of your reports, 24,000, almost 25,000
2180 hazardous ingredients? Were any of those carcinogens,
2181 mutagens and reproductive toxins that were reported to you?

2182 Mr. {DiBartolomeis.} The law requires chemicals that
2183 are known or suspected to cause cancer, reproductive harm or
2184 birth defects to be reported to us, so those 24,664
2185 ingredients would all be one of those, one or more of those
2186 hazardous effects.

2187 Mr. {Butt.} And more than half of those were titanium
2188 dioxide reports. Titanium dioxide is approved by FDA both as
2189 a color additive and as an active ingredient in sunscreen
2190 products, and yet it had to be reported under the California
2191 law as a dangerous ingredient.

2192 Ms. {Schakowsky.} And what about the other half?

2193 Mr. {Hutt.} The other half were a wide variety of
2194 substances.

2195 Ms. {Schakowsky.} Let me get this clear. So you are
2196 saying that not one of the 24,664 hazardous ingredients was
2197 in fact a hazardous ingredient?

2198 Mr. {Hutt.} I am not aware that we use in the United
2199 States things that are absolutely banned in Europe. There

2200 may be--

2201 Mr. {Schakowsky.} And what about among the 10 chemicals
2202 that the FDA has actually said are hazardous would include in
2203 Brazilian Blowout?

2204 Mr. {Hutt.} Formaldehyde.

2205 Ms. {Schakowsky.} And is that okay? Should that be in
2206 a product?

2207 Mr. {Hutt.} Let me turn that over to Dr. Breslawec.

2208 Ms. {Breslawec.} Formaldehyde can be used safely in
2209 cosmetics as a preservative at very low levels.

2210 Mr. {Schakowsky.} Okay. We have gone through the
2211 Brazilian Blowout situation, and if there is disagreement,
2212 and maybe you want to talk to that, Dr. D, because, you know,
2213 I have been very involved in that product as well and it
2214 seems indisputable to me that this is a hazardous product.

2215 But the question is whether or not there should be some
2216 authority to actually recall or ban before marketed products
2217 that are found, according to science, which everybody here
2218 agreed with, are dangerous to consumers.

2219 Mr. {DiBartolomeis.} Well, I think you have made an
2220 important distinction because what we were dealing with with
2221 Brazilian Blowout was well after it had been used for years,
2222 you know, formaldehyde in these products. It should never
2223 have gone on the market in the first place having levels,

2224 whether you call it methylene glycol or formaldehyde, at
2225 those levels where workers daily are going to be exposed to a
2226 carcinogen, a known human carcinogen. So really, we are
2227 talking about how do you prevent that from happening in the
2228 first place. I don't think it is an effective or efficient
2229 public health mechanism to deal with something that is after
2230 the effect and you are trying to clean up the mess. You
2231 really want to have it not go on the market in the first
2232 place.

2233 Ms. {Schakowsky.} The cosmetic industry's trade
2234 association argues that dose makes the poison and just a
2235 little bit of a known carcinogen or reproductive toxin in a
2236 cosmetic product won't hurt anyone if the product is ``used
2237 as directed.'' So again, Dr. D, if you could tell us whether
2238 you agree with that assessment.

2239 Mr. {DiBartolomeis.} There is a lot of science tied up
2240 in all that, but I guess the short answer is, for most
2241 products that contain chemical carcinogens, the dose and risk
2242 are very much a difficult thing to analyze, and what is
2243 acceptable risk to you might be not acceptable to me. So it
2244 is a really difficult situation, so I would have to say
2245 carcinogens should really not be in these products at all,
2246 especially when they are being used from infancy throughout
2247 the course of somebody's lifespan.

2248 Ms. {Schakowsky.} And just personally, I know that it
2249 is taking me longer and longer to use all the products that I
2250 now find as I age, and so I am concerned about the cumulative
2251 effect of the many products that I schlep around in my purse
2252 and in my cabinets. So I think that we need obviously, I
2253 think, to do more science and I think we need to get more
2254 legislation, and I appreciate your efforts in California.
2255 Thank you.

2256 Mr. {Pitts.} The chair thanks the gentlelady.

2257 That concludes the questioning of our panel. At this
2258 time I would like to request unanimous consent that
2259 statements from Personal Care Truth and Indie Beauty Network
2260 and Handcrafted Soap Makers Guild Inc. be submitted to the
2261 record. Without objection, so ordered.

2262 [The information follows:]

2263 ***** COMMITTEE INSERT *****

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2264 Mr. {Pitts.} I want to remind members that they have 10
2265 business days to submit questions for the record, and I ask
2266 the witnesses to respond to the questions promptly.

2267 Thank you very much for your testimony, for answering
2268 all of our questions, a very informative panel. Members
2269 should submit their questions by the close of business on
2270 Monday, April 9th.

2271 Without objection, the subcommittee is adjourned.

2272 [Whereupon, at 12:30 p.m., the Subcommittee was
2273 adjourned.]