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4 ``REGULATION OF NEW CHEMICALS, PROTECTION OF CONFIDENTIAL
5 BUSINESS INFORMATION, AND INNOVATION''
6 THURSDAY, JULY 11, 2013
7 House of Representatives,
8 Subcommittee on Environment and the Economy
9 Committee on Energy and Commerce
10 Washington, D.C.

11 The Subcommittee met, pursuant to call, at 9:43 a.m., in
12 Room 2322 of the Rayburn House Office Building, Hon. Phil
13 Gingrey [Vice Chairman of the Subcommittee] presiding.

14 Members present: Representatives Gingrey, Murphy, Latta,
15 Cassidy, Johnson, Tonko, Green, McNerney, Barrow, and Waxman
16 (ex officio).

17 Staff present: Nick Abraham, Legislative Clerk;
18 Charlotte Baker, Press Secretary; Sean Bonyun, Communications

19 Director; Jerry Couri, Senior Environmental Policy Advisor;
20 David McCarthy, Chief Counsel, Environment and the Economy;
21 Andrew Powaleny, Press Secretary; Jacqueline Cohen,
22 Democratic Senior Counsel; Greg Dotson, Democratic Staff
23 Director, Energy and Environment; and Caitlin Haberman,
24 Democratic Policy Analyst.

|
25 Dr. {Gingrey.} The committee will come to order. The
26 chair recognizes himself for 5 minutes for an opening
27 statement.

28 Last month, the subcommittee held a hearing on the
29 history and the impact of Title 1 of the Toxic Substance
30 Control Act, better known as TSCA. The June 13 hearing was a
31 good start to understanding a law as complex as it is broad.
32 Today, we take a deeper dive and focus on new chemical
33 regulation protection of sensitive businesses' information,
34 and their effect on innovation. I believe evaluating TSCA
35 Sections 5, New Chemicals, and 14, Disclosure of Data, is
36 fundamental to judging progress in new technologies and
37 manufacturing frontiers in our country.

38 Testimony in our June 13 hearing supports this notion.
39 American companies are on the cutting edge of chemical
40 innovation, and the new chemical structure in TSCA has
41 allowed us to lead the world. For example, the European
42 Union's new chemical requirements saw 3,000 new chemicals
43 introduced, while the United States saw six times as many new
44 chemicals introduced over that same period of time. One out
45 of six of the chemicals currently used in commerce did not
46 exist in 1979.

47 TSCA Section 5 does not merely set out the notification

48 requirements for these chemicals, it provides EPA an
49 opportunity to review and evaluate information about a
50 chemical to determine if its manufacture, if its processing,
51 commercial use, or disposal should be limited, delayed, or
52 prohibited. To do this job, pre-manufacturing notices, PMNs,
53 submitted to EPA include information on chemical identity,
54 description of byproducts, anticipated production volumes,
55 molecular formula, intended categories of use, and other
56 available information on the substance. EPA can employ
57 predictive modeling technologies to help it decide if a new
58 chemical raises concerns. EPA then may also extend the
59 review period of a chemical or new use of a chemical if it
60 needs more than 90 days to consider all of the facts before
61 acting. EPA then decides whether entry into commerce is
62 allowed, allowed with restrictions, allowed after submission
63 of additional data, or allowed with certain regulatory or
64 testing actions applied. As of May, 2013, I am told that 52
65 percent of chemicals for which EPA received a pre-
66 manufacturing notice, PMN, actually went to market.
67 According to former EPA Chemicals Office Director Charlie
68 Auer, who testified at our June hearing, 90 percent of new
69 chemicals program decisions are made within 90 days, and over
70 15,000 new chemicals, or 30 percent, have received some kind
71 of regulatory action under TSCA Section 5.

72 We want EPA to have information to make good decisions
73 about a chemical; however, we must be careful about
74 disclosure of that detailed information, obviously. In a
75 recent paper on trade secret privacy, William Fitzpatrick and
76 two others suggested that approximately 70 percent of the
77 market value of U.S. firms resides in their trade secrets and
78 their intellectual properties. This is what drives
79 innovation.

80 TSCA Section 14 protects information submitted to the
81 EPA as a privileged and confidential trade secret.
82 Disclosure by EPA employees is not permitted, except to other
83 federal employees, or when necessary to protect the health or
84 the environment. Beth Bosley, who with six employees
85 operates a specialty chemical maker in Pittsburgh, reinforced
86 these points at our last meeting: one, disclosure of
87 chemical identity may be all it takes to give a way a
88 competitive advantage to an offshore manufacturer; and
89 second, the majority of Freedom of Information, FOIA Act
90 requests to EPA on new chemicals come from potential
91 competitors, many of which are overseas, not curious members
92 of our public.

93 While we cannot have a system that prevents regulators
94 from having access to information that allows them to make
95 important judgments on risk, I think we should not be naïve

96 about the value of this information to non-regulatory
97 interests, their cleverness in trying to obtain and exploit,
98 and the real damage its leak could cause to American jobs and
99 our prosperity.

100 I want to thank our distinguished witnesses for joining
101 us today to help us get a better handle on what the law is,
102 how EPA has been implementing it, what it is like being
103 regulated under it, and where witnesses think its successes
104 and shortcomings lie. I urge members of the subcommittee to
105 make every effort at this hearing to learn the fundamentals
106 of these sections of this law, TSCA.

107 [The prepared statement Dr. Gingrey follows:]

108 ***** COMMITTEE INSERT *****

|
109 Dr. {Gingrey.} I now yield 5 minutes to the ranking
110 member of our subcommittee, Mr. Tonko from New York.

111 Mr. {Tonko.} Thank you, Mr. Chair. Good morning, and I
112 am pleased to be here this morning for this second hearing on
113 the Toxic Substances Control Act, better known as TSCA. And
114 thank you, Chair Gingrey, Dr. Gingrey. I am sure you will do
115 an excellent job of filling in for our colleague, Chairman
116 Shimkus, who cannot be with us today. It is a pleasure to be
117 with you at the hearing. And welcome to all of our
118 distinguished guests as members of the panel.

119 Our first hearing provided a very useful overview of the
120 Toxic Substances Program administered by the Environmental
121 Protection Agency. We have an opportunity today to hear from
122 an excellent panel of witnesses on two particular aspects of
123 this law, Section 5, the New Chemicals Review Program, and
124 Section 14, the provision that governs the handling of
125 confidential business information.

126 The New Chemicals provision was intended to provide an
127 opportunity to screen new chemicals coming into commerce for
128 possible safety problems. The process was also to provide
129 sufficient information about the chemicals in commerce to
130 enable EPA to make a credible evaluation of their safety.

131 The law currently falls short of these goals. The

132 information available on chemicals has failed to keep pace
133 with the numbers of chemicals in commerce. We have developed
134 incredible analytical, computational, and communications
135 tools over the past few decades. We should be able to apply
136 these tools more effectively to produce reliable information
137 about the chemicals in commerce and make it available to the
138 public, but this has not happened to the extent needed. An
139 effective early evaluation process also provides benefits to
140 industry. Prevention certainly is much less expensive than
141 mitigation. The earlier a company detects a potential
142 problem with their product, the easier and less expensive it
143 is to engineer around that problem or to pursue a different
144 design.

145 We need chemicals. We use them every day in a wide
146 range of products essential to the quality of our lives and
147 to our modern society. But these products must be safe for
148 people and must be safe for the environment. We need to find
149 the proper balance. The program must enable manufacturers to
150 bring new chemicals to the market while providing assurances
151 to the public that these substances are indeed safe. EPA
152 needs sufficient resources to evaluate chemicals in an
153 expeditious and reliable manner, and the authority to remove
154 problem substances from the market in a timely and orderly
155 fashion. In a fast-paced, competitive global economy,

156 protecting trade secrets is important and is challenging, but
157 an overuse of confidential business information claims is
158 unwarranted and serves only to bar the members of the public
159 from information they need to make informed choices about the
160 products they purchase and that they use.

161 I expect we will hear a variety of views today on the
162 type of extent of changes that are needed to improve this
163 law. Working together, however, we can update and improve
164 this law so that it works for everyone.

165 I look forward to the testimony of all of our expert
166 witnesses, and I thank you all for participating this morning
167 and for sharing your views on what I believe is an incredibly
168 important topic. Thank you.

169 With that, Mr. Chairman, I yield back.

170 [The prepared statement of Mr. Tonko follows:]

171 ***** COMMITTEE INSERT *****

|
172 Dr. {Gingrey.} I thank the gentleman from New York, and
173 if there are any other members seeking time for an opening
174 statement--seeing none, the chair wishes to recognize Mr.
175 Latta for the purpose of introducing the first two of our
176 witnesses. I yield to the gentleman from Ohio.

177 Mr. {Latta.} Well I thank the chairman for yielding to
178 me, and I appreciate it. I would just like to introduce our
179 two first witnesses today, and both from Ohio. You know, in
180 the Buckeye State, we like to stick together.

181 Our first witness that will be testifying today is Mr.
182 Craig Morrison, and Mr. Morrison is the President and Chief
183 Executive Officer of Momentive Performance Materials Holding,
184 and its operating subsidiaries--subsidiaries. It is based in
185 Columbus, Ohio, and Momentive is a world leader in specialty
186 chemicals and materials.

187 Our next witness that will be testifying is from Procter
188 and Gamble, and that is Mr. Len Sauers, who is Vice President
189 for Global Sustainability, Product Safety, and Regulatory
190 Affairs. Of course, Procter and Gamble is located in
191 Cincinnati.

192 I just want to thank you both for being here to testify,
193 and with that, Mr. Chairman, I yield back.

194 Dr. {Gingrey.} And I will now introduce our other three

195 witnesses. Mr. David Isaacs is Vice President of Government
196 Affairs for the Semiconductor Industry Association. Welcome,
197 Mr. Isaacs. Dr. Rainer Lohmann. Dr. Lohmann is a professor
198 of oceanography from the University of Rhode Island.
199 Welcome, Professor. And last, but certainly not least, Ms.
200 Heather White, Executive Director of the Environmental
201 Working Group. So I welcome all of our witnesses, and our
202 first witness, we will start with Mr. Morrison. You are
203 recognized for 5 minutes.

204 I want to tell the witnesses that I am going to have a
205 soft gavel, so don't worry about--I am not going to let you
206 go 10 minutes, but I certainly could let you go 5-1/2 to 6,
207 and anything that you want to say that you don't get time to
208 say, I ask unanimous consent for that to be submitted for the
209 record. Hearing none, so ordered, and we will start with Mr.
210 Craig Morrison.

|
211 ^STATEMENTS OF CRAIG MORRISON, CEO OF MOMENTIVE PERFORMANCE
212 MATERIALS HOLDING, LLC, AND CHAIRMAN OF THE EXECUTIVE
213 COMMITTEE, AMERICAN CHEMISTRY COUNCIL; LEN SAUERS, VICE
214 PRESIDENT, GLOBAL SUSTAINABILITY, PROCTER AND GAMBLE; DAVID
215 ISAACS, VICE PRESIDENT, GOVERNMENT AFFAIRS, SEMICONDUCTOR
216 INDUSTRY ASSOCIATION; RAINER LOHMANN, PROFESSOR OF
217 OCEANOGRAPHY, UNIVERSITY OF RHODE ISLAND; AND HEATHER WHITE,
218 EXECUTIVE DIRECTOR, ENVIRONMENTAL WORKING GROUP

|
219 ^STATEMENT OF CRAIG MORRISON

220 } Mr. {Morrison.} Thank you, Mr. Chairman. I am Craig
221 Morrison, President and Chief Executive Officer, and Chairman
222 of Momentive Performance Materials based in Columbus, Ohio.
223 I am testifying today on behalf of the American Chemistry
224 Council, the ACC, where I am currently chairman of the board
225 of directors. On behalf of the ACC and our members, I would
226 like to thank the chairman and the committee for holding
227 today's hearings.

228 Momentive is a world leader in the development and
229 production of specialty chemicals and materials. Momentive
230 chemistries are used in thousands of products that enhance
231 the safety, convenience, and efficiency of modern life. Our

232 products can be found in automotive, energy, construction,
233 personal care, electronics, and many other segments. In
234 fact, Momentive materials can be found in the semiconductors
235 produced by some of the members of the Semiconductors
236 Industry Association, represented here by my fellow panelist,
237 Mr. Isaacs. Momentive has over \$7 billion in sales and
238 operates 90 manufacturing facilities in 37 countries,
239 including 35 manufacturing facilities in 18 States in the
240 U.S., which provides approximately 4,000 American women and
241 men high paying manufacturing jobs.

242 Innovation is critical to the survival and growth of our
243 industry and the downstream industries that we supply. To
244 remain a market leader, our process of research, development,
245 product testing and introduction is nearly constant. That is
246 why an efficient, effective process to evaluate and approve
247 new chemical innovations is vitally important to the chemical
248 industry and why I will be focusing my comments on Section 5
249 of the Toxic Substances Control Act, known as the New
250 Chemicals Program.

251 There is broad agreement among industry and other
252 stakeholders that TSCA needs to be reformed in order to
253 reflect modern understanding of chemicals and today's
254 scientific knowledge. We have been encouraged by the recent
255 introduction of the bipartisan Chemical Safety Improvement

256 Act in the Senate and by this committee's interest in
257 examining current law to gain a better understanding of
258 needed reforms. But it is also widely understood that TSCA's
259 New Chemicals Program works well, a fact that has been
260 reinforced by senior officials from previous administrations
261 of both political parties.

262 New chemicals undergo a thorough but efficient multi-
263 step regulatory review before being approved for manufacture
264 and marketing. This well-functioning framework has three
265 particular strengths. First, the program ensures a
266 scientifically robust review of the potential hazards and
267 exposures associated with a chemical substance. Second, it
268 allows the EPA to tailor the process to fit the specific
269 characteristics of an individual chemistry. And third, the
270 process and timing of EPA's review generally meets demands of
271 the marketplace.

272 The program leverages significant data about chemicals
273 already available to the EPA, and employs advanced modeling
274 techniques to predict a new chemical's physical and chemical
275 properties, health hazards, and potential environmental
276 effects. Section 5 also gives the EPA, which it regularly
277 exercises, to request more testing and data about a new
278 chemical if the Agency feels it is necessary, and to manage
279 potential risks appropriately. This sophisticated risk-based

280 approach reduces the cost of innovation and time needed for
281 review and approval of new chemical products. It has
282 facilitated a dialog between manufacturers and regulators
283 that has helped industry move away from potentially
284 problematic chemistries and has enabled the introduction of
285 even safer and more sustainable chemistries.

286 Momentive submits, on average, 10 new chemistries for
287 review each year, and has submitted approximately 120 new
288 chemistries for review over the past 10 years. Thanks to the
289 EPA's efficient and well-functioning process, 90 percent of
290 these new products introduced in the last 5 years have been
291 able to come to market without the need for new animal
292 testing. The advantage created by TSCA Section 5 for
293 American innovation and competitiveness is clear. For
294 example, the chemical industry invests \$11 billion on average
295 each year in research and development. Roughly 20 percent of
296 all U.S. patents are chemistry-related. Three times more
297 chemical innovations are brought to the market in the U.S.
298 than other major regions of the world, such as Europe and
299 Japan. Taken together with abundant, affordable supplies of
300 domestic natural gas, the current New Chemicals Program helps
301 create a strong incentive for companies that rely on
302 chemistry to invest in the U.S. In fact, as of June, 2013,
303 more than 100 new plants, expansions, and restarts of

304 previously shuttered sites have been announced, which is
305 projected to create 310,000 new American jobs by 2020.

306 TSCA Section 5 established a rigorous process to
307 evaluate and approve new chemistries in a way that protects
308 health and the environment, enables continuous innovation,
309 and allows new transformative products to come to market.
310 Ensuring that this remains the case as part of any new effort
311 or reform to modernize TSCA should be a top priority.

312 Thank you very much for allowing me to participate, and
313 I am happy to answer any questions.

314 [The prepared statement of Mr. Morrison follows:]

315 ***** INSERT A *****

|

316 Dr. {Gingrey.} Mr. Morrison, thank you.

317 We will now hear from Mr. Len Sauers, Vice President of

318 Global Sustainability with Procter and Gamble. Mr. Sauers, 5

319 minutes.

|
320 ^STATEMENT OF LEN SAUERS

321 } Mr. {Sauers.} Thank you, Mr. Chairman and Ranking
322 Member Tonko, members of the committee. Thank you for
323 inviting me here today. As has been said, my name is Len
324 Sauers. I am the Vice President for Sustainability, Product
325 Safety, and Regulatory Affairs at the Procter and Gamble
326 Company.

327 P&G is the largest consumer products company in the
328 world. Our products are used by 4.6 billion people around
329 the world every day. We have operations in nearly 80
330 countries, and 99 percent of American households have at
331 least one P&G product in their home. Since our founding over
332 175 years ago, innovation has been integral to everything we
333 do, and has been critical to our success. To support our
334 innovation efforts today, we have dedicated R&D facilities in
335 five continents, and we employ over 9,000 R&D employees.

336 P&G supports comprehensive modernization of TSCA for two
337 primary reasons. First, federal action is urgently needed to
338 enhance consumer confidence in the safety of the ingredients
339 that they use in their everyday household products; and
340 secondly, reform will give States confidence in a strong
341 federal chemical management system, and thereby avoid a

342 patchwork of varying requirements across multiple States,
343 which will slow innovation and increase complexity.

344 I would like to turn now to the regulation of new
345 chemicals. Over the past 30 years, P&G has either submitted
346 or been the major contributor to over 175 pre-manufacture
347 notices. From our experience, we believe that both the law
348 and EPA's governance of the New Chemicals Program have
349 provided for scientifically robust reviews of the potential
350 hazards and exposures of new chemicals entering the U.S.
351 market and ensured appropriate health and environmental
352 protection.

353 There are many strengths to EPA's New Chemicals Program.
354 One is the ability to tailor customly the data submitted in a
355 PMN to the specific new chemical, as opposed to requiring a
356 minimum data set. This approach assures that the information
357 which is necessary and relevant to evaluate the safety of the
358 chemical is received. EPA also utilizes modern science, such
359 as sophisticated predictive models and structure activity
360 relationships to evaluate new chemicals. New safety data is
361 only requested when necessary to make decisions, thereby
362 avoiding unnecessary animal testing. EPA is very receptive
363 to pre-submission consultations with companies to help them
364 plan for and anticipate the needs that EPA will have during
365 their review. And finally, when deemed necessary, EPA has a

366 broad range of regulatory tools that they can use to limit
367 exposure to a new chemical.

368 New chemical review is a key element of TSCA. It is
369 P&G's opinion that the new chemical provisions of TSCA
370 function efficiently and effectively.

371 Now I would like to turn to confidential business
372 information. P&G invests over \$2 billion annually in
373 research and development. We have a significant interest in
374 protecting our new to the world chemistries and confidential
375 business information from public disclosure to our
376 competitors. We rely heavily on the protection of
377 confidential business information afforded by Section 14 of
378 TSCA to remain competitive in the marketplace, and are very
379 concerned with EPA's recent decision to reverse current
380 practice and publically disclose the specific structure of
381 chemicals for which companies currently consider
382 confidential, when the health and safety studies of these
383 chemicals are made public.

384 P&G fully supports transparency when health and safety
385 information in EPA's administration of TSCA Section 14 and we
386 agree that all health and safety data should be made public,
387 but the disclosure of specific, confidential chemical
388 identities is not needed for one to understand the safety of
389 a new chemical. Structurally descriptive, generic chemical

390 names, like those P&G provides today on its website as part
391 of our consumer information program are sufficient. For
392 example, consider P&G's development and market introduction
393 of Tide Cold Water laundry detergent. P&G's scientists
394 discovered a new technology that enabled consumers to get the
395 same cleaning performance in cold water as they expected in
396 hot or warm. This innovation enabled them to save money on
397 their energy bills and meaningfully decrease their greenhouse
398 gas emissions by no longer having to heat water for laundry.
399 P&G submitted two PMNs to EPA to create Tide Cold Water.
400 Over 150 pounds of safety data were submitted with the PMN,
401 and we requested that the specific chemical structure of our
402 new technologies be kept confidential to prevent our
403 competitors from piecing together the required chemistry
404 needed to duplicate the formula. P&G's development costs of
405 the two PMNs totaled about \$150 million. EPA'S new
406 interpretation of TSCA Section 14 would have meant disclosing
407 to competitors those confidential chemical identities and
408 allowing them to benefit from our work without an investment
409 on their part.

410 A modernized TSCA must continue to strike the right
411 balance of protection of confidential business information
412 with public access to health and safety information about
413 chemicals in commerce.

414 Mr. Chairman, Ranking Member Tonko, thank you again for
415 the invitation to testify this morning. P&G values our
416 partnership with you and this subcommittee, and we remain
417 committed to working with you to develop a practical,
418 scientifically sound, chemical management program that
419 strengthens protection of human health and the environment,
420 and ensures U.S. leadership of sustainable innovation in the
421 global marketplace. Thank you.

422 [The prepared statement of Mr. Sauers follows:]

423 ***** INSERT B *****

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424 Dr. {Gingrey.} Mr. Sauers, thank you.

425 Next witness, Mr. David Isaacs, Vice President of
426 Government Affairs, Semiconductor Industry Association. Mr.
427 Isaacs, you are up for 5 minutes.

|
428 ^STATEMENT OF DAVID ISAACS

429 } Mr. {Isaacs.} Thank you, Mr. Chairman and Ranking
430 Member Tonko, and members of the subcommittee. My name is
431 David Isaacs, and I am testifying on behalf of the
432 Semiconductor Industry Association.

433 SIA is the trade association of U.S.-based semiconductor
434 companies that design and manufacture semiconductors, and as
435 many of you know, semiconductors are the integrated circuits
436 or sometimes called computer chips that are the basic
437 building block for all modern electronics. These innovations
438 enable the revolution we have experienced in information
439 technology, communications, transportation, medical devices,
440 and national defense, so they are a fundamental part of our
441 economy and American economic leadership.

442 Our industry employs directly a quarter of a million
443 people in the United States, and supports over a million
444 indirect jobs. We are consistently among the top export
445 industries in the United States, and a key part of America's
446 advanced manufacturing infrastructure.

447 So before I speak to our views on the current TSCA
448 system, I wanted to provide some context on our industry's
449 use of chemicals. Our industry relies, in our manufacturing

450 processes, on the--on specific chemicals that have particular
451 chemical and physical properties and unique functional
452 attributes that enable us to produce, you know, up to a
453 billion transistors on a chip the size of your fingernail.
454 We integrate these chemicals in advanced manufacturing
455 equipment with high levels of precision, very rigorous
456 controls, and enclosed processes, high levels of automation,
457 and that results in a very precise process and also an
458 exemplary environmental and safety record. And that
459 background informs our views on the New Chemical Program. We
460 believe that the existing program generally strikes the right
461 balance between environmental protection and the approval of
462 new chemicals that help drive our innovation. It is
463 important to note that semiconductor companies do not
464 traditionally submit PMNs for approval by the EPA, and we
465 rely on our chemical suppliers for that function, but we have
466 a strong interest in ensuring our access to new chemicals
467 that can help drive our advances.

468 The key attributes of the current system are the risk-
469 based approach, and as others have mentioned, the tailored
470 and customized evaluation of chemical uses. In our industry,
471 the unique attributes of our manufacturing processes result
472 in very low levels of risk and exposure, and we believe that
473 that very much needs to be kept into account in any reform

474 efforts going forward.

475 My testimony outlines other attributes of the system
476 that we think are very important, such as an expedited
477 timeframe that allows speed to market, and critical
478 exemptions for activities like research and development. And
479 then, of course, the protection of confidential business
480 information is critical to our industry as well. Our
481 industry is very much driven by intellectual property. We
482 invest, on average, 18 percent of revenue into R&D. Last
483 year, that amounted to \$32 billion in R&D investments. We
484 are a leader in patents and many of our processes are
485 protected as trade secrets. So the protection of CBI under
486 the TSCA is very, very important to us, and we think it
487 generally works well and strikes the right balance between
488 the need for the public to have available information on
489 health and safety data while at the same time protecting
490 confidential business information.

491 So going forward, we look forward to working with the
492 Congress and this subcommittee on efforts to modernize TSCA
493 and we would like to play a constructive role in that effort.
494 So thank you very much for the opportunity to testify.

495 [The prepared statement of Mr. Isaacs follows:]

496 ***** INSERT C *****

|
497 Dr. {Gingrey.} Mr. Isaacs, thank you. Yielding back 13
498 seconds.

499 Next witness, Mr.--excuse me, Dr. Rainer Lohmann,
500 Professor of Oceanography at the University of Rhode Island.
501 Dr. Lohmann, 5 minutes.

|
502 ^STATEMENT OF RAINER LOHMANN

503 } Mr. {Lohmann.} Good morning. Dear members of the House
504 Committee on Environment and the Economy, I want to thank you
505 for inviting me to testify today. I would also like to thank
506 my wife for letting me go to D.C. on our wedding anniversary.
507 My name is--I will be back tonight. My name is Rainer
508 Lohmann. I am professor of oceanography at the University of
509 Rhode Island. I have spent the last 15 years researching
510 organic contaminants around the world. My written testimony
511 contains several more recommendations on TSCA reform that I
512 worked on with my colleagues, Dr. Heather Stapleton from
513 Duke, and Dr. Ron Hites from Indiana. I will use excerpts
514 here.

515 First, open dialog, not CBI. Let me frame my testimony
516 by quoting Andrew Liveris, CEO of Dow Chemical. ``Over the
517 decades, the chemical industry has not done enough to operate
518 with transparency and to lead on matters such as
519 sustainability, spawning legacy issues that we are still
520 resolving today. Further,'' he said, ``the chemical industry
521 went from defiance, then denial towards debate, and finally
522 has reached dialog.'' In this spirit, I submit that the
523 current use of CBI is in strong conflict with dialog and

524 transparency. TSCA does not limit the period in which a
525 chemical can be considered proprietary or a trade secret.
526 Even new pharmaceuticals, which are much more expensive, are
527 only pertinent for up to 20 years, providing a drug company
528 time to recoup its research investment and make a profit.
529 Within TSCA, the chemical industry should have limited time
530 during which the information submitted to the EPA will be
531 considered proprietary. After this time, information should
532 be publicly available, including site specific production
533 volumes. The public has a right to know what is produced and
534 where. This will foster dialog, build trust, and eventually
535 lead to safer chemicals on the market.

536 In addition, because research on many chemicals is
537 hindered by a lack of authentic standards, samples of any
538 chemical substance produced or imported into the U.S. should
539 be archived in a national repository funded by the chemical
540 industry. This will open dialog between industry academia
541 and geos to identify worst compounds and assess safer
542 alternatives.

543 Second, spur innovation. We need safer, newer, and
544 green chemicals as part of chemistry's contribution towards
545 sustainability. How do we get there? First, we need to
546 identify and replace the worst chemicals in commerce, those
547 which are strongly bioaccumulative, persistent, and toxic.

548 Priority should be given to reassessing the chemicals that
549 were grandfathered in TSCA. This will spur industry to
550 invent, establish and market safer alternatives.

551 How big is the problem? The TSCA inventory contains
552 probably hundreds to thousands of chemicals that are
553 persistent, bioaccumulative, and toxic at the same time.
554 Many of these are found in the environment and in humans.
555 Recent examples include perfluorinated compounds and
556 brominated flame retardants, both of which are present in
557 roughly 97 percent of the U.S. population, including
558 children, and the environment.

559 Our efforts to fully understand the presence and effects
560 of persistent organic chemicals in the environment are
561 hampered by a lack of basic information about the chemical
562 identity, properties, toxicology, and production volumes.
563 Some of that information is currently protected by CBI.

564 Moving forward, TSCA reform should make use of EU's
565 REACH Program. The information on chemicals that are
566 submitted as part of REACH should be able to be used in the
567 U.S. to move toward safer and greener chemicals at no
568 additional cost, basically.

569 Third, testing of new chemicals. Dr. Heather Stapleton
570 discovered Firemaster 550 by accident while she was screening
571 house dust samples for PBDEs, which are basically phased out

572 in the U.S. Her research on dust and hand wipe measurements
573 demonstrated that Firemaster 550 is a ubiquitous indoor
574 contaminant, and exposure is highest for infants and
575 toddlers, rather than adults. Last year, she already showed
576 that Firemaster 550 is the second most common flame retardant
577 in residential furniture today, and it might be number one as
578 we speak. In their most recent work, Dr. Stapleton and
579 colleagues demonstrated that prenatal exposure to Firemaster
580 550 in rats resulted in obesity, early puberty, insulin
581 resistance, and disruptive thyroid hormone signaling.

582 I would like to stress the effects of exposure to
583 chemicals in our households with typical modern health
584 problems, obesity, early puberty, diabetes. In 2005, EPA
585 issued a consent order requesting that Chemtura, the
586 manufacturer, conduct more testing on Firemaster 550's health
587 effects. Of the four ingredients that the Firemaster has,
588 two were grandfathered in TSCA, so EPA could only require
589 testing on the two new brominated compounds, and not the
590 entire mixture. This highlights the shortcomings of TSCA,
591 and how it violates common sense. If you market a chemical
592 mixture, you should perform toxicity tests on that whole
593 mixture as it will be used and how people will be exposed to
594 it in the environment and in their households.

595 Professor Stapleton's research on Firemaster 550 is the

596 only study to date to examine health effects from the mixture
597 as it is used today. The data demonstrated that significant
598 effects occur at much lower doses than what the chemical
599 company declared to be safe.

600 In closing, I would like to note that my research has
601 been funded by the NSF, the U.S. EPA, and the Hudson River
602 Foundation, and I thank you for your attention.

603 [The prepared statement of Mr. Lohmann follows:]

604 ***** INSERT D *****

|
605 Dr. {Gingrey.} Dr. Lohmann, thank you for your
606 testimony.

607 I will now turn to Ms. Heather White, Executive Director
608 of the Environmental Working Group. Ms. White, 5 minutes.

|
609 ^STATEMENT OF HEATHER WHITE

610 } Ms. {White.} Mr. Chairman and distinguished members of
611 the subcommittee, I am Heather White, Executive Director of
612 Environmental Working Group, a nonprofit research and
613 advocacy organization based in Washington, Iowa, and
614 California. Thank you for the opportunity to testify.

615 EWG wants the United States to be the world leader in
616 innovative chemical production. Some of the best and
617 brightest scientists in the world are at the companies
618 represented here today, but innovation is not just about
619 lowering costs and boosting profits. Americans believe that
620 innovation must also mean creating chemicals that are not
621 just cheap, but safe. Strong chemical regulation promotes
622 innovation. We cannot compete internationally on labor or
623 production costs. We will not win that race to the bottom.
624 But America ultimately will win on chemical quality and
625 safety through toxics law reform.

626 For 20 years, EWG has advocated greater protection of
627 people and the environment from toxic chemicals. Our
628 groundbreaking research detected nearly 300 toxic industrial
629 chemicals in the umbilical cord blood of newborn babies. The
630 reality is industrial chemical pollution begins in the womb.

631 Yet a century into the chemical revolution, we still don't
632 know what these low level exposures to substances, alone or
633 in combination, do to our health, especially our children's
634 health. No one has basic answers, not the government,
635 academic researchers, or the chemical industry.

636 In 2010, the President's Cancer Panel concluded that the
637 number of cancers caused by toxic chemicals is grossly
638 underestimated. Americans have lost faith in a chemical
639 regulatory system that they suspect, with good reason,
640 doesn't protect them and their children. Many of these
641 chemicals have not been adequately tested for safety under
642 the Toxic Substances Control Act. Its New Chemicals Program
643 is woefully inadequate, and its secrecy provisions threaten
644 human health.

645 There are three major problems with the New Chemicals
646 Program. First, most Americans assume that a chemical can't
647 be sold until proven safe. Not so. A chemical company can
648 get a new chemical on the market today without providing any
649 information about the toxicity of that chemical. Companies
650 do it every day. In fact, 85 percent of the pre-manufacture
651 submissions have zero information about the toxicity of these
652 new chemicals. Second, EPA faces a chemical Catch-22. The
653 agency cannot demand more test data without solid evidence
654 that the new chemical could be a reasonable risk, and it

655 cannot come up with that evidence without the test data. The
656 law places the burden on EPA, not the manufacturer, to
657 determine whether a new chemical is unsafe before it goes
658 into use. The trouble is that chemicals are entitled to a
659 presumption of innocence. That works in criminal law, but
660 that shouldn't exempt chemicals from investigation. Not
661 surprisingly, EPA attempts to restrict less than 10 percent
662 of new chemicals. Finally, chemical makers don't necessarily
663 know how the chemical might be used when they make it. After
664 a new chemical is approved, they do not have to tell EPA when
665 the planned use changes.

666 As for secrecy, the current law's Confidential Business
667 Information scheme is a regulatory black hole where critical
668 information goes in, and little comes out. Even the
669 intelligence community declassifies highly sensitive
670 information after a while, but TSCA confidentiality claims
671 never expire.

672 Companies have a legitimate interest in keeping some
673 information confidential, but unwarranted claims directly
674 threaten human health and the environment. TSCA permits a
675 manufacturer to claim confidentiality without substantiation
676 for virtually any information it submits to EPA.
677 Confidentiality claims mask the identities of nearly 2/3 of
678 all new chemicals introduced since 1976, including substances

679 used in consumer and children's products.

680 Chemical makers assert that secrecy protects their
681 competitive advantage, but they knew very well that
682 competitors commonly reverse engineer their products.
683 Everybody else is left in the dark: ordinary citizens, first
684 responders, workers, medical personnel, independent
685 researchers, State and local governments, and fence line
686 communities that are often hotspots of chemical exposure.

687 We deserve better. Congress can overhaul the broken
688 toxics law to protect public health and the environment, and
689 at the same time, spur development of better, safer,
690 innovative chemicals.

691 Thank you, and I welcome any questions you may have.

692 [The prepared statement of Ms. White follows:]

693 ***** INSERT E *****

|
694 Dr. {Gingrey.} Thank you, Ms. White.

695 We will now turn to questions from the members of the
696 subcommittee, and each will have 5 minutes. I will say to
697 the members, if you decide to speak for 4-1/2 minutes and
698 give a speech, and then ask a question in the last 30
699 seconds, I will let the witness respond to the question.

700 I will begin yielding to myself for the first 5 minutes,
701 and my first question is going to be to Monsieurs Morrison,
702 Sauers, and Isaacs, the first three witnesses. How do TSCA
703 regulations for new chemicals and new uses and TSCA
704 provisions on the production of Confidential Business
705 Information affect your ability to innovate? Mr. Morrison
706 first, then Mr. Sauers, then Mr. Isaacs.

707 Mr. {Morrison.} Thank you, Mr. Chairman. For us,
708 innovation is our lifeblood and what allows us to succeed and
709 our economy to succeed is delivering performance capability
710 to our customers, such as the two gentlemen to our left, with
711 unique products, and our chemical formulations are at the
712 heart of those products. What TSCA has allowed us to do is
713 drive that innovation and also ensure that it is safe from a
714 health and environmental standpoint, but protect the
715 necessary information so that it is not disseminated to
716 foreign governments, et cetera.

717 If you look at our company alone, we have had multiple
718 cyber attacks by foreign governments that we were unaware of
719 that the Federal Government made us aware of and notified us
720 that our IP and other trade secrets had been penetrated and
721 was being downloaded. That is exactly the information we are
722 discussing today and that we need to protect, and that we are
723 talking about if we change TSCA where we voluntarily disclose
724 that information, we lose the very competitive advantage that
725 we deliver to our company, to our customers, and to the U.S.
726 economy.

727 Dr. {Gingrey.} Mr. Sauers?

728 Mr. {Sauers.} Thank you, and maybe I will just add to
729 what Mr. Morrison has said. Innovation is quite important to
730 Procter and Gamble, you know, as a company of \$90 billion in
731 sales, 9,000 R&D employees. It is something that is very
732 important to us, and what we have appreciated most about TSCA
733 has been our ability to get our chemicals into commerce in a
734 very reasonable timeframe and work with an agency that is
735 highly competent in the evaluation of the safety of these
736 materials. We have appreciated very much the opportunity to
737 sit down with EPA scientists prior to the submission of a PMN
738 to talk about our chemical, talk about the safety needs that
739 TSCA will have, the EPA will have, to make sure that what we
740 bring forward to them is complete. We have appreciated the

741 risk-based approach that the agency has used. We have also
742 appreciated their sensitivity to animal testing. The Procter
743 and Gamble Company has spent about \$300 million over the
744 years developing methods to prevent the needless killing of
745 animals for safety testing through the development of
746 predictive methods, structure activity relationships,
747 modeling, and things like that, and we appreciated the EPA
748 incorporating those technologies.

749 Dr. {Gingrey.} Mr. Isaacs?

750 Mr. {Isaacs.} Mr. Chairman, as I outlined in my
751 comments and in my testimony, we very much rely on the
752 continued access to new chemicals as part of our ability to
753 advance in semiconductor manufacturing. We believe that our
754 processes are fundamentally based on automated systems and
755 enclosed processes that result in minimal exposure, very
756 limited releases to the environment, and therefore, we think
757 our responsible use of chemicals, along with other
758 environmental laws, protects human health and the environment
759 in an appropriate manner.

760 Dr. {Gingrey.} Thank you. In my time remaining, I am
761 going to--probably I will only time for one more question and
762 I will direct it to Mr. Morrison. How does TSCA's New
763 Chemicals Program work in practice? Could you walk me
764 through manufacture, pre-manufacturing notice submission,

765 that EPA 90-day review, and notice of commencement?

766 Mr. {Morrison.} Yes, sir. Well essentially we start
767 off by conducting our own tests on the chemicals, and then we
768 put together a pre-manufacturing notice, which is the PMN
769 submitted to the EPA. They scrutinize the data. They apply
770 that to predictive models and analogous materials. They then
771 go ahead and assess the various chemical properties. They
772 look at the exposure potentials and risks, and ultimately
773 come out with a ruling that could be a pass, a limited use, a
774 restricted, or in fact, stop the PMN from going forward and
775 require more testing.

776 If it is approved, either under restricted or fully
777 approved to go ahead, then we are given permission and we
778 issue a notice of commencement of the manufacturing process
779 at that point. Essentially, this usually takes approximately
780 a 90-day period, which is key because it allows us to turn
781 our innovation in a timely manner, and in many industries,
782 like semiconductor and others, that is absolutely critical
783 for their success.

784 Dr. {Gingrey.} You heard the testimony from Dr. Lohmann
785 and from Mrs. White--Ms. White, and their concerns. Are
786 there any exemptions, exclusions from the new chemicals
787 provisions of TSCA?

788 Mr. {Morrison.} There are some, such as certain sets of

789 polymers and other materials, that the EPA has very extensive
790 experience with that they know don't pose any hazard or risk,
791 and therefore, they are exempted from the process because it
792 makes the EPA and it makes the chemical companies much more
793 efficient, rather than just submitting everything where there
794 is no added benefit to submission.

795 Dr. {Gingrey.} I thank all three of you and I have gone
796 almost a minute over. At this point, I will yield 5 minutes
797 to the ranking member of the subcommittee, the gentleman from
798 New York, Mr. Tonko.

799 Mr. {Tonko.} Mr. Chair, the ranker of the Energy and
800 Commerce Committee has a conflict with scheduling, so I would
801 ask if you call upon your--

802 Dr. {Gingrey.} Absolutely. I will be glad to yield to
803 the ranking member of the overall Committee of Energy and
804 Commerce, the distinguished gentleman from California, Mr.
805 Waxman, for 5 minutes.

806 Mr. {Waxman.} Thank you, Mr. Chairman, thank you, Mr.
807 Tonko.

808 Four years ago, this committee spent a considerable time
809 examining the Toxic Substances Control Act, and worked to
810 craft policy solutions for its failures. It was a
811 challenging endeavor, because we found that even as some in
812 industry claim to want to make our regulatory system safer,

813 we found strong resistance to actual reform. Mr. Morrison,
814 you testified that Section 5 is ``one of the major successes
815 of TSCA, and that we should be careful to preserve its
816 essential elements.'' I would like to take a moment to
817 examine one chemical that has gone through Section 5 review,
818 Firemaster 550. It is a flame retardant that as Dr. Lohmann
819 has stated is gaining significant market share in the United
820 States. The maker of this flame retardant, Chemtura, markets
821 this chemical as a safer alternative, saying that it has ``an
822 improved environmental profile'' compared to its
823 predecessors. In promotional materials, Chemtura touts EPA's
824 review of Firemaster 550 under Section 5(s) ``extensive'' and
825 states that ``consumer exposure is extremely low.'' But as
826 Dr. Lohmann reports, scientists have shown that consumers are
827 being exposed to this product at significant and dangerous
828 levels.

829 Dr. Lohmann, can you elaborate briefly on some of the
830 exposure and hazard data that has been produced on Firemaster
831 550?

832 Mr. {Lohmann.} Thank you for the question. I should
833 point out that is Dr. Stapleton's work from Duke University.
834 What she has shown builds on a legacy--well, it is almost an
835 endless story. It starts off with flame retardants, PBB,
836 polybrominated biphenyls, that were discovered by accident

837 because they contaminated cows in Michigan. They were
838 withdrawn from the market and replaced by polybrominated
839 diphenyl ethers, which were found to accumulate in blood in
840 the U.S. adult population 10 times higher than Europe, so it
841 was finally withdrawn from the market to be replaced by
842 Firemaster 550, which could only be partially evaluated
843 because it was a mix of grandfathered in chemicals and new
844 chemicals. And as all other flame retardants, they are not
845 physically bound or chemically bound to the product, so they
846 escape over time and mostly the exposure for all of us is in
847 our houses through dust.

848 Mr. {Waxman.} Ms. White, you mentioned in your
849 testimony EPA didn't have access to all of the information it
850 needed to thoroughly evaluate Firemaster 550 before it went
851 on the market. Can you elaborate briefly on that?

852 Ms. {White.} Absolutely. Because of the draconian
853 measures of Confidential Business Information in TSCA, EPA's
854 own scientists weren't actually able to look at the full
855 health and safety profile, so the leading expert actually has
856 said on the record that if she had known about the issues of
857 Firemaster 550, then the chemical would not have been
858 approved and there certainly would have been a request for
859 more chemicals.

860 Mr. {Waxman.} EPA developed a work plan to conduct a

861 risk assessment of numerous chemicals identified as
862 potentially hazardous, including a chemical that is the
863 active ingredient in Firemaster 550 known as TBB. EPA gave
864 the active ingredient in Firemaster 550 the worst score
865 possible for exposure risks and plans to assess it this year,
866 yet the promotional materials for the product still say that
867 it has been approved by EPA and that consumer exposure is
868 low. Mr. Morrison, do you believe that Section 5 has worked
869 in the case of Firemaster 550?

870 Mr. {Morrison.} I think, you know, Section 5 in general
871 works very effectively. I haven't studied that in great
872 detail from a scientific standpoint or understand the full
873 history of it. I would be the first to admit that at times,
874 more information comes out and we have an obligation as an
875 industry when we identify a substantial risk, we have to
876 notify the EPA if we have additional data. Additionally, if
877 the EPA determines there is an unreasonable risk, they have
878 every right to go back in and revisit the chemical itself.

879 Mr. {Waxman.} So you would go back and revisit it, but
880 Ms. White, what do you think? Do you think that Section 5
881 worked in the case of Firemaster 550?

882 Ms. {White.} Absolutely not. I think that that really
883 is a great example of how everything is turned upside down
884 when it comes to the New Chemicals Program, because we have

885 the burden of proof being on the EPA to raise this situation
886 and raise concerns about chemical safety, as opposed to the
887 chemical manufacturer fully disclosing and testing in advance
888 and being required to test the chemicals before they go on
889 the market.

890 Mr. {Waxman.} Thank you. Firemaster 550 is already on
891 the market, in furniture, in baby products and other consumer
892 goods, and there are now serious questions about its safety.
893 I guess the question that I think that raises is would it
894 have been better--would the public have been better served
895 understanding these risks before it was brought into
896 widespread use?

897 I would like to introduce, Mr. Chairman, into the record
898 a letter from the Center for International Environmental Law
899 dated July 11, 2013. This letter summarizes work CIEL has
900 done to examine trends in chemicals regulation and patent
901 filings to evaluate the impacts of stronger rules for
902 hazardous chemicals on the innovation of new chemical
903 products. They find that stricter regulation of hazardous
904 chemicals drives innovation and creates a safer marketplace.
905 They explained that implementation of Section 5 has resulted
906 in one dangerous chemical being substituted for another
907 dangerous chemical. They point out that when a different
908 approach is taken, when dangerous chemicals are removed from

909 the market, it accelerates the invention of alternative
910 chemical products. It makes a lot of sense to me and I hope
911 we can focus on getting this policy right as it can be.

912 Dr. {Gingrey.} Without objection, the letter is
913 accepted into the record.

914 [The information follows:]

915 ***** COMMITTEE INSERT *****

|
916 Dr. {Gingrey.} We now turn to the subcommittee chairman
917 on oversight, the gentleman from Pennsylvania, Mr. Murphy,
918 for 5 minutes.

919 Mr. {Murphy.} I thank the panel for being here.

920 I want to start off, because it is always important for
921 me to hear from some of you your corporate philosophy, and I
922 want to ask you this, Mr. Sauers. Your corporate philosophy
923 with regard to dealing with the health and safety of your
924 customers and your employees when it comes to developing
925 chemicals, could you just describe to me what that is?

926 Mr. {Sauers.} Sure. Thank you, Congressman. I mean, I
927 can't think of anything more important to Procter and Gamble
928 than the safety of our customers and employees. Four point
929 six billion people use our products every day, so it is
930 imperative that we ensure that the products we put on the
931 market are safe for them and safe for the environment. I
932 think to illustrate that best, my department at Procter and
933 Gamble has 700 employees in it, 200 of whom have Ph.D.s in
934 sciences related to human and environmental safety. So
935 everything we evaluate for the--to go on the market has a
936 thorough and comprehensive risk assessment prepared for it to
937 ensure that it is safe.

938 Mr. {Murphy.} Mr. Isaacs, do you have a comment on

939 that?

940 Mr. {Isaacs.} Well as an industry, I think we have a
941 similar dedication to the protection of the environment and
942 our workers. My written testimony highlights some of the
943 successes we have had in substituting or phasing out
944 materials of concern in our processes and reducing emissions,
945 and that remains a very high priority for the industry
946 globally.

947 Mr. {Murphy.} And again, Mr. Sauers, in the developing
948 of chemicals in your company, do you--and following what you
949 said as far as your mission of corporate responsibility, do
950 you review chemicals and make decisions that some of them
951 should not be brought to the market because in your
952 determination, they are not passing muster for health and
953 safety?

954 Mr. {Sauers.} Yes, sir. We go through a complete
955 evaluation from the beginning of first proposal by our
956 technologists. Evaluating in the beginning, if we show that
957 materials will be problematic as they are marketed, for
958 example, show unreasonable sensitization, toxicities
959 associated with various organs or things like that, if we
960 think those issues will be a problem considering the exposure
961 that individuals will get to them, we will stop them. We
962 have done that in many instances. As a company, we chose not

963 to market nonylphenol ethoxylates, which were a major
964 surfactant because of environmental quality and their
965 inability to be completely biodegraded. So those decisions
966 are made every day by our toxicologists.

967 Mr. {Murphy.} Thank you. Now for Mr. Morrison, Sauer,
968 and Isaacs, a question. As Congress is probably going to be
969 dealing with the TTIP, that is, dealing with the
970 Transatlantic Trade--Pretrade agreement coming up, one of the
971 questions that is going to come up is with regard to
972 regulations between the United States and European nations,
973 and particularly, I am sure that the question of sharing of
974 CBI with State and foreign governments, the TSCA permits, et
975 cetera. I wanted to ask you if any of you are anticipating
976 any concerns in terms of should States and foreign
977 governments be permitted access to CBI, or if you have begun
978 to put any thoughts into how this would be handled? Mr.
979 Morrison?

980 Mr. {Morrison.} Yeah, at this time we do not, as the
981 ACC or I as the CEO of a company, support sharing CBI with
982 foreign governments. We don't feel we have the ability to
983 control and protect that information. We do take a different
984 stance on sharing information with States where they
985 demonstrate an ability to protect the information, as well as
986 an applicable use around safety or environmental purposes.

987 But we do not feel secure in today's environment passing out
988 CBI information internationally, so we would not support
989 that.

990 Mr. {Murphy.} Let me expand this, and the three of you,
991 as it goes through, because it is something we are going to
992 have to deal with, and there are regulatory issues how the
993 United States and the EU will deal with these issues to make
994 sure that any products that are sold across the Atlantic from
995 either side dealing with their environmental concerns and our
996 environmental concerns with health and safety of customers.
997 So how do each of you--what are your thoughts on does the EPA
998 protect trade secrets while still providing a mechanism for
999 evaluation of safety and health review? I will start with
1000 Mr. Morrison and go across.

1001 Mr. {Morrison.} Yeah, I think there is very much a
1002 capability to share the pertinent information without giving
1003 chemical identity and other things that we currently protect.
1004 So the important aspect around safety, environmental and et
1005 cetera, we feel we are very capable of sharing that. What we
1006 don't agree with is sharing the proprietary information such
1007 as chemical identity.

1008 Mr. {Murphy.} Do you feel that they protect that
1009 information, or does it get out?

1010 Mr. {Morrison.} Well, we have ability to protect that

1011 with generic names that we talked about before, but we are
1012 afraid if you gave out chemical identity, once it goes to
1013 other governments you lose control of the ability to protect
1014 chemical identity.

1015 Mr. {Murphy.} A few more seconds. Mr. Sauers, with
1016 regard to the EPA protecting that proprietary data while it
1017 is still providing information to help them evaluate health
1018 and safety, do you feel confident that they protect that top
1019 proprietary information?

1020 Mr. {Sauers.} Yes, I do, and I think there is a balance
1021 that needs to be weighed here. There no CBI with the EPA
1022 itself. I mean, they get full access to all the information
1023 and the specific chemical names. I mean, they have full
1024 access so they are able to make their evaluation. And then a
1025 generic, less descriptive chemical name is given and that is
1026 what is made public, which allows the public to be able to
1027 draw their own conclusions about the material. And as a
1028 toxicologist, that information that is provided is sufficient
1029 for individuals to make evaluation and draw to corollary
1030 materials, for which there is available information.

1031 Mr. {Murphy.} Thank you. Mr. Chairman, I see my time
1032 expired but I would hope that that question could also be
1033 forwarded to the other panel members and ask for their
1034 response as well. Thank you.

1035 Dr. {Gingrey.} Thank you, Mr. Murphy. We now turn to
1036 the ranking member from New York, Mr. Tonko, for 5 minutes.

1037 Mr. {Tonko.} Thank you, Mr. Chair. Reviews by the
1038 Government Accountability Office and testimony that we had
1039 heard at our last hearing indicated shortcomings with respect
1040 to Section 5 of TSCA. Last year, EPA announced a work plan
1041 to conduct the risk assessment of numerous chemicals
1042 identified as potentially harming children's health, causing
1043 cancer or posing other health concerns. Several of these
1044 chemicals were reviewed under TSCA's Section 5 New Chemicals
1045 Program, but made it on the market anyway.

1046 So to Dr. Lohmann, my question is if we suspect a
1047 chemical harms children's health or has another serious
1048 effect, shouldn't we try to understand that before it goes on
1049 to the market rather than after?

1050 Mr. {Lohmann.} I would fully concur. You would expect
1051 these days that we would first make sure a chemical is safe
1052 before we produce it. Unfortunately, that is not the way it
1053 works in this country right now.

1054 Mr. {Tonko.} Well how could a stronger Section 5
1055 provide proactive protection for the American public?

1056 Mr. {Lohmann.} What you see happening in Europe under
1057 the REACH Program is that the manufacturers have to take
1058 responsibility for their product and have to convince the

1059 regulatory agency, in this case, the European Chemicals
1060 Agency, to show that their product is safe in its different
1061 uses. So the manufacturer has to go all the way through from
1062 cradle to grave what I am producing is safe and where it is
1063 going to be used. And that kind of approach really means the
1064 responsibility is with the person or the company who makes
1065 it, and they have to show it is safe. And that, I think, is
1066 a much more forward looking approach than just having here is
1067 a new chemical, EPA, just evaluate it quickly and we will
1068 market it anyhow.

1069 Mr. {Tonko.} Thank you. Ms. White, you testified that
1070 the current structure of Section 5 leaves EPA without the
1071 data it needs to effectively evaluate chemicals and that the
1072 structure creates a disincentive to producing that post data.
1073 Could you please elaborate on that?

1074 Ms. {White.} Absolutely. So EPA right now is not able
1075 to require testing before a chemical goes on the market. If
1076 the industry has tests, it is supposed to disclose them. But
1077 in order to request more information, it has to find two
1078 things. That one, there is an unreasonable risk of injury,
1079 or two, that the chemical is going to be manufactured in such
1080 a high volume that there would be a significant human
1081 exposure. So what happens is, there is this chemical Catch-
1082 22, which EPA has to try to figure out that there may be a

1083 risk, but it can't require testing until it has evaluated
1084 testing. So it is this really difficult cycle. It is like
1085 grading students without actually asking them to take a test.
1086 So for example, I will just give you an A because I know that
1087 maybe your son was a really good student and maybe you are a
1088 neighbor of so-and-so, but I am not actually requiring you to
1089 take any tests. So it is a very difficult situation that EPA
1090 is in.

1091 Mr. {Tonko.} EPA can't thoroughly review new chemicals
1092 for potential health effects if it doesn't have adequate data
1093 to do so. One policy that has been discussed over the years
1094 is the concept of requiring a certain minimum amount, minimal
1095 amount of data prior to a new chemical being brought onto the
1096 market. What do you think of this approach? Does it have
1097 merit?

1098 Ms. {White.} It absolutely has merit, and frankly, I
1099 think most Americans assume that that is already in place.
1100 They are very surprised to find out that EPA doesn't require
1101 a series of tests before chemicals go on the market, so that
1102 is absolutely where we should be heading, and that is where
1103 we should be targeting reform for Section 5.

1104 Mr. {Tonko.} And Dr. Lohmann, your thinking on the data
1105 requirement?

1106 Mr. {Lohmann.} I certainly agree, and that is--most

1107 global players who deliver to the European market have to
1108 provide this kind of data now to get onto the European
1109 market, get reevaluated, or reassessed, reauthorized for
1110 their chemicals. So the best thing the U.S. should do is
1111 find an agreement with the European program to use the
1112 dossiers that are provided anyhow, and they will all have to
1113 provide data. If you have no data on your chemicals, there
1114 is no market in the EU. It seems a very logical approach.

1115 Mr. {Tonko.} Mr. Morrison, it seems to me that building
1116 safety into the developmental process earlier is likely to be
1117 a better approach to product development. This is the idea,
1118 I believe, behind the green chemistry movement. Would you
1119 agree with that in concept?

1120 Mr. {Morrison.} Well, I think there is a basic
1121 underlying assumption in your comment, which is we don't
1122 build safety, and I think we do extensive testing. We have
1123 the greatest to lose if we put products on the market that
1124 are hazardous, that hurt health, that hurt environmental, et
1125 cetera, so we do extensive testing when we develop new
1126 products. All of that information is turned over to the EPA.
1127 They have very extensive databases that they run and they run
1128 on analogous materials. And so I think the underlying
1129 assumption that if the EPA doesn't force the test it isn't
1130 done, they don't have to force the test in many cases because

1131 it is already being done by us.

1132 As far as green, we fully support green where
1133 appropriate. Our company and many in the industry
1134 aggressively push it, but it is one form of innovation. It
1135 is not the only form of innovation.

1136 Mr. {Tonko.} Is there any chance for added safety by
1137 requiring the submission of a basic safety data set as part
1138 of the initial pre-market review process?

1139 Mr. {Morrison.} I actually think it would have an
1140 adverse effect, because what you have to take into account is
1141 the workload you would put on companies and EPA, you would
1142 take the higher hazardous and now be swamped with all
1143 chemicals there when there are much more effective and
1144 efficient ways to deal with the vast majority. And so you
1145 are creating an unneeded workload, which I believe would add
1146 very little or no benefit and would, in fact, just swamp the
1147 EPA and they wouldn't be able to prioritize their resources.
1148 It would also kill innovation. The reason we produce three
1149 times more chemical innovation than Europe, Japan, and others
1150 is because I think our process works very effectively.

1151 Mr. {Tonko.} I guess I am also hearing that they might
1152 require more resources for EPA also to develop that plan, but
1153 I believe I have extended my amount of time, so--exhausted my
1154 amount of time, so I will yield back.

1155 Dr. {Gingrey.} Thank the gentleman, and we now turn to
1156 the gentleman from West Virginia, Mr. McKinley, for 5
1157 minutes.

1158 Mr. {McKinley.} Ms. White, I want to see whether I
1159 heard it properly. Did I hear you say that often products
1160 going to the market are not confirmed prior to going to
1161 market for toxicity?

1162 Ms. {White.} That is correct. According to EPA, 85
1163 percent of the pre-manufacture notice, this approval process
1164 for chemicals, do not have toxicity data. They have not
1165 submitted that to EPA.

1166 Mr. {McKinley.} Are you contending, then, that--are you
1167 suggesting that they are trying to circumvent something by
1168 doing that?

1169 Ms. {White.} I am suggesting that the system is broken.
1170 There actually isn't incentive for testing. There is an
1171 incentive not to test because if you don't--

1172 Mr. {McKinley.} You think that they are testing
1173 themselves?

1174 Ms. {White.} If they are, they are required to give
1175 that to EPA.

1176 Mr. {McKinley.} Okay, thank you.

1177 Ms. {White.} But in 85 percent of instances, they
1178 don't.

1179 Mr. {McKinley.} The other three panelists, can you
1180 respond to that? I thought that was an interesting comment.
1181 I guess I did hear that properly. Do you want to respond
1182 back to the going to market without testing for toxicity?

1183 Mr. {Morrison.} You know, where appropriate and data is
1184 required, we of course test for toxicity and the idea that we
1185 would put out products where we thought there was a risk
1186 simply for economic reasons, first of all, it doesn't make
1187 any economic sense because the risks would overwhelm any
1188 sales potential. B, we apply the tests that are appropriate
1189 but we don't blindly apply all tests to everything. It is
1190 not economically viable, either. So I think the underlying
1191 assumption is one I don't agree with.

1192 Mr. {McKinley.} Mr. Sauers?

1193 Mr. {Sauers.} And I think we have to distinguish
1194 between the EPA's ability to do an evaluation of a chemical,
1195 and then the toxicity data that is being mentioned here. You
1196 can evaluate the safety of a material without having animal
1197 toxicity data. There are other avenues available to you.
1198 The EPA has it its disposal, you know, a vast database of
1199 animal data on historical chemicals and they are experts in
1200 applying structure activity to the relationships and
1201 productive modeling type systems to evaluate the safety of
1202 materials. So just because they don't get new animal testing

1203 data on a chemical that is coming in does not mean that they
1204 don't have an ability to evaluate that chemical for safety.

1205 Mr. {McKinley.} Thank you. Mr. Isaacs?

1206 Mr. {Isaacs.} Yes, sir. We actually think there would
1207 be a benefit to improved tools and better predictive modeling
1208 at the agency, and we also think that increased access and
1209 transparency to existing data that is out there would benefit
1210 the system as a whole. I understand that EPA is making some
1211 efforts in that direction and we look forward to seeing the
1212 results of that.

1213 Mr. {McKinley.} Thank you for your responses back on
1214 that. I am just curious, the fact that apple juice has
1215 arsenic traces, arsenic in it. Should we be banning the
1216 drinking of apple juice in America because there is a trace
1217 level of toxicity in that material? Ms. White?

1218 Ms. {White.} We would not say we need to ban apple
1219 juice, but certainly a cause for concern when we have all
1220 these situations where these low doses of chemicals--and
1221 arsenic is a different situation--but when we are talking
1222 about chemicals that are manufactured and not required to be
1223 tested before they go on the market, that is shocking for
1224 most Americans.

1225 Mr. {McKinley.} Ms. White, I just think I am with you
1226 more than you realize, but I am also wondering how often we

1227 get to maybe hysteria levels on some things. When we are
1228 burning coal, we have the issue of toxicity that people use
1229 exaggerated numbers and fears that are unwarranted and it
1230 puts the fear in the minds of people, and the same thing. So
1231 I really do appreciate the responses that we have had here
1232 today. If people are going to market without checking for
1233 toxicity, whether it is internal or through the agency, I
1234 think we need to determine that but it sure sounds like the
1235 companies are doing the job themselves, it appears, and I
1236 would hope that we wouldn't be putting out false concerns to
1237 the public if they are out there on that.

1238 So with that, thank you and I yield back the balance of
1239 my time.

1240 Dr. {Gingrey.} Thank the gentleman, and I turn to the
1241 gentleman from California, Mr. McNerney, for 5 minutes.

1242 Mr. {McNerney.} Thank you, Mr. Chairman. I thank the
1243 witnesses this morning.

1244 I think it is pretty clear there is a conflict between
1245 the industry's legitimate wish to keep trade secrets
1246 confidential, and on the other hand, the risk of releasing
1247 chemicals whose long-term and low exposure health impacts may
1248 not be very well understood, especially when they are put in
1249 an environment where they are going to be mixed with other
1250 very complex chemicals. So everyone understands that it is

1251 in the industry's interest to have consumer safety and
1252 consumer confidence. There is no problem there. It is our
1253 duty, it is our job as a committee, as a subcommittee, to try
1254 and resolve that conflict. We are going to do the best we
1255 can and I appreciate your participating this morning.

1256 Mr. Sauers, I think I heard you say that an update of
1257 TSCA is urgently needed. One of the reasons is to give
1258 consumers confidence in the process, and I think that is
1259 pretty well agreed to. But then you said later that the
1260 EPA's recent decision to disclose specific confidential
1261 information is hurtful. So I see that that is a little bit
1262 of a conflict in my mind between wanting to improve consumer
1263 confidence and yet thinking the EPA's decisions are
1264 problematic.

1265 Mr. {Sauers.} Sure, and maybe just to clarify, we just
1266 had a discussion about questions being raised about trace
1267 levels of arsenic, for example, in apple juice. That does
1268 raise concern to consumers' minds about the safety of
1269 products that are in the marketplace. Many times a company
1270 like Procter and Gamble doesn't have all the credibility as
1271 it communicates to consumers about safety. The EPA does, so
1272 having and EPA with a very robust system in place that is
1273 recognized will give a credibility when they say that
1274 materials are safe, and we would support that very much. We

1275 think that they do have the tools today to do that with the
1276 information that is provided as part of the PMN process.

1277 Mr. {McNerney.} Well I will just suggest that, you
1278 know, implying that EPA's new rules to release the
1279 information might actually help in terms of the company's
1280 long-term credibility, so that is my two bits on that.

1281 Mr. Lohmann, you mentioned that one of the things we
1282 should do is ID and replace the most dangerous chemicals,
1283 including grandfathered chemicals. How big of a job would
1284 that be?

1285 Mr. {Lohmann.} It would certainly be a major
1286 undertaking, but luckily, the Europeans are doing that now
1287 anyhow, so they are taking care of that and most global
1288 companies, like Procter and Gamble, have filed all their
1289 dossiers so information on most of those chemicals will be
1290 available. As I will also point out, it will actually spur
1291 innovation towards safer chemicals so I think it is a
1292 worthwhile endeavor.

1293 Mr. {McNerney.} So it might spur innovation and
1294 profitability then?

1295 Mr. {Lohmann.} Because some of the comments we have
1296 already brought, most right now in the environment were
1297 grandfathered in. They had no testing. Some of the new ones
1298 we also worry about, but certainly the grandfathered in are--

1299 should be reassessed.

1300 Mr. {McNerney.} Well one of the most striking things
1301 you said was that there is a strong correlation between
1302 chemicals in households and health problems that we are
1303 experiencing in our country. Did you want to expand on that
1304 a little bit?

1305 Mr. {Lohmann.} Certainly. I guess we can never know
1306 for sure because etymology is very difficult to do, but it is
1307 striking that a lot of the results that we see from either
1308 controlled tests or even in the field of animals to low doses
1309 are exactly the health problems that we see in modern
1310 society. So I am not saying that chemicals are the sole
1311 cause of all the problems, but there is probably a
1312 correlation, and that should worry us.

1313 Mr. {McNerney.} Mr. Lohmann and Ms. White, have you
1314 heard of the term chemical trespass, and if so, would you
1315 describe what you think that term means?

1316 Ms. {White.} Yes, chemical trespass means there is
1317 unwanted chemicals that are in your body and rather than
1318 trespassing on someone's land, in fact, a chemical has
1319 trespassed into your body. It is a developing concept in
1320 tort law, and there is certainly a lot of concern. Our
1321 studies have shown that, in fact, these chemicals that we
1322 find in consumer products like lotions and stain removers and

1323 laundry detergents and nail polish are actually building up
1324 in people's bodies, and as I said in my testimony, also in
1325 newborn babies.

1326 Mr. {McNerney.} Would you, Ms. White, offer some
1327 specific suggestions on how to improve the TSCA process?

1328 Ms. {White.} Absolutely. With respect to the new
1329 chemicals provision, we really need to make sure that the
1330 burden of proof shifts from EPA to the manufacturers to show
1331 that their products are safe before they go on the market.
1332 We also do need a minimum data set so we know what the rule
1333 are, and so consumers, we hear a lot about confidence.
1334 Consumers want to know that when they have a nap mat, you
1335 know, where our colleagues at the Center for Environmental
1336 Health released a really great study that nap mats have flame
1337 retardants it is really concerning. Parents want to know
1338 when their kids are taking a nap at preschool that they
1339 aren't going to have a chemical in their body, and that
1340 certainty would be really key.

1341 Mr. {McNerney.} Mr. Lohmann, would you agree with that
1342 response?

1343 Mr. {Lohmann.} I would agree.

1344 Mr. {McNerney.} I am sorry, I said Mr. Lohmann and I
1345 was looking at Mr. Morrison. Mr. Morrison?

1346 Mr. {Morrison.} Which element of a response, just to

1347 make sure that--

1348 Mr. {McNerney.} Well, if the--I will let my time expire
1349 on that.

1350 Mr. {Johnson.} [Presiding] I thank the gentleman for
1351 yielding, and Dr. Gingrey went to the Floor, so I am going to
1352 sit in for him. I am Congressman Bill Johnson from Ohio, and
1353 I will take my 5 minutes now. I would like to thank the
1354 panel for--you want me to go ahead? I was next until Dr.
1355 Cassidy walked in.

1356 Okay, restart the clock. I would like to thank the
1357 panel for being here. Thank you so much.

1358 Mr. Sauers, since testing is not required when you first
1359 file a Section 5 pre-manufacturing notice, does that mean you
1360 have not tested that chemical?

1361 Mr. {Sauers.} I think I will maybe answer by saying
1362 that evaluations are made of the material and there are many
1363 ways of making an evaluation of a chemical for safety. One
1364 way is to do safety testing, you know, rodent test like an
1365 oral toxicity test in rodents. There are also other ways to
1366 evaluate the safety of a material, using tissue culture,
1367 using structure activity relationships, predictive modeling,
1368 and things like that. So materials are always evaluated.
1369 How they are evaluated can be different, depending on the
1370 circumstance.

1371 Mr. {Johnson.} Well, if you do testing before
1372 submitting a PMN, do you assess a broad range of possible
1373 hazards?

1374 Mr. {Sauers.} Um-hum, and it really would depend on the
1375 exposure that one expects the material to have. So if it
1376 broad scale exposure, you will find testing and evaluation
1377 across a variety of toxicity end points. If it is specific
1378 for inhalation, it will be different. If it is going to be a
1379 large volume exposure versus a very small exposure, the
1380 degree of testing could be different.

1381 Mr. {Johnson.} Okay. How standard is this practice
1382 within the industry?

1383 Mr. {Sauers.} I would say that most companies approach
1384 it the same way, a risk-based approach of assessing exposure
1385 and hazard. Most companies have toxicologists, like Procter
1386 and Gamble, that will approach it this way.

1387 Mr. {Johnson.} Okay. Do you do additional tests on
1388 your own after the PMN has been submitted?

1389 Mr. {Sauers.} Generally by the time we have submitted
1390 the PMN, the bulk of our testing is done because we are
1391 commencing to manufacture and put the material in the
1392 marketplace, so we want to have a full assurance of safety
1393 prior to that happening. If in the course of marketing
1394 something comes through our 800 line or through consumer

1395 comments that could cause a question to be raised, we would
1396 go back and evaluate it.

1397 Mr. {Johnson.} Okay. Mr. Morrison, do you agree with
1398 these responses, consistent your--

1399 Mr. {Morrison.} Yes, absolutely. You know, as an
1400 industry, the chemical industry, we have a responsible care
1401 management system that we share across all chemical companies
1402 that are part of it, and that is the vast majority, and
1403 common best practices are shared and employed, and I think we
1404 are very consistent with Mr. Sauers' answers.

1405 Mr. {Johnson.} Okay. Do other forms of intellectual
1406 properties, such as patents, provide adequate protection to
1407 confidential chemical identities, in your view?

1408 Mr. {Sauers.} Yes, they do provide some protection, but
1409 it is not complete. There are very strict--

1410 Mr. {Johnson.} Operative word was adequate, so do you
1411 consider them to be adequate?

1412 Mr. {Sauers.} Patents--for the purpose of patents and
1413 what they cover, they are adequate.

1414 Mr. {Johnson.} Okay, Mr. Morrison?

1415 Mr. {Morrison.} There is much confidential information
1416 that is not covered by patents, and so while patents are
1417 effective for the, you know, actual material that is under a
1418 patent, that is fine, but there are many others that come

1419 under trade secrets that are just as critical to our business
1420 and we don't patent for very specific reasons.

1421 Mr. {Johnson.} Okay. Mr. Isaacs, Ms. White and Dr.
1422 Lohmann have suggested that TSCA chemical review operate like
1423 reviews for drugs by the Food and Drug Administration. What
1424 do you think could be a reasonable reaction from your members
1425 if this were to occur?

1426 Mr. {Isaacs.} Well, of course I am not an expert in the
1427 drug review process, but I think that would not be the right
1428 approach. I think that would be--impose a time delay that
1429 would impede the time to market that we require, but at the
1430 same time, the key point that we would like to emphasize in
1431 all this is the need for chemical assessments to be tailored
1432 to the risks and exposure to the use in question. And we are
1433 confident that in our industry, with the high degree of
1434 controls that we impose on our processes, that the exposure
1435 and releases are very, very low and the chemicals that we use
1436 are done safely and responsibly.

1437 Mr. {Johnson.} Okay. Mr. Sauers, back to you. Doesn't
1438 Europe require manufacturers to submit a minimum information
1439 set on new chemicals?

1440 Mr. {Sauers.} Yes, as part of REACH.

1441 Mr. {Johnson.} Okay, so if you are doing it in Europe,
1442 why not do the same thing here in the United States?

1443 Mr. {Sauers.} I think this is what we appreciate most
1444 about TSCA is that the amount of data that is submitted is
1445 tailored to the chemical and the exposure that individuals
1446 can expect from it and its toxicity. You know, like Procter
1447 and Gamble, a new chemical that is going into a laundry
1448 detergent, for example, there will be vast exposure to that
1449 so that is something you want to have a full, complete
1450 toxicity data set on. And you can contrast that all the way
1451 back to maybe an intermediate in manufacturing for which
1452 there is no exposure. So really the amount of data needed
1453 for something like that is minimal. So this ability to
1454 tailor the amount of information to the need of the chemical
1455 to assure safety is really the best approach.

1456 Mr. {Johnson.} Okay, thank you. Thank you all for your
1457 answers. At this time, we will go to Mr. Barrow from
1458 Georgia.

1459 Mr. {Barrow.} Thank you, Mr. Chairman. Something we
1460 have talked a lot about is the over-classification of
1461 Confidential Business Information problem here. We haven't
1462 talked much about efforts to declassify stuff that is no
1463 longer necessary. Mr. Morrison, in your written testimony, I
1464 think you talk about a voluntary effort that is underway
1465 between the EPA and the industry to try and declassify stuff
1466 that is no longer nor needs to be confidential. Can you

1467 share--tell the committee what that effort looks like?

1468 Mr. {Morrison.} Yeah, it is essentially with the EPA
1469 there is an effort to identify what you might consider
1470 obsolete and information that doesn't have to be classified
1471 anymore, and actually working through a backlog of that and
1472 declassifying, and it is one of the areas of opportunity that
1473 we think as the new bill comes out hopefully that we can be
1474 more progressive about and more effective with, both in
1475 classifying originally on a CBI basis, but also
1476 declassifying.

1477 Mr. {Barrow.} Building on that, and talking about
1478 conflicting demands between the right to know between claims
1479 that everybody has a right to know everything about this, and
1480 there is a legitimate interest in keeping things
1481 confidential. I want to shift just a little bit from
1482 competing demands about the right to know, to a more
1483 pragmatic understanding about what we can do to share
1484 information to folks who have need to know. For example, Ms.
1485 White, in your testimony you talk about the needs that some
1486 folks have, the legitimate needs of first responders in
1487 emergency situations, and Mr. Morrison, you talk about
1488 efforts to declassify stuff that no longer needs to be kept
1489 confidential. Is there any kind of process that you all can
1490 agree on that would sort of if not address completely to

1491 everyone's satisfaction the issue of one's right to know
1492 would still result in a practical dissemination of stuff to
1493 folks who have a need to know? Is there some kind of process
1494 that we can agree on that would move us forward in that
1495 direction? Mr. Morrison, then you, Ms. White.

1496 Mr. {Morrison.} There is actually a process in place
1497 now that when an emergency situation happens, a spill, other
1498 type of emergency situations for emergency responders, there
1499 is information that is mandated, including material safety
1500 data sheets, et cetera, which are very explicit and the up-
1501 front section is all about emergency response to that
1502 particular material.

1503 So when you are in an emergency situation, either health
1504 or environmental, the rules change automatically and we
1505 disseminate information on it on an as-needed basis. So that
1506 is already addressed, but we certainly look forward in the
1507 new TSCA bill to see if there are any gaps that we can be
1508 more effective.

1509 Mr. {Barrow.} Ms. White, how would you address that
1510 subject?

1511 Ms. {White.} I would say that we all basically want the
1512 same thing. We want to make sure that chemicals are proved
1513 by a trusted regulator and that the chemical industry is
1514 vibrant. I think there is a lot of opportunity here for us

1515 to come up with sunset provisions, for example, for
1516 Confidential Business Information, also to make sure there is
1517 resubstantiation within a certain amount of time. I think
1518 that there is an important carve-out for medical personnel
1519 and emergency responders, and there is a real opportunity for
1520 us to work together.

1521 Mr. {Barrow.} Thanks. Mr. Sauers, it would be a poor
1522 dog who won't wag his own tail, and since you won't do it, I
1523 will do it for you. I have enjoyed my visit to P&G's
1524 facility in Augusta back in 2010 and look forward to my next
1525 visit coming up in the fall. Can you share with us anything
1526 about--you talk about the importance of not creating
1527 disincentives for innovation in this area. I know there are
1528 conflicting views about whether or not total dissemination of
1529 everything is going to actually promote innovation or not.
1530 What are the disincentives you would want to avoid in a kind
1531 of revamp of TSCA?

1532 Mr. {Sauers.} I would say that anything that would lead
1533 to a loss of competitiveness, and I think this is where the
1534 CBI comes in. I think that there is a balance that can be
1535 brought between ensuring that everyone has the health and
1536 safety information that they need to be able to make a
1537 conclusion on a material, and the ability to protect
1538 competitiveness for companies like Procter and Gamble. I

1539 think the process today where the EPA is given full
1540 disclosure of all information, even that which is
1541 confidential, enables them to make an assessment, and then
1542 the public release of the health and safety information with
1543 the generic descriptive form of the chemical enables
1544 individuals to get an understanding and draw parallels to
1545 other materials that are in the marketplace to ensure health
1546 and safety. So I think there can be a balance that can be
1547 brought there.

1548 Mr. {Barrow.} I hope you all understand with votes
1549 pending on the Floor, no time left on the Floor, I am going
1550 to yield the rest of my time. Thank you so much. Thank you,
1551 Mr. Chairman.

1552 Mr. {Johnson.} I thank the gentleman for yielding back.
1553 We will go now to Dr. Cassidy from Louisiana.

1554 Dr. {Cassidy.} Let me stress there is no time left to
1555 increase my anxiety level. I apologize. I stepped out so if
1556 you all addressed some of this, I have a question that is
1557 kind of for across the board.

1558 Dr. Lohmann mentioned that REACH in Europe is requiring
1559 a lot of things that frankly I gather make some of your
1560 proprietary information held by a government agency regarding
1561 some of the testing, and I tried to Google it, and REACH is a
1562 long, long PDF. I think your point, Dr. Lohmann, was that,

1563 heck, this is already being required. It is just being
1564 required by the Europeans and not by us. That is kind of an
1565 interesting argument. What would you all say to that? Why
1566 don't we just do what the Europeans are doing, because
1567 frankly, if they are doing it, then your chain is only as
1568 strong as the weakest link and the Europeans are kind of the
1569 weak link, perhaps, in some of this, so to speak. Or maybe
1570 they are the strong link. But how would you all respond to
1571 that?

1572 Mr. {Morrison.} I mean, we operate under both REACH and
1573 the EPA current guidelines, and we find REACH to be
1574 excessively bureaucratic and we don't find it necessarily
1575 adds incremental benefit. We think that the databases that
1576 the EPA has, the analogous materials they work with, we can
1577 innovate faster under the EPA system than we can as required
1578 under REACH.

1579 Dr. {Cassidy.} Then let me ask, because each of you all
1580 is so big. I kind of knew that you would be in the European
1581 market as here, and that market is so large you can't ignore
1582 it. But do you have a different product line, whether it is
1583 a U.S. market versus a European market?

1584 Mr. {Morrison.} In many cases, our products are
1585 modified on a global basis by region, whether it is consumer
1586 or others, for a wide variety of reasons, so sometimes there

1587 are very significant differences.

1588 Dr. {Cassidy.} Okay, now they just told me I got to
1589 hustle, or else there will be an attack out on me on my next
1590 campaign.

1591 So Dr. Lohmann, next question for you. I looked up some
1592 of your references. Now for example, eight weak estrogenic
1593 chemicals combined at concentration below--produce
1594 significant mixture effects. You mentioned this was in rats.
1595 What would be required to produce--put it this way. It is
1596 hard to show a negative. Now if we are going to establish
1597 safety and we had rat data in which eight chemicals were
1598 combined to have an effect, we don't know whether that would
1599 translate into humans, and indeed, some of those effects
1600 might not be seen for decades. So I guess my question would
1601 be the--at what point--these guys could be tied up forever
1602 proving safety of something, but you can't ever prove quite
1603 that something bad is not going to happen. You see where I
1604 am going with this. What would be the standard by which you
1605 could accept that something was truly safe?

1606 Mr. {Lohmann.} That is a very good question. I am not
1607 sure we know the full answer right now, but I think being
1608 cautious is helpful. Mix toxicity is the biggest unknown
1609 that everybody is working on, because we know we are exposed
1610 to hundreds or thousands of chemicals at the same time at

1611 trace levels, of course.

1612 Dr. {Cassidy.} And we don't know if those trace levels
1613 are physiologically important, or pathophysiologically
1614 important. It may be, but we don't know that.

1615 Mr. {Lohmann.} That is correct, but we also know that
1616 toxicity has become much, much more concerned about trace
1617 levels over the time.

1618 Dr. {Cassidy.} I absolutely can agree with that. Of
1619 course, intuitively you know since EPA has been operating our
1620 environment has become cleaner, and so if you will, there
1621 should have been a higher toxicity exposure in times past
1622 than now, and not for everything, but for many things.

1623 Mr. {Lohmann.} That is correct. We certainly are
1624 cleaner with respect to PCPs, but we certainly have increased
1625 in perfluorinated compounds. We have more flame retardants,
1626 so it is a give and take.

1627 Dr. {Cassidy.} Yes.

1628 Mr. {Lohmann.} I am not sure if we are much healthier
1629 that way.

1630 Dr. {Cassidy.} Much less mercury and much less lead.
1631 So I guess--so I am not sure, it would always be a moving
1632 target. I am sure we have now decreased lead, we are still
1633 seeing something trace. How do we ever prove safety? If we
1634 are going to establish safety beyond a doubt, will we ever

1635 have anything established?

1636 Mr. {Lohmann.} Well, one way to do this is to just wait
1637 and see if the Europeans become healthier because of REACH
1638 and the U.S. does not.

1639 Dr. {Cassidy.} See, the problem is--and I read an
1640 article that kind of critiqued this--was that there are so
1641 many secular effects, and if you look at the effect of
1642 obesity, for example, and the effects of it on breast cancer,
1643 it so much outweighs the things that we know have an effect,
1644 alcohol, cigarettes, family history, obesity are so powerful
1645 that even if there is an effect of a trace element, then that
1646 effect might be drowned out by the secular.

1647 It is 33 seconds left. I am about to miss a vote. I
1648 have to leave it there. Thank you very much.

1649 Dr. {Gingrey.} Thank the gentleman, and we are going to
1650 actually take a little break. We are waiting for Congressman
1651 Green from Texas to return from that vote. He should be here
1652 momentarily. I want to ask that all members have 5 days--ask
1653 for unanimous consent, of course, that all members have 5
1654 days to submit opening statements for the record, that
1655 letters to this subcommittee from 3M, the Cleaning Institute,
1656 the Consumer Specialty Products Association be included in
1657 the record of this hearing, and that members have 10 days to
1658 submit questions to the chair that will be forwarded to our

1659 witnesses for their responses to be included in the record.

1660 Hearing no objection, so ordered.

1661 [The information follows:]

1662 ***** COMMITTEE INSERT *****

|
1663 Dr. {Gingrey.} I now yield to the gentleman from Texas
1664 for 5 minutes of questioning, Mr. Green.

1665 Mr. {Green.} Again, thank you, and I know this panel
1666 knows we have one vote on the House Floor and you will be
1667 seeing us come in and out, although hopefully that vote won't
1668 take an hour, only the typical 15 minutes. I appreciate the
1669 panel here. I want to thank the majority for calling a number
1670 of hearings on TSCA reform. I come from an area where TSCA
1671 reform is really important. I have--in fact, I think Procter
1672 and Gamble is probably the only company that doesn't have a
1673 plant in our district that relates to chemicals. But we know
1674 we need to reform and it needs to be done in a reasonable
1675 way, so that is what we are hopefully the Bitter-Lautenberg
1676 bill or the draft is something we can use on our side, on the
1677 House side, as a guide.

1678 Mr. Morrison, I am hoping you would share with our
1679 subcommittee some of the end products that are a result of
1680 chemicals manufactured by your company.

1681 Mr. {Morrison.} Some of the end products would be wind
1682 energy blades, solar panels--is that--you are talking about
1683 end use markets?

1684 Mr. {Green.} Yeah.

1685 Mr. {Morrison.} Medical applications in terms of

1686 devices we go down into, we have more than 50 applications in
1687 automotive, all wood products that you have touched probably
1688 use our chemicals. We are in aircraft. We are extremely
1689 broad. We are in electronics, so your cell phones, your
1690 iPads, we have components and chemicals that go into all of
1691 that.

1692 Mr. {Green.} One of the things we may need to look at
1693 as a committee, that certain chemicals--you know, we may have
1694 a higher standard for baby bottles, for example, or for
1695 bottles of Diet Coke or water or anything else, than we would
1696 for windmill blades, or even automotive parts that we are not
1697 going to have contact in. So you know, that is one of the
1698 things we need to factor in on some of the issues.

1699 Do you believe that chemicals developed by Momentive
1700 could have developed under the regulatory regime of the
1701 European Union?

1702 Mr. {Morrison.} In some cases, yes, but in other cases,
1703 we believe that the speed is not there, that it is a much
1704 more bureaucratic system. It now requires a minimum data
1705 set. It doesn't react as quickly, and so in some cases, we
1706 would not be able to innovate at the same rate, and that is
1707 why the U.S. innovates at approximately three times the rate
1708 of the European Union on new chemicals.

1709 Mr. {Green.} Well as a side, since we are talking about

1710 North Atlantic Free Trade Agreement, you know, having common
1711 standards as something we may need to deal with on a separate
1712 venue and hopefully our committee will be able to deal with
1713 it instead of just adopting whatever the European community
1714 does. You have already given the answer about the regulatory
1715 regime provided by the advantages of our competitive system.
1716 In your testimony, you state that EPA and chemical
1717 manufacturers developed a dialog over the years that benefits
1718 both the EPA and the industry. Is that correct?

1719 Mr. {Morrison.} Yes.

1720 Mr. {Green.} Can you share how this dialog would help
1721 industry develop new chemicals, particularly as it relates to
1722 protecting human health and the environment?

1723 Mr. {Morrison.} Yes. A lot of times, I mean, when the
1724 EPA puts out guidelines, et cetera, dialogs back and forth,
1725 we self-regulate in many cases as was described earlier where
1726 we will start down a path developing something. If we find
1727 it has certain characteristics that may not pass EPA muster
1728 or our own muster, we will actually pull that product before
1729 it ever goes. Having an ability to communicate back and
1730 forth with the EPA allows us to proactively do that. It
1731 saves us the time from developing something that won't hit
1732 the market, and it also saves the EPA time. Conversely, I
1733 think because the process is quite effective and it does lend

1734 towards innovation, it also allows us to expedite things that
1735 will be successful and bring new innovation quicker to the
1736 market than places like Europe.

1737 Mr. {Green.} You noted in your testimony that EPA does
1738 not require CBI claims to be justified. Is that correct?

1739 Mr. {Morrison.} Yes.

1740 Mr. {Green.} Do you think you could--we could still
1741 have the innovation technology if EPA had the authority to
1742 say--you know, of course, we also are very proprietary
1743 interest, but do you think if EPA had that authority you
1744 could still have the success you are having?

1745 Mr. {Morrison.} We like to believe that as far as
1746 justification of CBI and the new Bitter-Lautenberg bill it
1747 actually does change how CBI information is handled. That is
1748 one of the modifications that might be an improvement to the
1749 process today, and is something we could work with.

1750 Mr. {Green.} Mr. Sauers, can you share two or three
1751 reasons why you are opposed to requiring the industry provide
1752 a minimum safety data on all new chemicals?

1753 Mr. {Sauers.} It can be a waste of resources. As we
1754 approach a new chemical, we understand the exposure, we
1755 understand the safety testing or the safety evaluation that
1756 is needed. We can tailor the program specifically to the
1757 needs of that chemical. That is the approach that the EPA

1758 uses today as we go forward with them in the PMN process. So
1759 this ability to tailor the safety program to the specific
1760 needs of the chemical is very important. You don't have that
1761 with a minimal set database. Also, the decrease in animal
1762 testing that one gets with the current EPA approach is very
1763 important. If you look at the minimum data set, it is
1764 usually requiring tests like acute oral toxicity tests. I am
1765 not sure who runs those tests anymore. They are really not
1766 necessary to use animals to conduct such a toxicity
1767 evaluation today. There are many other ways of evaluating
1768 acute toxicity using structure activity relationships. So a
1769 lot of testing will be generated that is just not necessary
1770 as part of those minimum data sets.

1771 Mr. {Green.} And I know the EU chemical regimen in your
1772 testimony was lacking science-based chemical prioritization
1773 process. It seems today because of CBI and with the advances
1774 in reverse engineering is it is almost likely that there is
1775 no real secrets that we can deal with, and would you agree
1776 that having such a capacity that is readily available for
1777 chemicals that should make it ineligible for CBI protection
1778 for the industry?

1779 Mr. {Sauers.} I would disagree with that. CBI is very,
1780 very important for companies like Procter and Gamble to
1781 maintain competitiveness. Now with that said, that does not

1782 mean that information is held confidential to the point that
1783 it prevents an agency from evaluating the safety of a
1784 material. You know, there is no CBI for the EPA, for
1785 example. They get all the information and then there is a
1786 generic-type form of the chemical nomenclature that is
1787 released publicly with the health and safety information so
1788 the public can make their own evaluations.

1789 Mr. {Green.} Mr. Chairman, I know you have been great
1790 with the time. I have some other questions I will submit,
1791 but one of them to Ms. White. I represent a very urban
1792 district. We have a lot of chemical facilities, refineries
1793 in a very urban area. A lot of ours--and we probably have
1794 the most monitored air-monitored district in the country,
1795 with lots of different levels from the State, our county, our
1796 city, and of course EPA has some monitoring there, too. I
1797 have some questions I would like to ask on how we can even do
1798 better. We want the jobs and the industry, but we also want
1799 it to be done as safely as we can.

1800 Ms. {White.} Absolutely. Thank you, sir.

1801 Mr. {Green.} Mr. Chairman, thank you for your courtesy.

1802 Dr. {Gingrey.} Absolutely. I thank the gentleman from
1803 Texas.

1804 The minority has asked unanimous consent to include a
1805 letter from the Department of Toxic Substances Control from

1806 the State of California to be included in the record, and
1807 without objection, so ordered.

1808 [The information follows:]

1809 ***** COMMITTEE INSERT *****

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1810 Dr. {Gingrey.} I want to thank all of our five
1811 witnesses. I think this has been an excellent hearing. I
1812 think all would agree. We apologize for the interruptions,
1813 but believe me, if you have been to other hearings you know
1814 that this is mild compared to some of the interruptions that
1815 we have. And we got through with everything we needed to
1816 cover, and I thank all of our witnesses and without
1817 objection, the subcommittee is now adjourned.

1818 [Whereupon, at 11:28 a.m., the subcommittee was
1819 adjourned.]