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6 EXPOSING EPA EFFORTS TO LIMIT CHEMICALS

7 NEEDED FOR LIFE-SAVING MEDICAL DEVICES

8 AND OTHER ESSENTIAL PRODUCTS

9 WEDNESDAY, OCTOBER 18, 2023

10 House of Representatives,

11 Subcommittee on Environment, Manufacturing,

12 and Critical Materials,

13 Committee on Energy and Commerce,

14 Washington, D.C.

15

16

17

18 The subcommittee met, pursuant to call, at 10:30 a.m.,

19 in Room 2322 Rayburn House Office Building, Hon. Bill Johnson

20 [chairman of the subcommittee] presiding.

21

22 Present: Representatives Johnson, Carter, Palmer,

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23 Joyce, Weber, Allen, Balderson, Fulcher, Pfluger, Miller-
24 Meeks, Obernolte, Rodgers (ex officio); Tonko, Sarbanes,
25 Ruiz, Peters, and Pallone (ex officio).
26

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27 Also present: Representative Bucshon.

28

29 Staff present: Kate Arey, Digital Director; Sarah
30 Burke, Deputy Staff Director; Jerry Couri, Deputy Chief
31 Counsel; Sydney Greene, Director of Operations; Nate Hodson,
32 Staff Director; Tara Hupman, Chief Counsel; Daniel Kelly,
33 Press Assistant; Sean Kelly, Press Secretary; Alex Khlopin,
34 Staff Assistant; Peter Kielty, General Counsel; Emily King,
35 Member Services Director; Mary Martin, Chief Counsel; Kaitlyn
36 Peterson, Clerk; Karli Plucker, Director Operations (shared
37 staff); Carla Rafael, Senior Staff Assistant; Emma
38 Schultheis, Staff Assistant; Peter Spencer, Senior
39 Professional Staff Member; Dray Thorne, Director of
40 Information Technology; Hannah Anton, Minority Policy
41 Analyst; Keegan Cardman, Minority Staff Assistant; Waverly
42 Gordon, Minority Deputy Staff Director and General Counsel;
43 Daniel Greene, Minority Professional Staff Member; Tiffany
44 Guarascio, Minority Staff Director; Lisa Hone, Minority Chief
45 Counsel; Joe Orlando, Minority Junior Professional Staff
46 Member; and Cornell Harris, Minority Intern.

47

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48 *Mr. Johnson. The subcommittee will come to order. And
49 before I -- before I begin my opening remarks and we start
50 the formal part of the morning, just so everyone knows,
51 unless there is something that I don't know, we are going to
52 have to recess at around 11:00 for activity -- required
53 activity on the floor for all members, so we are going to try
54 to get through as much of the opening remarks and things that
55 we can this morning before that happens, but just so
56 everybody is aware.

57 But welcome to today's hearing and thank you to my
58 colleagues and our witnesses for being with us. You know,
59 chemicals are the building blocks of America's modern
60 economy. Everything around us in this hearing room, for
61 example, including our clothes, our cellphones, our
62 transportation to get here, all of this is largely made
63 possible because of innovations in the chemical sector.

64 Friends, chemicals, all sorts of chemicals, quite
65 literally make modern life possible. Now I don't take issue
66 with the EPA taking the necessary steps to reduce risk or to
67 regulate responsibly because we need that. But the scope,
68 timing, and breadth of EPA's recent activities gives me
69 pause, especially when the Biden administration constantly

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70 claims to have a robust industrial policy.

71 On the one hand, we see the EPA, the Commerce
72 Department, the White House touting the new next generation
73 semiconductor facilities, the battery plants, electric
74 vehicles. These shiny, new finished products will be made in
75 America, they say. But at the same time, they pull the
76 permits, slow the approvals, and bring their own regulatory
77 hammer down on all the chemicals, and I am talking about the
78 plastics and the critical materials in the supply chain that
79 are needed for the finished products they continuously brag
80 about that they want.

81 We need our chemical regulatory framework to make sense.
82 The dots need to be connected. To give an example, the EPA
83 is working through more than a dozen simultaneous actions
84 that will directly and negatively impact the chemical
85 manufacturing sector.

86 In April 2023 alone, the EPA proposed new source
87 performance standards and national emission standards for the
88 synthetic organic chemical manufacturing industry that
89 condensed six unique rulemakings into one proposal, an
90 advance notice of proposed rulemaking to solicit public input
91 on designated PFAS chemicals as hazardous substances under

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92 CERCLA, and national emissions standards for ethylene oxide,
93 or EtO emissions that would severely threaten patient safety
94 and disrupt our Nation's healthcare system.

95 On EtO specifically, Chair Rodgers and Health Committee
96 -- Subcommittee Chair Guthrie joined me in a letter to the
97 Biden administration raising questions about the impact of
98 EPA's proposal on the availability of sterile medical devices
99 and on patient care. EtO is used to sterilize half of all
100 the medical devices and 95 percent of surgical kits in the
101 United States. I hope that my colleagues on both sides of
102 the aisle with medical backgrounds share my concerns with the
103 potential adverse health impacts of EPA's proposal. On top
104 of medical applications, because chemicals are required to
105 manufacture the vast majority of everyday products, the
106 impact of these rulemakings across the supply chain is
107 staggering.

108 Additionally, EPA's actions contradict its stated desire
109 to follow the best available science. In a recent review of
110 EPA's Integrated Risk Information System, or IRIS, on that
111 work on formaldehyde, the National Academies of Sciences,
112 Engineering, and Medicine emphasized that EPA did not follow
113 specific recommendations for problem formulation and protocol

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114 development. Despite questions around the validity of IRIS's
115 values, the EPA surprisingly continues to use IRIS
116 assessments in all rulemakings.

117 EPA's actions have also been unpredictable because the
118 Agency has failed to meet statutory deadlines under the Toxic
119 Substances Control Act, or TSCA. TSCA Section 5 requires EPA
120 to make a risk determination about a new chemical or a new
121 use of an existing chemical within 90 days, or 180 days if
122 the Agency needs an extension. However, the Government
123 Accountability Office indicated that 90 percent of new
124 chemical applications did not receive a decision from the EPA
125 within the extended 180 days.

126 How are companies supposed to innovate if EPA cannot
127 make a decision in a timely manner? EPA's seeming lack of
128 objectivity and regulating chemical manufacturing, whether
129 for operating permits or risk determinations and management,
130 highlights the need for congressional engagement and the
131 importance of our hearing today. And I look forward to
132 hearing from our witnesses about the practical real-life
133 impacts of EPA's regulatory regime in the chemical sector and
134 the consequences for manufacturing across the board.

135 The Federal Government should wield its authority to

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136 foster innovation, not stifle progress across industries. We
137 all want clean air, clean water, and clean products, but
138 there must be a consideration of the balances of regulating
139 critical life-saving chemical building blocks to the point
140 that we are dependent on even more critical materials from
141 overseas, especially from countries like China.

142 [The prepared statement of Mr. Johnson follows:]

143

144 *****COMMITTEE INSERT*****

145

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146 *Mr. Johnson. With that, I yield back, and the chair
147 now recognizes the ranking member, Mr. Tonko from New York,
148 for his opening statement.

149 *Mr. Tonko. Thank you, Mr. Chair. I appreciate you
150 holding this hearing. I am always supportive of the
151 subcommittee carrying out its responsibility to conduct
152 oversight over the programs within our jurisdiction.

153 However, I feel compelled to mention that as we continue
154 to operate in a speaker-less House, it disrupts and certainly
155 distracts from important work that needs to be done by
156 Congress, so it is delaying the enactment of essential
157 assistance to our allies abroad, for example, and rather than
158 fully funding EPA for Fiscal Year 2024 to ensure that the
159 Agency has the resources and personnel necessary to improve
160 its chemical safety program, we are inching closer to another
161 reckless and unnecessary government shutdown standoff.

162 But with that said, let me turn to the focus of today's
163 hearing before we must recess. And I would like to begin by
164 acknowledging that there certainly are chemicals that play an
165 important role in modern American life. No one here would
166 deny that. I also don't think anyone would suggest that a
167 chemical, no matter how essential it is perceived to be,

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168 should be given a free pass from our environmental laws. No
169 one would defend a chemical being allowed to be produced with
170 unlimited air pollution or disposed of anywhere or in any
171 manner that the producer liked. And no chemical is so
172 important that we shouldn't seek to protect workers and
173 vulnerable people, such as pregnant women and children, with
174 commonsense safeguards to reduce exposure risks.

175 So I hope we can agree that this is really about finding
176 a balance to implement a chemical safety regulatory regime
177 that considers essential needs while also protecting our
178 public health and our environment. And from where I sit, I
179 think it is obvious that we historically have not found that
180 right balance. You need only look at how many millions of
181 American are dealing with the consequences of PFAS in their
182 drinking water, because that is what can happen when we allow
183 dangerous chemicals into commerce without proper
184 consideration for how they will be produced, how they will be
185 used, and how they will be disposed of.

186 I noticed that a couple of the witnesses testimonies
187 mention methylene chloride. It wasn't that long ago that any
188 of us could have gone to a local hardware store and purchased
189 a paint stripper containing methylene chloride, and you know

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190 what happened because of that. Dozens of Americans died
191 including people that did everything right. They took
192 precautions and worked in well-ventilated spaces. I have met
193 with some of their families. I have met with people that
194 have suffered and died from asbestos-related diseases, and I
195 have met with people who connect their rare forms of cancer
196 to PFAS exposures.

197 So I appreciate that the chemical industry does create
198 jobs and that there may be some high-risk chemicals necessary
199 for certain essential uses, but let's not pretend there isn't
200 a cost to a lax chemical safety regulatory regime. And it is
201 not measured in dollars, it is measured more importantly in
202 lives.

203 So, no, I don't believe EPA is overreaching today. The
204 Agency is responding to the reality that for most of our
205 history, including the first 40 years of TSCA, we had a very
206 limited and ineffective chemical safety program. It is long
207 past time to restore a semblance of balance.

208 I know from firsthand experience that the effort to
209 reform TSCA was a hard-fought negotiation, and while I did
210 not support the final legislation at the time, I have never
211 once sought to undermine that agreement. And I would

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212 strongly caution everyone against thinking it would be easy
213 to reopen any portion of those talks without reopening
214 everything.

215 But I do want to see EPA administer an effective and
216 efficient program and I am happy to work across the aisle in
217 good faith efforts to improve these processes provided it
218 does not compromise public health protections. But what I
219 cannot tolerate is a suggestion that we return to a time when
220 corporate bottom lines are held above all other regulatory
221 considerations because I am not convinced that environmental
222 protections are ultimately harmful to our economy or our
223 competitiveness. Setting aside the health benefits,
224 regulations are often catalysts for innovation, driving
225 industry to develop safer alternative chemistries, production
226 methods, and pollution controls that they otherwise would not
227 have been incentivized to pursue.

228 I do want to thank our witnesses for joining us and I
229 look forward to their testimony. And I want to especially
230 express my appreciation to Dr. Woodruff for her efforts to
231 ensure that EPA is using sound science to inform its risk
232 evaluation methods. I thank you.

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

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235 *****COMMITTEE INSERT*****

236

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237 *Mr. Tonko. And thank you again, Mr. Chair, and with
238 that, I yield back.

239 *Mr. Johnson. The gentleman yields back. The chair now
240 recognizes the chair of the full committee, Chair Rodgers,
241 for five minutes for her opening statement.

242 *The Chair. Good morning. Boosting U.S. manufacturing
243 is key to winning the future. For decades, America has been
244 the best place to live, raise a family, and build a business.
245 Historically we have done more than any other country to
246 improve people's lives, thanks in large part to our
247 leadership in everything from healthcare to energy, national
248 security, and technology, all of which rely heavily on
249 chemical manufacturing and its supply chain.

250 That includes medical devices, surgical equipment, heart
251 valves for infants, and drinking water treatments. It
252 includes protective gear for law enforcement and our troops
253 and it is essential for building semiconductors, which are
254 key to securing our competitive edge against countries like
255 China. These products save lives, energy, and advance our
256 standard of living, and they are all currently under threat
257 by the EPA.

258 A recent report found that there is going to be a

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259 decline in the growth rate of the demand for chemical
260 products. According to the report, this decline is the
261 result of both rising competition from China and harmful
262 regulations in the U.S. that are forcing businesses and jobs
263 out of the country. President Biden's systematic shutdown of
264 American industry is increasing our cost of living and
265 forcing us to rely on other countries like China with worse
266 environmental and human rights records.

267 Just as we are seeing with the auto sector, the policies
268 of the Biden administration are weakening American leadership
269 and strengthening China. The EPA is at the center of this
270 regulatory stranglehold. Many of the Agency's recent
271 regulatory actions go far beyond what is reasonable to keep
272 people safe. For example, by delaying evaluations and policy
273 decisions for new and existing chemicals, the EPA is creating
274 expensive uncertainty for businesses and harming innovators.

275 These regulations span multiple laws and raise serious
276 concerns regarding EPA's motives as well as the methods and
277 models used to justify many of its decisions. Like many of
278 my colleagues, I am very concerned, for example, of how the
279 EPA is trying to regulate the chemical used to sterilize
280 approximately half of all medical devices and 95 percent of

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281 all surgical kits in the United States. EPA is taking steps
282 to drastically restrict its use which will significantly
283 disrupt patient access to emergency care and threaten patient
284 safety from hospital-borne infections. The Food and Drug
285 Administration has acknowledged the life-threatening
286 consequences for patients if our healthcare system lacks
287 adequate sterilization. It isn't clear to us that EPA is
288 listening.

289 The reality is many more of EPA's proposed restrictions
290 will create more harm than good. By all measures, America
291 has significantly improved the Nation's air quality and
292 enhanced people's protections from pollution. Our
293 environmental standards are the best in the world.

294 Despite this progress, however, the Biden EPA has moved
295 ahead with these far-reaching regulatory attacks. The longer
296 we continue down this path, the more jobs, innovation, and
297 investment we will force out of the United States leaving in
298 an opening for more products and chemicals to come in from
299 China, the largest polluter in the world with the worst
300 environmental standards. That is putting polluters over
301 people.

302 We should be focusing on how we make our -- make

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303 people's lives better and safer, and I look forward to
304 hearing from our witnesses today who can shed light on how
305 manufacturing has been affected and how these efforts are
306 limiting America's ability to create and produce critical,
307 often life-saving products used every day.

308 [The prepared statement of The Chair follows:]

309

310 *****COMMITTEE INSERT*****

311

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312 *The Chair. I look forward to discussing these issues
313 today, and I yield back.

314 *Mr. Johnson. The gentlelady yields back. I now
315 recognize my friend and the gentleman from New Jersey, the
316 ranking member of the full committee, Mr. Pallone, for his
317 opening statement.

318 *Mr. Pallone. Thank you, Mr. Chairman. It is now six
319 -- it is now Day 16 of the House being paralyzed without a
320 Speaker, and we are 30 days away from another potential
321 government shutdown. This hearing comes at a time when House
322 Republicans' dysfunction is hurting the American people,
323 weakening our economy, and undermining our national security.

324 All year, House Republicans have caved to the extreme
325 elements in their party who have no interest in governing.
326 They have forced cuts to critical federal programs in spite
327 of a funding agreement between the former Speaker and
328 President Biden, and they came close, dangerously close, to a
329 government shutdown that would have cost our national economy
330 upwards of 13 billion dollars a week and forced our troops to
331 work without pay.

332 I just think the American people deserve better.
333 Democrats have repeatedly tried to stop this chaos from

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334 hurting everyday Americans, but it is long past time for
335 House Republicans to reject the extremists in their party.
336 We should be working together to lower costs for American
337 families and to grow our economy in the middle class. It is
338 time for the chaos and the dysfunction to end.

339 Unfortunately, committee Republicans are once again
340 rejecting bipartisanship today in an effort to continue their
341 partisan attacks against the EPA. The Republicans criticized
342 the EPA for simply following the law and fulfilling its
343 mission of protecting Americans' health and the environment.
344 Republicans are simply wrong when they claim that EPA
345 protections hurt jobs and the economy. This is nothing but a
346 false narrative designed to further their polluters over
347 people agenda.

348 And ,in fact, it is just the opposite. History has
349 shown that EPA's protections yield more benefits for
350 Americans than any other agency and its benefits outweigh its
351 cost by more than 13 to 1. EPA has made significant strides
352 in reducing pollution and exposure to toxic contaminants over
353 the last 50 years while our Nation's economy has continued to
354 grow. And yet committee Republicans continue to do the
355 bidding of their polluter friends, even now attacking

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356 environmental laws that they themselves supported.

357 Committee Republicans are attacking the updates we made
358 to the Toxic Substance Control Act, or TSCA, six years ago.
359 The Frank R. Lautenberg Chemical Safety For The 21st Century
360 Act strengthened the 40-year-old law by ensuring that EPA
361 determines -- that EPA determines the chemical is safe before
362 it is put on the market. It also requires that safety
363 determinations be based solely on health and environmental
364 risk and this is common sense and that is why it passed out
365 of this committee and became law with overwhelming bipartisan
366 support.

367 But again, House Republicans are not the same as they
368 were six years ago. Earlier this year they tried to gut
369 these reforms and would once again allow chemicals into the
370 market without a determination of safety, and that's putting
371 American lives at risk. Republicans are also attempting an
372 EPA -- or I should say attacking an EPA proposal to curb
373 ethylene oxide or EtO pollution, a carcinogenic gas used to
374 sterilize products like medical equipment.

375 Workers and residents in the communities around
376 commercial sterilization facilities have tremendously high
377 cancer risk. EPA has worked closely with its federal

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378 partners on this proposal to reduce exposure to EtO while
379 maintaining the integrity of the supply chain, and this will
380 help ensure that patients and providers have continued access
381 to the sterile devices they need. But again, these
382 Republican attacks are putting the lives of more than 14
383 million people at risk. These people live within 5 miles of
384 an EtO-emitting facility and are at risk of various cancers
385 of the blood and breast cancer.

386 And Republicans also want to undercut protections to
387 expedite review of PFAS, which would allow potential
388 dangerous chemicals into the homes of millions of Americans.
389 It stands in stark contrast to the PFAS Action Act that the
390 House passed last Congress under Democratic leadership which
391 would have protected our air, land, and water from harmful
392 PFAS contamination. So it is bad enough that Republicans are
393 trying to undermine public health and environmental
394 protection at every turn, but they have also proposed
395 dangerous cuts to EPA funding that helps the Agency carry out
396 these vital programs.

397 So today, EPA is providing a robust federal framework to
398 review and appropriately control potentially dangerous
399 chemicals, to prevent harmful exposures, and protect the

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400 environment. These protections are helping to drive
401 innovation, grow our economy, and protect public health all
402 at the same time. It is time for Republicans to stop pushing
403 the industry line and work with Democrats to start supporting
404 safeguards that benefit all Americans.

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

406

407 *****COMMITTEE INSERT*****

408

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409 *Mr. Pallone. And with that, Mr. Chairman, I yield back
410 the balance of my time.

411 *Mr. Johnson. The gentleman yields back. And now our
412 witnesses for today. We have Mr. Peter Huntsman, President
413 and CEO of the Huntsman Corporation. Thank you, sir, for
414 being here.

415 Mr. Scott Whitaker, President and CEO of the Advanced
416 Medical Technology Association. Thank you, sir.

417 Ms. Tracey Woodruff, Professor and Director for the
418 Program on Reproductive Health and the Environment at the
419 University of California San Francisco. Ms. Woodruff, thank
420 you for being here.

421 And Mr. Chris Jahn, President and CEO of the American
422 Chemistry Council.

423 Mr. Huntsman, you are now recognized for five minutes
424 for your opening comment.

425

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426 STATEMENT OF PETER HUNTSMAN, PRESIDENT AND CEO, HUNTSMAN
427 CORPORATION; SCOTT WHITAKER, PRESIDENT AND CEO, ADVANCED
428 MEDICAL TECHNOLOGY ASSOCIATION; TRACEY WOODRUFF, PHD, MPH,
429 UCSF PROGRAM ON REPRODUCTIVE HEALTH AND THE ENVIRONMENT; AND
430 CHRIS JAHN, PRESIDENT AND CEO, AMERICAN CHEMISTRY COUNCIL

431

432 STATEMENT OF PETER HUNTSMAN

433

434 *Mr. Huntsman. Thank you very much, Mr. Chairman.
435 Members of the committee, thank you for the opportunity to
436 testify on regulation of the American chemical sector.

437 I am here to share my observations on policy, political,
438 business, and cultural forces that I believe present imminent
439 risk to the American chemical sector. If there is one
440 conclusion I want members of this committee to come away with
441 from my testimony, it is this: American prosperity, security,
442 and power are entirely dependent on a strong, thriving, and
443 properly regulated chemical sector. Without it, our way of
444 life is not possible. That is not hyperbole, it is physical,
445 mutable reality.

446 1937, my father's life began in an Idaho home with no
447 running water. By the end of his life in 2018, he had built

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448 a global chemical company with billions of dollars in revenue
449 and dozens of operations in multiple countries, tens of
450 thousands of employees. He donated his life's work to endow
451 the Huntsman Cancer Institute as well as other causes dealing
452 with homelessness, mental health, and education. His was a
453 story that could only happen in America.

454 After dropping out of college, I started my career in
455 1983 as a truck driver. Over 40 years I have witnessed the
456 boom and bust business cycles, mergers and acquisitions,
457 multiple iterations of peak oil, the collapse of the Soviet
458 Union, the unification of Europe, the rise of China, the
459 creation of the internet, and the transformational impact of
460 hydraulic fracturing, among others.

461 I have also observed the policy and regulatory
462 environment around the chemical sector ebb and flow across
463 Democrat and Republican administrations and Congress. Our
464 company in the chemical industry has played a role in all of
465 it.

466 In the chemical industry, we take atoms and molecules,
467 break them apart and put them back together to make the
468 building blocks of virtually everything we see and touch in
469 modern life. Automobiles, airplanes, smartphones, homes,

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470 buildings, pharmaceuticals, wind turbines, EV batteries,
471 solar panels, clothing, cosmetics, shoes, clean drinking
472 water, and crop fertilizers, just to name a few. Pretty much
473 everything.

474 The most utilized starting atoms or feedstock for
475 chemical manufacturing are hydrocarbons derived from
476 petroleum, natural gas, natural gas liquids, otherwise known
477 as fossil fuels. Without abundant access to fossil fuel
478 feedstocks, we cannot manufacture chemicals. I am
479 increasingly concerned that many government and business
480 leaders lack an understanding of how things are made.

481 I believe the main reason for this is because in the
482 post-Cold War era of globalization, the United States
483 underwent a form of deindustrialization and outsourced our
484 manufacturing. Wall Street and Silicon Valley became the
485 centers of gravity in America. Making things went out of
486 vogue. This manufacturing exodus led people to forget how
487 things are made in the most basic molecular level. When I
488 look at an iPhone, I see a device consisting of minerals and
489 elements extracted from Earth and refined thousands of times
490 over into chemicals, plastics, glass, and other materials.
491 The same is true for millions of other products that we use

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492 in our daily lives.

493 One of the biggest threats to the American way of life
494 is the belief that we can choose not to develop our natural
495 resources. Until the advent of new technology and a massive
496 expansion in nuclear power, the idea that American society
497 can simply transition away from fossil fuels and chemicals
498 and somehow maintain our way of life I believe is both naïve
499 and dangerous. This is not physically possible. Serious
500 countries and people understand this reality.

501 The goal of government in business is reduce greenhouse
502 gas emissions across society. Policy and regulation should
503 be calibrated to increase natural resource extraction and
504 chemical manufacturing more efficiently and productively. It
505 is the chemical sector that leads the molecules that allows
506 individuals and society collectively to lower their
507 emissions. The United States, with its combination of
508 freedom, capitalism, scientific inquiry, deep capital
509 markets, legal protection, and entrepreneurial spirit possess
510 the power to solve humanity's problems.

511 As the geopolitical tides turn and countries reassess
512 their priorities in a more dangerous world, decisions around
513 natural resources, energy, chemicals, and material innovation

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514 will return to the forefront for governments and businesses.
515 This is not the time to further outsource our energy and
516 manufacturing capabilities. History shows that such policy
517 decisions determine the fate of nations and societies.

518 I look forward to your questions. Thank you very much.

519 [The prepared statement of Mr. Huntsman follows:]

520

521 *****COMMITTEE INSERT*****

522

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523 *Mr. Johnson. Thank you, Mr. Huntsman.

524 Mr. Whitaker, you are now recognized for five minutes

525 opening comment.

526

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527 STATEMENT OF SCOTT WHITAKER

528

529 *Mr. Whitaker. Chairman Johnson, and Ranking Member
530 Tonko, and all members of the committee, thank you for the
531 opportunity to testify before this committee on such an
532 important matter.

533 I am Scott Whitaker. I am the President and CEO of
534 AdvaMed, it is the med tech association, and we represent 450
535 medical technology companies from the smallest startups to
536 the mid-size companies to the largest global medical
537 manufacturers as well, all of which serve patients in every
538 healthcare setting with lifesaving and life-enhancing medical
539 technologies.

540 Half of all medical devices produced every year in the
541 United States are sterilized with ethylene oxide. That is
542 approximately 20 billion devices. And we accomplish all of
543 that while using less than half of one percent of all
544 ethylene oxide used commercially in the United States.

545 The list of critical everyday medical equipment that
546 relies solely on this sterilization method is long. Surgical
547 kits with instruments such as scopes, and clamps, and
548 scalpels, and tubings, and scalpers, all the tools necessary

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549 to conduct a surgery. Heart valves, pacemakers, respirators,
550 IV sets, endoscopes, kidney dialysis instruments, continuous
551 glucose monitors, and insulin infusion kits, all are
552 sterilized with ethylene oxide and regulated by the FDA.

553 The FDA has been clear that it is concerned about the
554 availability of these 20 billion medical devices if the EPA's
555 proposed rules are not done right. On March 15th, the FDA
556 wrote, without EtO, there would be a significant
557 sterilization shortfall with no commensurate sterilization
558 alternative available, saying those shortfalls of a variety
559 of critical medical devices would be imminent. These
560 disruptions, they say, stemming from a lack of EtO, would
561 have significant impacts on patient health, access, and
562 critical medical devices. That's their quote.

563 Safe ethylene oxide usage by commercial sterilizers has
564 been regulated by the EPA for decades. We follow all federal
565 and state requirements, and we have made it clear that we
566 welcome updated regulations. Afterall, our industry's
567 commitment to saving and improving lives does not end where
568 sterilization begins.

569 It bears repeating, we welcome updated rules. But it is
570 absolutely critical that the regulations be done right.

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571 Sterilization is currently at capacity and no new EtO
572 sterilization facilities are currently under construction in
573 the United States. Our industry is and has been working to
574 develop new sterilization methods. However, they do not
575 currently exist at the scale or the effectiveness of EtO, and
576 FDA agrees.

577 The reality is according to a gap analysis of our
578 industry, if EPA's proposed rules are finalized as written,
579 the U.S. could face a 30 to 50 percent reduction in medical
580 devices available to patients today. This would have a
581 disastrous effect on patient care because 95 percent of all
582 surgical instruments are sterilized with EtO. Virtually
583 every patient awaiting surgeries could be impacted. C-
584 sections, heart valve repairs, open heart surgeries, hip
585 replacements, knee replacements, brain surgeries, cancer
586 biopsies, the list could go on and on. All could be
587 disrupted.

588 The FDA has been very clear, and we agree with the FDA,
589 we simply cannot afford this risk. The EPA's mandate to
590 protect the public is critical, which is why we have
591 approached the EPA as partners not as adversaries. For the
592 rules to be updated in a way that continues to protect

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593 surrounding communities and ensures medical device
594 availability, we are seeking a series of changes which we
595 have outlined in our public comments to the EPA. We remain
596 hopeful that the EPA will take them to heart.

597 Finally, let me say in closing a quick word about PFAS
598 as it relates to and will be discussed later today. It is
599 hard to imagine the medical industry without many important
600 products that contain fluoropolymers. CPAP machines,
601 prosthetics, IV bags, surgical instruments, as I mentioned
602 earlier, and many other medical technologies contain PFAS.
603 These medical devices are critical to the treatment and the
604 health of all Americans. Much like the regulations on EtO,
605 it is essential that any regulation on PFAS takes into
606 account the manufacturing and the availability of essential
607 medical devices.

608 When it comes to the regulatory process, congressional
609 oversight is vital. Hearings such as this are important to
610 make sure regulations meet their intent and do not harm the
611 patients and the innovators who will be impacted by them.

612 So with that, Mr. Chairman, thank you again for inviting
613 me to testify on this critical, important public health
614 issue.

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615 [The prepared statement of Mr. Whitaker follows:]

616

617 *****COMMITTEE INSERT*****

618

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619 *Mr. Johnson. Thank you, Mr. Whitaker.

620 Ms. Woodruff and Mr. Jahn, unfortunately we are not
621 going to get to you until after the recess. We have no
622 choice. We are due down on the floor.

623 We will now recess for floor activity. The subcommittee
624 will stand in recess subject to the call of the chair.

625 [Recess.]

626 *Mr. Johnson. The committee will come to order and we
627 will now resume with witness testimony.

628 Dr. Woodruff, you are recognized for your five minutes.
629 And let me reassure, Dr. Woodruff and Mr. Jahn, your
630 testimony will be a part of the record in spite of the fact
631 that we are -- we still have members coming back, but I want
632 to be respectful of your time that you have given us today,
633 so we are not going to delay any longer. So if you would --
634 Dr. Woodruff, you are recognized for five minutes.

635

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636 STATEMENT OF TRACEY WOODRUFF

637

638 *Dr. Woodruff. All right, thank you. Chairman Rodgers,
639 Chairman Johnson, and Ranking Members Pallone and Tonko,
640 thank you for the opportunity to testify.

641 I am Dr. Tracey Woodruff, a professor from the
642 University of California San Francisco and Director of the
643 Program on Reproductive Health and the Environment. We
644 conduct research to understand how industrial chemicals and
645 environmental pollutants impact people's health.

646 Toxic chemicals are widespread in our air, water, food,
647 homes, and workplaces, and consequently, exposures begin
648 before birth and continue throughout life. We know these
649 exposures take a measurable toll on people's health and can
650 increase the risk of cancer, infertility, asthma,
651 neurological disease, cardiovascular disease, and multiple
652 adverse child -- impacts on child development.

653 Environmental regulations came about from necessity.
654 Before EPA was established and laws including the Clean Air
655 Act and the Clean Air Act -- Water Act were enacted, toxic
656 waste and chemicals were literally dumped into our air and
657 water unchecked. Pictures of cities like New York and

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658 Pittsburgh before and after the 1970s show a stark
659 improvement.

660 Here is the very good news. Environmental regulations
661 and clean environment are good for people's health and the
662 economy. Since 1970, environmental regulations led to a 78
663 percent decrease in six different air pollutants while at the
664 same time RGDP increased 304 percent. The success is due to
665 both environmental regulations and American innovators.

666 Environmental regulations are innovation generators
667 resulting in new businesses, new jobs, and new products safer
668 for consumers, workers, and communities. EPA regulated
669 formaldehyde and pressed-wood products after it was
670 discovered formaldehyde was harming people living in trailers
671 after Hurricane Katrina. The manufacturing of formaldehyde-
672 free pressed-wood products increased the soy-based adhesive
673 industry, which has manufacturers in the U.S., is predicted
674 to grow almost eight percent a year, which is also
675 economically beneficial to U.S. soybean farmers.

676 Environmental regulations also produce enormous societal
677 benefits from reduced health problems. OMB reported that
678 over a ten-year span, the annual benefits to the American
679 public of EPA major rules ranged from 194 billion to 687

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680 billion dollars per year, almost all from reduced health
681 risks due to lowered pollutant emissions and it far
682 outweighed the estimated costs.

683 As another example, EPA's recent proposed drinking water
684 regulations for six PFAS would provide health benefits as
685 high as two billion dollars a year and represents an
686 important step forward in addressing the health risks of
687 these forever chemicals. In a recent nationwide public
688 opinion survey, over 90 percent of voters, including
689 Republicans, Democrats, and Independents, agreed the Federal
690 Government should require products to be proven safe before
691 companies are allowed to put them on the market, and it is
692 important for companies to keep harmful chemicals out of
693 everyday products, even if it increased costs.

694 Congress updated the Toxic Substances Control Act, or
695 TSCA, in 2016 to ensure EPA did a better job of protecting
696 susceptible populations like pregnant women, children,
697 workers, and people living in proximity to clusters of
698 polluting facilities from harmful chemicals. But because our
699 system to regulate toxic chemicals has allowed companies to
700 put products into the marketplace before we are sure they are
701 safe, and allowed companies to release known toxic chemicals

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702 into the environment, we continue to see problems like
703 widespread PFAS contamination crisis and fence-line community
704 exposures to dangerous levels of carcinogens like ethylene
705 oxide.

706 In 2016 after extensive external peer review and public
707 comment, EPA concluded ethylene oxide inhalation is
708 carcinogenic to humans. Studies also find ethylene oxide
709 associated with neurological, respiratory, and reproductive
710 harm. Multiple communities in the U.S., often low-income and
711 communities of color, are exposed to dangerous levels of
712 ethylene oxide from sterilization facilities. The EPA now
713 has an opportunity to significantly reduce exposures to
714 cancer-causing EtO by issuing a necessary update to its
715 emissions standards for sterilization facilities.

716 I know you have witnesses here today representing
717 industries concerned about the regulation of EtO and other
718 chemicals, and it is important to hear from all affected
719 stakeholders. However, it is also critical we prioritize
720 health in environmental regulations and use science free of
721 financial conflicts and interests who are biased towards the
722 industries that may have a vested financial interest in
723 minimizing EPA's regulations.

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724 I encourage you to read our recent paper, *The Devil We*
725 *Know*, which analyzes internal industry documents from PFAS
726 manufacturers and show the industry knew about health harms
727 decades before the public. This is an example of how it is
728 important that financial interests be made transparent and
729 demonstrates why it is essential to have a strong EPA using
730 the best scientific methods to help protect people and
731 communities from the impact of harmful chemicals which in
732 turn ensures a strong economy.

733 Thank you.

734

735

736 [The prepared statement of Dr. Woodruff follows:]

737

738 *****COMMITTEE INSERT*****

739

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

740 *Mr. Johnson. The gentlelady yields back.

741 Now the chair recognizes Mr. Jahn for five minutes of

742 testimony.

743

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744 STATEMENT OF CHRIS JAHN

745

746 *Mr. Jahn. Thank you, Mr. Chairman, Ranking Member
747 Tonko, members of the subcommittee. We appreciate you
748 holding this important hearing today examining the impact of
749 regulations on the chemical sector and the opportunity to
750 discuss the vital role that chemistry plays in improving our
751 quality of life.

752 Today's hearing is coming at a time of unprecedented
753 regulatory activity, so Congress must be actively involved to
754 make sure that regulations are built on a sound foundation
755 and deliver demonstrable benefits. Equally important is
756 helping the Biden administration see the big picture and
757 understand that regulations should not work against national
758 priorities, including the manufacturing economy.

759 You can see the products that we enable simply by
760 looking around this room. Everything starts with
761 manufacturing and chemistry. Your clothes, your phone, the
762 chair you are sitting in, everything. The products of
763 American chemistry support about 25 percent of USGDP, provide
764 good-paying jobs to over a half-a-million Americans, and four
765 more million Americans rely on our industry to support their

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766 own jobs.

767 Today our industry is innovating to manufacture crucial
768 ingredients, producing semiconductors, automotive parts,
769 lifesaving healthcare devices, building and construction
770 materials, all critical components of modern life. The world
771 is counting on us to create solutions for a safer, healthier
772 future for generations to come. So if there is anything that
773 you take away from my testimony today, it is that American
774 success relies on American chemistry.

775 But we need to get the right policy environment for that
776 to happen. And, unfortunately, recent regulatory actions by
777 the Biden administration stand in the way of that success.
778 And to be clear, this is not personal, it is about far more
779 than chemical regulations under TSCA, it is across the board,
780 it is air, water, climate, plastics, and more. In fact, we
781 have identified more than a dozen proposals specifically
782 targeting the chemical industry that impose a collective cost
783 to the U.S. economy of over seven billion dollars per year
784 using the Federal Government's own numbers.

785 The mounting regulatory challenges we face jeopardizes
786 America's economy and our ability to compete with countries
787 like China. The heavy-handed approach the administration is

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788 taking will disrupt the supply chain for critical
789 technologies and everyday products.

790 Recently, ACC launched an initiative focused at making
791 sure the Biden administration and Congress understand just
792 how vital our industry is to the manufacturing supply chain
793 and achieving a range of national priorities. We call it
794 Chemistry Creates, America Competes. Chemistry creates jobs,
795 chemistry creates innovations, chemistry creates the products
796 and solutions that America needs, and if we allow chemistry
797 to create, then America competes and America will win.

798 Now let me be clear, I think this is really important,
799 the chemical industry supports responsible regulation. It
800 needs to be driven by science, it needs to promote
801 innovation, and it needs to support supply chain resiliency.
802 However, a growing number of proposed federal regulations do
803 not meet these criteria.

804 The administration, and specifically EPA, must put
805 science first and develop regulations that protect health in
806 the environment without killing innovation, weakening supply
807 chain resiliency, and sending jobs to countries like China.
808 For instance, the new chemical program at EPA is hampering
809 innovation. There are 411 chemicals under review at EPA

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810 right now, 88 percent of which are behind their statutory
811 deadline.

812 As a result, more than 70 percent of our members are
813 looking at bringing new chemistries to market outside of the
814 United States. This is a direct example of regulations
815 undercutting American innovation and competitiveness.
816 Congressional oversight is needed to examine how proposed EPA
817 regulations on the chemical sector will cut off access to
818 products and technologies needed to support American
819 manufacturing. Today's hearing is a good first step in this
820 direction.

821 We also urge Congress to consider legislation to improve
822 the regulatory process, streamline permits, replace overly
823 conservative regulations with flexible, smart, science-based
824 policy approaches. We must work together to find a more
825 thoughtful way to regulate our industry that does not
826 sacrifice America's competitive advantage.

827 So I will close with a cautionary tale. I recently
828 spent time in Europe meeting my counterparts, and I saw
829 firsthand the ultimate impact of poor policy choices. Once a
830 manufacturing powerhouse, Europe's share of worldwide
831 chemical production is half of what it was two decades ago.

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832 We are witnessing the deindustrialization of Europe across
833 most manufacturing sectors. This is a direct result of ill-
834 conceived regulations and energy policies. The consequences
835 are fewer jobs, less innovation, and higher prices.

836 Please do not let America fall into that trap. And
837 remember that American success relies on American chemistry.
838 Thank you.

839 [The prepared statement of Mr. Jahn follows:]

840

841 *****COMMITTEE INSERT*****

842

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843 *Mr. Johnson. Thank you, Mr. Jahn, and thank you
844 witnesses for your testimony.

845 We will now begin the question session and the chair
846 recognizes himself for five minutes to begin questioning.

847 You know, we want technology made in America under the
848 strongest environmental and labor standards that not only
849 protect the environment but that also protect our energy
850 security and our ability to be mobile and live our everyday
851 lives. Yet we have government policies that discourage the
852 essential steps to accomplish those goals.

853 And I will point out and reiterate what Mr. Jahn just
854 said. 88 percent of the requests for chemical permits before
855 the EPA have exceeded their statutory authority, the limit,
856 the law, the statutory limit. Why do they think they are
857 above the law? I don't know.

858 In Ohio, we are proud of a major effort to build a
859 semiconductor facility to manufacture the next generation
860 microchip technology in our state. This facility needs one
861 specific chemical to be able to make and etch these chips and
862 only one plant outside of Asia could supply this factory with
863 that material, a U.S. company with chemical manufacturing in
864 a nearby state. However, EPA is slow-walking a permit for

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865 the plant's expansion necessary to supply the semiconductor
866 facility with this vital ingredient.

867 So, Mr. Jahn, are situations like this unique for the
868 chemical industry? Between permitting issues and EPA's
869 mismanagement of the TSCA program for new chemicals, is there
870 a serious risk of your members offshoring chemical
871 manufacturing to other countries?

872 *Mr. Jahn. Unfortunately, that situation occurs all too
873 often. In the situation you cited, it took tremendous
874 political pressure from both sides of the aisle, organized
875 labor to get EPA to make the right decision at the 11th hour.
876 The problem is we are not able to do that for all of the
877 permits, for all of the facilities, for all the chemistries
878 that we manufacture, it is just not practical. So they need
879 to take a smarter approach.

880 And specifically in the new chemicals programs, as you
881 said, we have got nearly three-quarters of our members who
882 are saying, look, if we can't get a decision in a timely
883 fashion, we are going to have to take those chemistries
884 elsewhere.

885 *Mr. Johnson. Okay.

886 *Mr. Jahn. We have a member last week who told us that

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887 EPA told them it would be at least six to 12 months. On
888 average, it is about 700 days to get a decision.

889 *Mr. Johnson. What would the supply chain impacts be of
890 allowing chemical production to occur outside of the United
891 States on a large scale?

892 *Mr. Jahn. So the United States is the second biggest
893 chemical producer in the world. China is by far, it is three
894 times bigger than the United States. But it is a globally
895 competitive market, so if we are not able to innovate, that
896 innovation will go somewhere else, most likely China or other
897 chemical producing countries, and we will lose the ability to
898 control our supply chain.

899 *Mr. Johnson. And that is creating jobs over there
900 and --

901 *Mr. Jahn. Correct.

902 *Mr. Johnson. -- it is making us more dependent on
903 them.

904 *Mr. Jahn. Correct. If we have learned anything from
905 the pandemic is that we need to regain control of our
906 manufacturing supply chain, and the fact that if we want to
907 continue to innovate and lead the world on some of the
908 things, semiconductors is one example, there are plenty of

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909 others, that we need to move quickly and that the issue --
910 the decisions that EPA makes has broad implications for that.

911 *Mr. Johnson. Okay. Would you -- Mr. Jahn, would you
912 consider EPA's recently proposed regulations to be
913 reasonable, I mean, are they balanced?

914 *Mr. Jahn. We are concerned that they are not balanced
915 in the -- from the standpoint of when you look at the
916 scientific evidence that they are choosing to either ban or
917 have de facto bans on chemistries because they set the levels
918 so low for those chemistries.

919 So just to give you an example, there is a list of at
920 least six chemistries right now pending before EPA where they
921 are lower than the lowest levels of anywhere else on Earth,
922 somewhere between two and 438 times, depending on the
923 chemistry.

924 *Mr. Johnson. Okay. So will the domestic chemical
925 industry be able to innovate and compete globally our
926 American market and keep jobs in America if these EPA rules
927 continue in their unbalanced state that they are in?

928 *Mr. Jahn. It will be incredibly difficult to continue
929 to invest here. There is a lot of decisions that go into
930 making that investment. But the fact is we are one of the

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931 leaders in the world and we cannot fumble this opportunity
932 because of regulatory overreach taking place at EPA.

933 *Mr. Johnson. I am sorry for rushing you, but are your
934 members looking -- are you hearing from your members that
935 some are looking to move overseas for manufacturing?

936 *Mr. Jahn. Our members are gravely concerned about the
937 regulatory environment --

938 *Mr. Johnson. All right.

939 *Mr. Jahn. -- and where they make investment decisions
940 going forward.

941 *Mr. Johnson. Well, Mr. Jahn, Mr. Huntsman, and Mr.
942 Whitaker, take this -- my time has expired so I am going to
943 let you take this one and if you would get back to me. The
944 lack of critical manufacturing and supply chains in the
945 United States is of a huge concern today. Why doesn't simply
946 throwing money at this problem work and what is the real
947 world impact of duplicative, overly burdensome, or
948 overlapping regulations? If you would take that question and
949 get back to us, I would appreciate it, and if you need -- if
950 you need us to forward it to you, we will do that, too.

951 I yield, and now I recognize the ranking member for five
952 minutes for his questions.

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953 *Mr. Tonko. Thank you to our chair and thank you again
954 to our witnesses for your testimony.

955 We know that PFAS exposure is connected to devastating
956 health consequences. So, Dr. Woodruff, could -- can you
957 share with us any thoughts about the health effects of PFAS
958 exposure?

959 *Dr. Woodruff. Yes. Perfluorinated chemicals,
960 perfluoroalkyl substances which you are talking about,
961 comprises a class of 12,000 chemicals. The most famous ones
962 are PFOA and PFAS, along with six other ones. And we know
963 from --both from many scientific studies published and a
964 review of those studies by the National Academy of Sciences
965 as well as other evidence-based reviews that PFAS can
966 increase the risk of a number of different health outcomes
967 including lower birth weight babies, cancer risk,
968 cardiovascular risk due to cholesterol changes, and thyroid
969 problems as well as effects on the immune system. And those
970 are the health effects that we know about.

971 I just want to comment that it is really hard to know
972 about all the health effects of chemicals because the
973 industry is not required for chemicals that are already
974 existing on the marketplace to give information to the

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975 government on a complete set of data for us to understand
976 what the potential health effects from these chemicals are,
977 which would include all the 12,000 -- many of the PFAS that
978 were already on the market starting in 1976.

979 So when EPA regulated -- has proposed regulation for six
980 of the PFAS in drinking water, it turns out that we will
981 save, as I mentioned, two billions dollars a year just from
982 reduced cardiovascular risk, increased birth weight among
983 infants that are born in the United States, which also will
984 reduce infant mortalities across the United States. And as
985 you know, millions of Americans live with contaminated PFAS
986 water systems, so it is really important that we understand
987 -- that we know -- to act on the information that we have now
988 about the PFAS and continue to focus on the activities that
989 the Biden administration is doing to address the remaining
990 thousands of PFAS that are still in use.

991 *Mr. Tonko. Thank you. And you mentioned the six PFAS
992 chemicals that are in drinking water that they are currently
993 examining at the EPA. You talk about the economic benefits
994 outweighing the costs. How has EPA sought to quantify those
995 benefits in this and other rules?

996 *Dr. Woodruff. Yeah, so EPA will use scientific

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997 methods. They both use an evidence-based method, the -- so
998 under the Toxic Substances Control Act, and actually in the
999 IRIS Program they are required to use a more rigorous method
1000 for evaluating the science which is called systematic
1001 reviews, and they look at all the evidence and then they
1002 characterize the relationship between the exposures and the
1003 health response, and they use that information to quantify
1004 the number of cases.

1005 However, currently EPA's approach only is applied to
1006 chemicals that result in cancer. So, for example, PFAS --
1007 and in some cases where they have human evidence, they also
1008 look at -- quantify the relationship between those exposures
1009 and health outcomes. So for PFAS, they were able to do
1010 cardiovascular health effects as well as effects on birth
1011 weight in infants.

1012 However, for the vast majority of chemicals that EPA is
1013 regulating and for those that are currently under risk
1014 management proposed rulemakings under TSCA, EPA does not --
1015 is not using the most up-to-date methods to quantify the
1016 risks for health effects that are not cancer, so that can
1017 include neurological effects, so like similar to what might
1018 be seen in Parkinson's patients, adverse effects on the liver

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1019 like fatty acid type effects which include precursors to non-
1020 alcoholic fatty liver disease and liver toxicity.

1021 There are methods that EPA can use to quantify those
1022 health effects that have been developed by WHO, and we have
1023 shown that unfortunately since -- under the proposed
1024 rulemakings for the risk management rules that EPA has
1025 proposed, that the current levels that they are going to
1026 allow in occupational settings could result in up to one in
1027 200 risk levels. So there will be health effects to those
1028 occupational exposures.

1029 And, finally, so EPA can do this. It is completely
1030 possible. Though I would acknowledge that the agency is
1031 highly under-resourced and so it is very difficult to do all
1032 the many requirements that are legally required under many --
1033 the legal requirements of the laws passed by Congress in
1034 order to do all the many things like do the new chemicals
1035 programs, do all the permitting, do all the cleanups, because
1036 it takes a lot of people because they have such an enormous
1037 responsibility for protecting the public's health, and that
1038 is why resourcing EPA would help and research on these
1039 chemicals would help improve our ability to identify and
1040 switch to safer alternatives.

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1041 *Mr. Tonko. Well, I think you for that, and I do hear
1042 staffing is a concern and they are working on that. But I
1043 encourage the Agency to use the best available science and
1044 full understanding of the benefits of its proposed rules as
1045 it works toward protecting American's health and their
1046 environment.

1047 So with that, Mr. Chair, I yield back.

1048 *Mr. Johnson. The gentleman yields back. The chair now
1049 recognizes the gentleman from Georgia, Mr. Carter, for five
1050 minutes.

1051 *Mr. Carter. Thank you. And thank you all for being
1052 here and I apologize for the delays. It is beyond our
1053 control, but I appreciate your patience, your persistence.

1054 I have had the opportunity twice this year to travel to
1055 Houston to meet with a lot of the energy companies and
1056 obviously Energy and Commerce Committee. And, Mr. Huntsman,
1057 I had the opportunity earlier this year to meet with you, and
1058 I appreciate that. A very good conversation, very
1059 educational, and helped me a lot in understanding.

1060 But the one overriding thing that I keep hearing from
1061 all the companies is the permitting. Permitting. It is just
1062 crushing us, crushing us. But it is not just the

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1063 restrictions and the overregulation that I see from the EPA.
1064 I mean, it looks like EPA is just playing by their own rules,
1065 and they set them up as they want just to get the decision
1066 that they like, and that is not the way this was set up by
1067 Congress.

1068 And, for instance, I understand -- and, Mr. Jahn, I
1069 believe you mentioned this that the EPA is missing
1070 congressionally-mandated deadlines to review and approve
1071 chemicals, and it has gotten so bad that even the
1072 environmental groups are complaining about it. I mean, it is
1073 ridiculous what is going on here.

1074 Let me start with you, Mr. Huntsman, and ask you, you --
1075 I know you make decisions about where to locate and what to
1076 build based on permitting environments and as well as stable
1077 and predictable compliance regimes. What lessons would a
1078 company like yours learn about building in America when you
1079 see, and I don't use this word lightly, I think it is
1080 accurate, when you see nothing less than hostility, the -- in
1081 both permitting and regulations to your plants, to your
1082 feedstocks, and to your products?

1083 *Mr. Huntsman. Well, thank you very much for the
1084 question. And you are always welcome to come to Texas.

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1085 Two things. First of all, just the building and the
1086 permitting time when you have people like Mayor Bloomberg who
1087 is spending hundreds of millions of his own dollars to get
1088 "beyond petrochemicals," that somehow we are going to go
1089 back and live in a world of caves or something like that.
1090 That it is going to take the litigious and the delays of just
1091 building a new technology, bringing a new technology to
1092 market can take years and years.

1093 It is ironic that we are sitting here talking about PFAS
1094 because if I wanted to make a replacement product -- now
1095 think about this, and I agree with much of what you said,
1096 Congressman Tonko, and Dr. Woodruff as well. If I wanted to
1097 make an alteration to PFAS, that is actually easier to make
1098 an alteration with PFAS chemistry using existing technologies
1099 to the EPA than if I were to come up with a completely new
1100 innovative idea. I probably would be waiting multiple years
1101 versus just a year or two. Three to five years on some of
1102 that.

1103 Why on earth would I invest in something today that I am
1104 not even sure is going to be able to hit the market for years
1105 and years. If I want to replace a PFAS technology, I am
1106 actually disincentivized to use new technology. I am

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1107 actually disincentivized to build a new facility.

1108 I can go to China and build that facility in two years,
1109 get it permitted, built, probably financed, and have it
1110 running off of coal-based electricity. And that is what we
1111 are up against right now when we talk about returning money
1112 to shareholders.

1113 *Mr. Carter. Well, that was my next question I wanted
1114 to ask you, as well as you, Mr. Jahn, because you mentioned
1115 it in your testimony as well. If people really want to
1116 reshore American manufacturing, and I can assure we want to,
1117 we want to make sure that we are reshoring American
1118 manufacturing. But if you wanted to do that and you wanted
1119 to create any actual domestic supply chain, Mr. Jahn, as you
1120 pointed out we need to do that, we did indeed learn that
1121 lesson during the pandemic, what needs to happen? What needs
1122 -- and, Mr. Huntsman, you just mentioned some of it right
1123 there. But what needs to happen to make companies like yours
1124 willing to move back or to stay here in America?

1125 *Mr. Huntsman. Well, I can answer that very briefly.
1126 It really is about rewarding innovation. You look at
1127 something as simple as this water bottle. This water bottle
1128 10 years ago took enough plastic to probably produce 10 water

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1129 bottles today. And that is about innovation, it is about
1130 reducing resources. This is very profitable to make
1131 something like that because you are reducing raw materials,
1132 and it is also better for the environment.

1133 This is also raw material for our company. We consume
1134 nearly two billion of these bottles as a raw material for a
1135 polyurethane foam to insulate houses. So this is both the
1136 raw material, it is technology, it is innovation. We need to
1137 be rewarding and we need to be -- we don't -- we are not
1138 asking for government help, just --

1139 *Mr. Carter. Great.

1140 *Mr. Huntsman. -- stay out of the way on some of these
1141 things.

1142 *Mr. Carter. Great. Mr. Jahn, do you want to take a
1143 stab at that?

1144 *Mr. Jahn. Sure. So, again, you look at the new
1145 chemicals program. We have got a member company that has got
1146 a chemistry pending at EPA for five years that goes into
1147 electric vehicle batteries. And so, again, we have to reward
1148 innovation so the investment here in the United States to
1149 achieve our national priority goals. So I think what our
1150 members are looking for overall is regulatory certainty. If

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1151 the process works the way it's supposed to work and its done
1152 on time.

1153 *Mr. Carter. Great. Well, again, thank all of you for
1154 being here. This is extremely important, and I hope that we
1155 are listening. We got the business community right here
1156 telling us what we need to be doing, and no one knows better
1157 than they do. So thank you.

1158 And I'll yield back, Mr. Chairman.

1159 *Mr. Johnson. The gentlemen yields. The chair now
1160 recognizes Mr. Sarbanes for five minutes.

1161 *Mr. Sarbanes. Thanks very much, Mr. Chairman. Thank
1162 you all.

1163 Six years ago Congress passed the Frank R. Lautenberg
1164 Chemical Safety For The 21st Century Act, as you know, which
1165 was the first major reform to the Toxic Substances Control
1166 Act, or TSCA, since it was originally passed nearly 50 years
1167 ago, so it was a very needed update. The bipartisan
1168 Lautenberg Act made critical updates that strengthened EPA's
1169 ability to protect public health and provided greater
1170 assurances for both consumers and for industry. Chief among
1171 these were requiring EPA to make safety determinations before
1172 a chemical can enter commerce and ensuring that these safety

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1173 determinations are based solely on health and environmental
1174 risks, including requiring consideration of risk to
1175 vulnerable populations.

1176 Dr. Woodruff, how important were these revisions to TSCA
1177 in terms of guarding human and environmental health and
1178 safety, and can you speak specifically to the law's impacts
1179 on vulnerable populations?

1180 *Dr. Woodruff. Yes. So first I want to say that prior
1181 to the updates in 2016 for chemicals that were existing on
1182 the marketplace, which is 40,000 -- well, actually, the -- at
1183 the time it was 80,000 -- since it is -- the inventory has
1184 been updated, it is 40,000 chemicals, there was almost no
1185 ability for EPA to regulate those chemicals. A good example
1186 is asbestos. EPA tried to regulate asbestos which causes
1187 cancer and mesothelioma, and they could not.

1188 So, essentially, the chemical industry could continue to
1189 use the 40,000 chemicals which includes solvents like TCE,
1190 perchloroethylene, PFAS chemicals, BPA, plasticizers, without
1191 any regulatory consequences. That led to widespread
1192 exposures to these chemicals in the U.S. population.

1193 So studies that we have done, both at UCSF as well as
1194 studies that have been done in consortium with the National

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1195 Institutes for Health Environmental Influences on Child
1196 Health Outcomes, shows that pregnant women are exposed to
1197 dozens of different industrial chemicals, including the
1198 chemicals that should have been regulated under TSCA, so
1199 phthalates, BPA, and PFAS, flame retardant chemicals. And so
1200 before TSCA was amended, it was difficult to regulate these
1201 chemicals.

1202 Since TSCA has been amended, had -- EPA has a schedule.
1203 It is a challenging schedule, however, because the -- for all
1204 the existing chemicals on the marketplace, which is 40,000 of
1205 them, they have to go through a prioritization process. So
1206 it is not -- those chemicals can still remain on the market.

1207 There is no requirement that the chemical industry
1208 provide information about their potential to adversely impact
1209 health until they get to the point where EPA starts to
1210 consider them as a high-priority chemical and then evaluates
1211 those high-priority chemicals under a risk evaluation that
1212 now does not have to include a benefit cost test.

1213 So what we are seeing is that EPA has the capacity. It
1214 is really important that the law requires that EPA must
1215 consider risks to vulnerable populations, particularly during
1216 pregnancy, childhood, and occupational exposures, and that is

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1217 because those are periods where the population is more
1218 vulnerable to effects of toxic chemical exposures due to
1219 development, and exposures during pregnancy can increase the
1220 risk of multiple childhood conditions, including
1221 neurodevelopmental disorders, metabolic disease, as well as
1222 asthma, all of which are increasing in the population. So
1223 now EPA must consider those.

1224 We are continuing to monitor how well EPA is considering
1225 those pregnancy and childhood susceptibilities as well as
1226 occupational exposures. I will note that while EPA has to do
1227 that as we have just recently -- as we have commented on the
1228 recent proposed rulemakings -- risk management rulemakings,
1229 they are still going to be setting the levels at a pretty
1230 excessive risk for occupational health workers, anywhere from
1231 100, 200.

1232 *Mr. Sarbanes. I presume that you would agree that EPA
1233 needs resources in order to do all of these measures and put
1234 the protections in place, and the TSCA office hasn't really
1235 seen a commensurate increase in funding that would go with
1236 the increased responsibilities it now has under this updated
1237 version of the -- of TSCA.

1238 Mr. Chairman, without objection I would like to enter

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1239 into the record a report prepared by the Environmental
1240 Working Group describing how uncertainty around funding,
1241 these government shutdowns, congressional operations,
1242 shutdowns makes it even more difficult for EPA to effectively
1243 review and regulate chemicals. Without objection, Mr.
1244 Chairman?

1245 *Mr. Johnson. Without objection.

1246 [The information follows:]

1247

1248 *****COMMITTEE INSERT*****

1249

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1250 *Mr. Sarbanes. Thank you, I appreciate that.

1251 And I appreciate the testimony. Had some other
1252 questions, but I really just want to emphasize, we got to
1253 make sure we get the resources to EPA in order to do the job
1254 that we have given them.

1255 And with that, I yield back.

1256 *Mr. Johnson. The gentleman yields back. The chair now
1257 recognizes the gentleman from Alabama, Mr. Palmer, for five
1258 minutes.

1259 *Mr. Palmer. I thank the chairman. It is interesting
1260 some of the comments that I have heard from my Democratic
1261 colleagues when -- in just over two years, the Biden
1262 administration and the Democratic majority added over 10
1263 trillion dollars in government spending that launched a
1264 massive rise in inflation that has drained people's savings
1265 and put a tremendous strain on households that are struggling
1266 to make ends meet. They can't afford their groceries, can't
1267 afford to put gas in their cars, can't afford to adequately
1268 heat their homes. And it just concerns me that the delays
1269 that we are seeing in regulation from the regulatory regime
1270 of this administration is doing even more harm to people.

1271 You talked about a climate of uncertainty that has been

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1272 created. I tell people all the time that money is just like
1273 water, it will always seek the path of least resistance. And
1274 if you want innovation, you want entrepreneurship, if you
1275 want to see products brought to the market that help people,
1276 that lower costs, then you have got to have some certainty in
1277 the regulatory environment as well.

1278 And that said, assuming that the EPA would not approve
1279 anything that causes harm, how does the delays in these
1280 approvals of the 88 chemicals that you guys have mentioned
1281 impact the economic wellbeing of lower and middle income
1282 families? Are there any of those chemicals that could be
1283 applied to products that would be of benefit to people,
1284 whether it means reducing the cost of goods and services or
1285 potential new jobs? Mr. Whitaker?

1286 *Mr. Whitaker. Well, with respect to the medical
1287 industry and the medical devices that we manufacture,
1288 anything that slows down the process of getting products to
1289 market through new regulations that aren't in sync with the
1290 public health needs is going to cause problems for everyone,
1291 including people in low-income communities and those that
1292 don't have access to the health care system. So the answer
1293 is yes, which is why we urge EPA to work closely with us and

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1294 move together toward a solution rather than something that's
1295 going to cause harm.

1296 *Mr. Palmer. In that regard, and again, assuming that
1297 the EPA will not approve anything that would cause harm, do
1298 -- is it possible that the delays in the approvals of these
1299 new chemicals could possibly deny somebody a lifesaving
1300 pharmaceutical, or a lifesaving medical device, or a life-
1301 improving -- improving the quality of life, is that possible?

1302 *Mr. Whitaker. Theoretically it is possible. I would
1303 defer to Mr. Jahn on the 88 chemicals, but I could say from
1304 our perspective, they go through the FDA to ensure that they
1305 are safe after the EPA has reviewed them as well to double
1306 check.

1307 *Mr. Palmer. Mr. Jahn, why would they hold up something
1308 that could potentially save someone's life or improve the
1309 quality of life of somebody struggling with a debilitating
1310 condition?

1311 *Mr. Jahn. And so I want to add to that. So, again, it
1312 is 88 percent of the new chemicals --

1313 *Mr. Palmer. 88 percent, okay.

1314 *Mr. Jahn. -- that -- so there is 411 pending, even
1315 though the statutory deadline is 90 days. The challenge is

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1316 -- the administration has with the program is on staffing, is
1317 on process, is on the ability to execute effectively against
1318 its plan, and that is not a reason to throw money -- more
1319 money at the program. We ought to see a plan to fix it and
1320 then we can talk about what the appropriate resources are to
1321 complete --

1322 *Mr. Palmer. You realize you are talking about the
1323 Biden administration when say a plan?

1324 *Mr. Jahn. I want to believe that everybody wants to do
1325 this as quickly as possible. And I would say to the Biden
1326 administration, I have, I have talked to the administrator
1327 directly, it is like, it is in your own interest to move
1328 ahead on these things. Many of these chemicals that are
1329 pending in the queue have better environmental performance.

1330 *Mr. Palmer. How many of them may or may not be
1331 critical to our national defense? Because a lot of the -- of
1332 the chemicals that you guys produce are critical to our
1333 munitions production and other --

1334 *Mr. Jahn. Absolutely, sir.

1335 *Mr. Palmer. -- applications in our national defense.
1336 So --

1337 *Mr. Jahn. So there is a lot of discussion about PFAS

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1338 in the last conversation. The Department of Defense came out
1339 with a report last week. I encourage all of you to look at
1340 it. It has details about how DOD needs PFAS to be able to go
1341 into applications that defend our country. It made very
1342 definitive statements about the cost not only to defense but
1343 to United States society. That came out just last Thursday,
1344 I believe. I encourage everybody on the committee to take a
1345 very close look at that.

1346 *Mr. Palmer. Mr. Huntsman, in your testimony, you made
1347 the point that I tried to make a moment ago about people not
1348 being able to afford to warm their homes. We have seen this
1349 played out in Europe. The Economist Magazine reported there
1350 were 68,000 people died last winter in Europe because they
1351 couldn't afford their household utility bills. They couldn't
1352 keep them adequately heated.

1353 *Mr. Huntsman. Look, all these regulations, and I am
1354 not saying they are not needed, but we have got to understand
1355 there is a cost that goes with them, and that cost is
1356 incredibly regressive through society. If you look at
1357 Europe, and that is more around their energy policy, you are
1358 absolutely right, it is a complete catastrophe and it is --
1359 last year was one of the worst winters that they had from the

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1360 point of view that you just mentioned, and it was also one of
1361 the warmest winters that they have had.

1362 *Mr. Palmer. And that is a great point.

1363 Well, Mr. Chairman, my time is expired. I thank you for
1364 the indulgence. I yield back.

1365 *Mr. Johnson. The gentleman yields back. The chair now
1366 recognizes the gentleman from California, Mr. Peters, for
1367 five minutes.

1368 *Mr. Peters. So I actually hadn't remembered to say
1369 this, but I -- my first job out of college was working at the
1370 EPA in the Office of Toxic Substances under the TSCA, and the
1371 Regulatory Impacts Branch of the Office of Toxic Substances
1372 way back in the day, and I will tell you I was trying to
1373 decide whether to become an economist or a lawyer. I was an
1374 economist, I was -- supposed to be looking at cost-benefit
1375 assessments of new chemicals, and I decided to go to law
1376 school because no one listened to the economist; everyone
1377 listened to the lawyers. And here we are today.

1378 I -- first of all, I want to say to Mr. Jahn, I am in --
1379 working on -- spending a lot of time figuring out how to
1380 deploy the American investment in climate action that is in
1381 the IRA, and one of the most frustrating things for me is the

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1382 delays that this government occasions on people who are
1383 applying for stuff. I think it is possible that there are --
1384 there are chemicals that want to come along that are safer,
1385 that we are delaying from replacing more dangerous things. I
1386 totally buy that. I think it is completely plausible; it
1387 doesn't surprise me a bit.

1388 And I have always said in my practice, when I practiced
1389 environmental law, I said, you know, no is the second best
1390 answer. I would rather you tell me yes, but if you are going
1391 to tell me no, tell me now so I can go on to something else.
1392 And I want -- just want to say I would love to work with you
1393 on that. I don't know if it's just a matter of resources, I
1394 suspect that is part of it, but if there is specific fixes
1395 that you think would be helpful so that we can get, you know,
1396 yesses and noes rather than nots, and I would be happy to
1397 help on that.

1398 This conversation has been a little bit unspecific, sort
1399 of like our regulation is good, our regulation is bad, do
1400 regulations have costs, do regulations have benefits. Of
1401 course they do. I am struggling with figuring out like what
1402 we are supposed to do in the face of this.

1403 But one observation I will make, and I have a question

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1404 about it is that the conversation within the EPA doesn't
1405 account for all the tradeoffs that we are talking about, in
1406 particular, the chemistry supply chains that are essential to
1407 clean energy technologies like electric vehicles. And maybe,
1408 Mr. Jahn, you can speak to that. What -- you know, what is
1409 the role of chemistry, or plastics, or however you want to
1410 rate -- characterize it in deploying the energy transition
1411 that we are looking at in the IRA?

1412 *Mr. Jahn. So chemistry is essential science, and it is
1413 the central science on making progress on climate. So if
1414 every possible alternative energy source, any source of any
1415 kind of energy, but as well as alternative sources starts
1416 with chemistry. So you look at the hydrogen hub announcement
1417 last week, we had multiple members involved in that. Solar
1418 panels, wind turbines, direct air capture, carbon capture
1419 utilization and storage. We have members that are leading
1420 the charge on all of those things and we are going to need
1421 new innovative chemistries to make progress on that. I
1422 already gave an example today about electric vehicle
1423 batteries, waiting five years for an answer on that.

1424 What we can't do is if you want to continue to make
1425 progress on some of these priorities is have a system that

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1426 does not work and allow us to innovate and move forward
1427 quickly on that. And I would be happy to work with you on
1428 that.

1429 They -- I will say the -- there was legislation that
1430 came out of this committee earlier this year that would
1431 address for energy, and it would put a shot clock on the
1432 deadline for the review of those chemicals in the energy
1433 space. We are supportive of that and we are happy to work
1434 with everybody on the subcommittee to try to move forward.

1435 *Mr. Peters. Maybe just ask you specifically, do you
1436 have specific ideas for us on how to make this go faster? A
1437 shot clock would be one.

1438 *Mr. Jahn. Yes.

1439 *Mr. Peters. In other words, if it -- the shot clock
1440 runs out, it is approved?

1441 *Mr. Jahn. Correct. Right.

1442 *Mr. Peters. Any other ideas --

1443 *Mr. Huntsman. How about prioritize results?

1444 *Mr. Peters. Okay. So how would you measure that?

1445 *Mr. Huntsman. I would look at what is the impact on a
1446 per application basis. Going to electric vehicles, for
1447 example, we are dealing with now a battery that can have a

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1448 runway reaction of up to a thousand degrees, right? And the
1449 materials that go around that, that protect around heat, that
1450 have better reactivity in a battery.

1451 If you have a simple chemistry that can extend a battery
1452 by four or five percent, because we are talking -- that is in
1453 the world of batteries, that is an enormous leap forward. We
1454 produced those products today in the United States. Some of
1455 them we are sitting on, some of them we can't compete because
1456 we are competing against Chinese imports.

1457 And so as we look at the actual benefit from an
1458 environmental point of view, there ought to be some sort of
1459 benefit -- some sort of range that you could be able to look
1460 at and prioritize. If the EPA is going to be spending money
1461 on electric school busses, should this maybe take priority
1462 over something like that? Is that what the EPA ought to be
1463 involved in?

1464 *Mr. Peters. So, I mean, actually you are coming back
1465 to what I said at the beginning. So you are asking the EPA
1466 to look at some of the economic effects of the choices it is
1467 making?

1468 *Mr. Huntsman. It is about priorities.

1469 *Mr. Jahn. And if I -- and we could prioritize for them

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1470 by providing a financial incentive. They don't get paid
1471 until they get the work done. We pay for these reviews. To
1472 be really clear about this, we put money on the table to ask
1473 the government to review it before we go to market. You
1474 don't get your money until you get the job done.

1475 *Mr. Peters. My time is expired, but if you have
1476 specific ideas for me, I would love to have them in writing.

1477 *Mr. Jahn. Yes, sir.

1478 *Mr. Peters. And thank you, Mr. Chairman, I yield back.

1479 *Mr. Johnson. The gentleman yields back. The chair now
1480 recognizes the gentleman from Pennsylvania, Dr. Joyce, the
1481 vice chair of our subcommittee, for five minutes.

1482 *Mr. Joyce. First I want to thank Chairman Johnson for
1483 holding this hearing today and thank the witnesses for being
1484 here. Apologies for the delay.

1485 I am very concerned about the EPA's proposed ethylene
1486 oxide emissions and draft regulation decision, and I am not
1487 the only one. At an event on April 28th, FDA Commissioner
1488 Califf was asked about ethylene oxide rulemaking, and he
1489 responded and I quote, "This issue is very much on the
1490 forefront for all of us. We are highly aware of it and we
1491 are engaged in discussions.'" He concluded with, "I am very

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1492 worried.'" Those worries today are even more so.

1493 In college, I spent a summer in central supply in a
1494 sterilization unit at a community hospital. I can say with
1495 firsthand knowledge how critical adequate sterilizing
1496 procedures are in regarding procedures, surgeries, and
1497 ultimately regarding patient safety. This may sound
1498 hyperbolic, but restricting ethylene oxide can paralyze
1499 American's medical services because of the lack of an
1500 effective alternative to ensure appropriate, safe patient
1501 care.

1502 I am a physician. Previously I was responsible on a
1503 daily basis for 25 or 30 patients and their safety. Today,
1504 my responsibility is for the safety of 750,000 constituents.
1505 750,000 constituents who rely on safely sterilized equipment
1506 for their medical procedures.

1507 Beside me is a poster, and you can see the differences
1508 to the naked eye in this poster that is beside me. There are
1509 glass syringes, some treated with gamma radiation, and the
1510 ones on top are treated with ethylene oxide. You see the
1511 clear difference. The clear difference. The clarity that
1512 remains with the ethylene oxide treated syringes and how the
1513 gamma radiation discolors those syringes. In contrast, it is

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1514 stark.

1515 My first question is for you, Mr. Whitaker. Why is
1516 essential that ethylene oxide is used for medical instruments
1517 and devices for tiny parts and the crevices that needs to be
1518 sterilized?

1519 *Mr. Whitaker. Yeah. It is a great question. Thank
1520 you for that question. There are about 40 to 50 million
1521 surgeries a year in the United States, so we are talking
1522 about millions and millions of instruments. And the reality
1523 is, if you don't do those safely with sterilized products,
1524 patients are going to be harmed by that. And the reality is
1525 today, and this is why Commissioner Califf was so concerned,
1526 there is not another sterilization product that gets to all
1527 the areas of the most intricate medical supplies as it is
1528 needed. And the result is that it is going to be the
1529 likelihood of poor execution on a surgery or infections that
1530 may come from that.

1531 So what you have outlined there is one great example,
1532 but there are plenty of others and other platforms as well
1533 that would be negatively affected by using the wrong
1534 sterilization method.

1535 *Mr. Joyce. I think the clarity resonates by seeing the

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1536 inability to maintain clear syringes which will be used in a
1537 multiple of surgeries and procedures.

1538 Mr. Whitaker, AdvaMed has publicly stated that the EPA's
1539 proposed, as drafted, will result in an estimated total
1540 capacity reduction at sterilization facilities of
1541 approximately 30 to 50 percent, or even upwards of 70 percent
1542 in some facilities. Paint me a picture, please, of what
1543 healthcare in America looks like if 50 percent our Nation's
1544 20 billion manufactured medical devices cannot be adequately
1545 sterilized? How would that ultimately affect patient care?

1546 *Mr. Whitaker. A terrible effect on patients. It would
1547 bring surgeries and procedure in some cases to a screeching
1548 halt. You would have supply shortages in hospitals that we
1549 have never seen before. And it is real. This is not
1550 hyperbole, we are not just making this up, it is real.

1551 At the end of the day, the risk associated with
1552 executing this rule in its current form is a major risk to
1553 access and patient health, and at its core, that is why we
1554 are most concerned. Now we have suggested to FDA -- or to
1555 EPA a number of ways to make this palatable, but we have yet
1556 to get an answer from them on that, but we remain hopeful
1557 that we can improve it.

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1558 *Mr. Joyce. Do you think we are on the cusp of a
1559 potential healthcare crisis, another one, having just come
1560 through COVID?

1561 *Mr. Whitaker. Well, there's no question it would cause
1562 a crisis if the regulation goes into effect as it is
1563 currently drafted.

1564 *Mr. Joyce. Mr. Whitaker, the proposed rules issued by
1565 the EPA earlier this year to implement additional regulations
1566 for sterilization facilities may result in facilities ceasing
1567 their operation and put a supply chain crisis here in the
1568 United States. It is an alarming EPA proposal that aims to
1569 change the processes for medical device sterilization. Do
1570 you believe the EPA has fully consulted with the FDA on the
1571 appropriate methods necessary to ensure medical devices are
1572 sterilized?

1573 *Mr. Whitaker. I would hope they have. I am not sure
1574 that they have. Had they, I would suggest Commissioner
1575 Califf would not still be concerned. Though if he is still
1576 concerned, I would suggest more consultation is required
1577 because we have to get this right.

1578 *Mr. Joyce. Thank you for your clear answers. Your
1579 concern are our concerns on this committee as well.

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1580 Mr. Chairman, I yield.

1581 *Mr. Johnson. The gentleman yields back. The chair now
1582 recognizes the gentleman from Texas, Mr. Weber, for five
1583 minutes.

1584 *Mr. Weber. Thank you, Mr. Chairman.

1585 Mr. Huntsman, thank you for being here. Good to see you
1586 again. I want to come back to actually something you
1587 actually said in your remarks. I am going to quote it
1588 verbatim. "U.S. has the strongest most effective
1589 environmental laws governing clean air and water in the
1590 world. It is not always that way, and our industry has made
1591 mistakes. However, when you compare the environment in the
1592 developed world today to even 1980, the progress is
1593 staggering. This is -- the water in the Potomac River, the
1594 air in Los Angeles, and our rivers and streams are all
1595 cleaner. This is due to the combination of strong government
1596 regulations, corporations being held legally accountable for
1597 wrongdoing, and because wealthy nations have the final
1598 resources to prioritize the environment.'"

1599 The -- and you make a great statement. "The more
1600 prosperous a society becomes, the better it can manage the
1601 environment.'" That is a great statement. And I would

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1602 postulate, too, that it also includes the medical community,
1603 what the good doctor here was just talking about. If there
1604 is nothing better than ethylene oxide, I am going to just --
1605 I am not a medical doctor. Of course, I owned an air
1606 conditioner company for 35 years, small business guy.

1607 But I am just thinking in chlorine in bleach, right? I
1608 mean, you don't -- chlorine -- strong -- in strong enough
1609 doses could really be detrimental to you, but it does help us
1610 keep our clothes clean, clean things up that -- so we are not
1611 going to outline chlorine, right? That is just kind of a
1612 simple analogy I am going to draw there.

1613 The fact that you remarked that when -- as countries
1614 become more prosperous, the better we at these things. I am
1615 appalled to hear that one rule, Mr. Jahn, takes five years to
1616 get that through. That is absolutely appalling.

1617 So with that said as my personal opinion, let me jump
1618 over to a question. Mr. Huntsman, your family has been
1619 instrumental in the Golf Coast of Texas, and for that -- that
1620 is jobs, that is industry, that is developing things that
1621 most of the people in this room don't even know, but we thank
1622 you for that. We really do thank you for that.

1623 You mentioned Germany, that would -- we talked about

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1624 producing critical products in America and the countries
1625 don't do it, and then you mentioned Germany. How is that
1626 working for Germany? Elaborate on that, producing critical
1627 products, what they are not doing.

1628 *Mr. Huntsman. Well, it was mentioned earlier, and I
1629 think that you can simply see that the production, the
1630 chemical production in Germany has been reduced by roughly 22
1631 percent in the last year and a half, and that is not just
1632 because of the Russian invasion of Ukraine, it started before
1633 that.

1634 And so Europe, for the first time in over 50 years, is a
1635 net importer of chemicals. Those chemicals that are coming
1636 from China, and from other Middle Eastern countries, and
1637 other places do not have anywhere near the regulatory
1638 environment the Europeans do or that the U.S. does, and so
1639 they are basically outsourcing their emissions.

1640 *Mr. Weber. You are probably aware of this. Mr. Jahn,
1641 I bet you are, too. The oldest chemical company in the
1642 world, BASF, right, and I forget how many hundreds of
1643 thousands of people they employ, and you know where they are
1644 from? Germany. And so apparently Germany didn't learn its
1645 lesson.

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1646 Mr. Jahn, I am going to come to you. One of my greatest
1647 concerns is the attack on the chemical industry, that it
1648 feels like often or not based on reliable science. The
1649 attacks threaten our supply chains, I am sure you all have
1650 been talking about it, only to serve and increase our
1651 reliance on foreign nations. In 2020, we all witnessed
1652 supply chain shortages for medical equipment firsthand during
1653 the pandemic. Could this administration's regulatory assault
1654 on American production lead to supply shortages of critical
1655 products like PPE, surgical devices, and any others you would
1656 like to mention?

1657 *Mr. Jahn. Yes, sir. Exactly those things. We lived
1658 through that during the pandemic and I hope that we can learn
1659 the lesson from the pandemic and make sure that we all ensure
1660 not only the manufacture of those materials but the advanced
1661 materials that go into the manufacture of that.

1662 Let me give you just one example and that is
1663 semiconductors. We have talked about that a little bit
1664 already today. Believe it or not, you need about 500
1665 different chemistries to manufacture a computer chip. So if
1666 we -- for all this work that we have done to bring these
1667 facilities to make this in this country, we need to all

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1668 ensure the supply chain for semiconductors as well, and there
1669 are a number of different rules pending at EPA that would
1670 impede our ability to do that. There is five different
1671 chemistries that would be impacted.

1672 There is a good colloquy here about ethylene oxide, for
1673 example. You need ethylene oxide to sterilize the facility
1674 so that you can manufacture that computer chip. So what I
1675 would say is, and this is not quoting us, is the
1676 semiconductor industry called a recent EPA rule devastating
1677 and would result in the semiconductor industry being unable
1678 to manufacture devices in the United States. So that is
1679 where we are at right now.

1680 *Mr. Weber. That is a great statement. And ethylene
1681 oxide that the doctor was talking about, you were talking
1682 about, you said 40 to 50 million surgeries a year in the
1683 United States, is that what we said?

1684 *Mr. Whitaker. Yeah, between 40 and 50 million
1685 surgeries, yeah.

1686 *Mr. Weber. Okay.

1687 *Mr. Whitaker. And 95 percent of the surgical
1688 instruments that are used are sterilized with ethylene oxide
1689 today.

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1690 *Mr. Weber. Think about hamstringing that, what that
1691 would do to the medical industry. And I appreciate you all
1692 being here.

1693 Mr. Chairman, I yield back.

1694 *Mr. Johnson. The gentlemen yields back. The chair now
1695 recognizes the gentleman from Georgia, Mr. Allen, for five
1696 minutes.

1697 *Mr. Allen. Thank you, Chair Johnson, for holding this
1698 important hearing on the impact that the regulations coming
1699 out of the environmental protection agency and what that has
1700 -- the impact that will have on the chemical industry and
1701 that are vital to medical devices and other essential
1702 products.

1703 I have become increasingly concerned with the EPA
1704 overreach in this administration, especially in the chemical
1705 sector. Some regulations from the EPA are limiting the
1706 ability for manufacturers and companies to utilize chemicals
1707 that are integral to lifesaving medical devices. I would
1708 also like to highlight that the chemical industry has an
1709 important presence in my home State of Georgia and in my
1710 district. And Georgia is the best state to locate your
1711 business 10 years in a row, and we are glad to have you.

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1712 The chemical industry provides 600 direct jobs in my
1713 district with wages that are 19 percent higher than the
1714 average manufacturing wage in Georgia, 11 billion dollars in
1715 federal taxes generated by this industry in my district, and
1716 while they ship billions of dollars' worth of products to
1717 customers around the world.

1718 Mr. Jahn, former EPA administrators once quoted as
1719 saying the legality of the regulation is not as important as
1720 the signal it sends to the investors and marketplace. You
1721 represent numerous companies of all sizes that are at the
1722 forefront of innovative and life-enhancing products. These
1723 companies make investment and job decisions based on the
1724 existing and anticipated regulatory environment. And as that
1725 former EPA administrator pointed out, proposals send a
1726 message to these companies and create uncertainty in the
1727 marketplace.

1728 So can you speak to the negative consequences of some of
1729 these unreasonable proposed rules coming out of the EPA and
1730 what that will have on future investments in American's
1731 retirement?

1732 *Mr. Jahn. Yes, sir. So one thing I want to be clear
1733 on as I start my answer here is that we are not against

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1734 regulation, we are against non-science-based approaches to
1735 regulate in our industry. The chemical industry is already
1736 the most heavily regulated sector of American manufacturing.
1737 I am not here to complain about any of that today. What I am
1738 concerned about, though, is the cumulative, regulatory impact
1739 that is unprecedented in our industry's history.

1740 Let me just give you an example of that. There are 13
1741 proposed regs on our industry and the cost to the American
1742 economy is over seven billion dollars based on the
1743 administration's own figures. That increased the compliance
1744 cost of our industry, which are already in the billions of
1745 dollars, by 50 percent. Additionally, there are seven
1746 economically significant regulations of those 13. That is
1747 more than the Obama, Trump, and Biden -- excuse me, Bush
1748 administration's combined. Those three administrations.
1749 There is more happening right now than those previous three.

1750 So those are the facts. They have tremendous
1751 consequences. We have talked a lot about Europe today. They
1752 have gone in the wrong direction and we have already seen how
1753 that movie ends. We can take a different course.

1754 And so, again, we want to work with everybody on this
1755 committee and work with the administrator and his folks to

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1756 make sures that we get on track and so that we can continue
1757 to invest in this company and not fumble the opportunity that
1758 we have been given because of the shale gas revolution and
1759 the tremendous growth and investment that we have made in the
1760 past decade.

1761 *Mr. Allen. And all of that additional cost is going
1762 direct to the consumer.

1763 *Mr. Jahn. Correct. So there was a discussion about
1764 inflation before.

1765 *Mr. Allen. Yeah.

1766 *Mr. Jahn. That all gets passed along --

1767 *Mr. Allen. Yeah.

1768 *Mr. Jahn. -- to the end consumer, correct.

1769 *Mr. Allen. Yeah, exactly. Mr. Jahn and Mr. Huntsman,
1770 many people in -- many people in support of an aggressive
1771 regulatory posture on existing chemicals believe that the
1772 marketplace will quickly be filled with cipher replacement
1773 chemicals. Can you both speak to how realistic that scenario
1774 is in the United States, especially considering the results
1775 of new chemical approvals at EPA?

1776 *Mr. Jahn. It is not realistic. We just talked about
1777 regulatory certainty. We got a situation where the statute

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1778 says 90 days and you get another additional period of time if
1779 you can't meet that. The way it really works in reality is
1780 at about 700 days. And so there is about three-quarters of
1781 our members who are looking at introducing new chemistries to
1782 market somewhere else other than the United States.

1783 *Mr. Allen. Mr. Huntsman?

1784 *Mr. Huntsman. I would just note that when you -- as I
1785 said earlier, if I am altering chemistry, first is if I come
1786 in with somewhere new. And, again, when we are talking about
1787 lightweighting airplanes, we are talking about lightweighting
1788 EVs and the battery technologies, we are talking about all
1789 the innovations, and the chip industry, and so forth, we need
1790 a whole new family of chemistries, not just altering 20, 30,
1791 40 year old formulations.

1792 Every five years, 30 percent of our chemistry changes
1793 and it improves every time we change. We need to be able to
1794 do that even faster. We need to be able to do that quicker
1795 and we got to be, again, incentivized to come up with new
1796 technologies rather than just taking old technology --

1797 *Mr. Allen. Yeah, and this stifles innovation which
1798 stifles our worldwide competitiveness --

1799 *Mr. Huntsman. That's right.

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1800 *Mr. Allen. -- because you -- you know, you have to be
1801 innovative to be competitive.

1802 Mr. Chairman, I am out of time, and I yield back.

1803 *Mr. Johnson. The gentleman yields back. The chair now
1804 recognizes my friend and colleague from Ohio, Mr. Balderson,
1805 for five minutes.

1806 *Mr. Balderson. Thank you, Mr. Chairman. From Ohio.
1807 Appreciate that. Thank you all for being here today.

1808 Mr. Whitaker, you are up first. Thank you for being
1809 here. But the EPA rules, if finalized, would require FDA to
1810 reevaluate the sterilization process for a large number of
1811 medical devices to ensure that the devices are sterile.
1812 Given the quick compliance timelines, EPA seems to have
1813 underestimated the amount of time and resources that this
1814 would require.

1815 Mr. Whitaker, what timelines do you believe would be --
1816 would provide the medical device industry with enough time to
1817 comply with FDA requirements for revalidating medical
1818 devices?

1819 *Mr. Whitaker. I am not sure I can put a specific
1820 timeline on the industry more broadly because of the depth
1821 and breadth of the work we do, so it would depend on the

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1822 product particularly, right? So -- but I will say to go
1823 through that revalidation process and the reapproval process
1824 can take years to get done, right? And so if we were set
1825 back on products we are already producing and going through a
1826 revalidation process that could take years to complete,
1827 obviously the impact that has on the medical supply chain is
1828 tremendous.

1829 *Mr. Balderson. Agreed. Thank you. I feel better now.
1830 I get a little nervous when I try without my glasses.

1831 Mr. Jahn, good to see you. Thank you. And this has
1832 been mentioned several times with the ethylene oxide or the
1833 EtO. It is naturally present in the environment. The risk
1834 assessment the EPA is using would suggest that every location
1835 in the Nation is exceedingly hazardous.

1836 The risk assessment proposed for sterilization
1837 facilities rules is a magnitude higher than levels
1838 individuals are exposed to everyday, whether from natural
1839 human biology -- biological processes or other sources such
1840 as car motors and grills. Recognizing this, and at the
1841 request of Texas regulators, my good friend Texas, the
1842 National Academy of Sciences, Engineering, and Medicine
1843 initiated an effort recently to review Texas's risk

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1844 assessment of EtO, what is the industry's assessment of the
1845 Texas standard as we compare to what is being proposed in the
1846 EPA rules.

1847 *Mr. Jahn. Yes. So in our view, it takes a more
1848 balances scientific approach. It has been peer reviewed.
1849 And TCQ's approach seeks to ground truth the selection of
1850 important scientific evidence that is critically missing in
1851 EPA's IRIS risk assessment. To be honest, that is a
1852 different approach than what we suggested based on other
1853 studies, but it is a more realistic analysis of the human
1854 health impacts of ethylene oxide.

1855 And, again, I want to be clear on this. We are not
1856 saying that there shouldn't be a standard for ethylene oxide.
1857 We should -- we are saying there is an appropriate
1858 scientific-based standard. As you said, the human body
1859 produces 19,000 times the level of the EPA standard.

1860 *Mr. Balderson. Thank you. Follow-up. Mr. Jahn, do
1861 you believe it is a good idea for the EPA to move forward
1862 with regulations before the National Academy completes its
1863 review of the Texas standard?

1864 *Mr. Jahn. No.

1865 *Mr. Balderson. Thank you.

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1866 Mr. Chairman, I yield back.

1867 *Mr. Johnson. The gentleman yields back. The chair now
1868 recognizes the gentleman from Idaho, Mr. Fulcher, for five
1869 minutes.

1870 *Mr. Fulcher. Thank you, Mr. Chairman. And to the
1871 panelists, thank you for your participation here today.

1872 And I realize -- I am going to direct this to Mr. Jahn,
1873 and I realize that you are not EPA directly here but you may
1874 have some insight. I hope you do.

1875 There is a company in my district in Idaho called BASF,
1876 they are a very large company but there is a major facility
1877 in Parma, Idaho, about 150 employees there. But the EPA is
1878 behind on providing what is called a risk determination for
1879 chemicals slated for commercial manufacturing.

1880 There are parts of Section 5 and 6 of the Toxic
1881 Substances Control Act, must provide a registration
1882 determination after at least 90 days but no more than 180
1883 days. That is the parameter. And we have learned that the
1884 EPA has taken more than 365 days. And I have got a whole
1885 list of other statistics that I am not going to go into
1886 because it would probably take my entire time to -- but it
1887 basically describes and provides evidence of some of the

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1888 shortcomings of the EPA when it comes to these activities.

1889 I just want to know from your vantage point and your
1890 experience, can you provide some insight on what really the
1891 problem is with EPA when it comes to these things?

1892 *Mr. Jahn. Yes. There is a significant challenge there
1893 and, unfortunately, BASF is not the only company that is
1894 dealing with this. There are 411 chemistries in the queue
1895 right now and 88 percent of them are behind the deadlines
1896 that you cited. So the challenge that EPA has is it needs to
1897 improve its process, it needs to enhance its talent
1898 acquisition to be able to deal with these applications. They
1899 need to ensure accountability. There is -- there are no
1900 consequences if EPA does not act. And it needs to improve
1901 the communication with the applicants.

1902 Let me give you an example of what really happens here.
1903 You have got a 90-day deadline. On Day 89, EPA comes back to
1904 the company and requests more information and it gives you
1905 two options as that member -- as that company. You can
1906 either give us -- we want more information. Sorry, left that
1907 out.

1908 So we want more information from the company on Day 89.
1909 We will give you the opportunity to delay the application to

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1910 submit that data, and then it goes down in the system as a
1911 manufacturer requested delay or EPA denies your permit. That
1912 is it. That is the way it works now.

1913 So I would suggest that we need to take a fresh look at
1914 how this program works, and we would be happy to work with
1915 this committee to see what we could do to make things move
1916 forward more effectively. We have talked previously about a
1917 shot clock, about funding and financial incentives to make
1918 sure that the administration does its job in a timely manner.

1919 *Mr. Fulcher. Thank you for that.

1920 Mr. Chairman, I am going to deviate from the general
1921 script and I am going to reflect back on your opening
1922 statement of the day, once upon a time before we did the
1923 break. And as part of your statement, you shared a situation
1924 in the semiconductor industry where so much of the critical
1925 mineral, the chemicals necessary for the semiconductor
1926 industry are not available or sourced in the United States,
1927 yet the administrative effort, and frankly a lot of the
1928 effort that Congress has made, including the CHIPS Act, is
1929 encouraging that manufacturing process to be done within the
1930 United States.

1931 I did just a little bit of homework since now and then.

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1932 I just want to state this for the record because I --
1933 semiconductor industry is near and dear to my heart. Much of
1934 my life before this was in that industry in micron
1935 technology.

1936 Here are the -- are top -- four of the top ingredients
1937 necessary for creating semiconductor, and here is the
1938 situation when it comes to sourcing. Arsenic. Zero percent
1939 of that is sourced in the United States, necessary for
1940 semiconductor manufacture. Primary source, China. Cobalt.
1941 Twenty-four percent is sourced in the United States,
1942 necessary for semiconductors. Primary source, China.

1943 Gallium arsenide. Zero percent sourced in the United
1944 States, necessary for semiconductors. Primary source, China.
1945 Palladium. Sixteen percent sourced in the United States, but
1946 here we at least get a little bit of deviation on the source.
1947 That comes from Russia.

1948 So, Mr. Chairman, I want to just put that on the record.
1949 What you said in your opening statement was dead on, and that
1950 means those of us in these seats need to be taking action to
1951 try to get that changed.

1952 Lastly before my time has gone out, changing gears
1953 again. Mr. Huntsman, I want to thank you and I want to thank

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1954 your family and the efforts that you all have contributed for
1955 lifesaving efforts that impacted a number of lives, including
1956 my own as I struggled with cancer. And so just a public
1957 thank you to you and for your family's work and legacy.

1958 Mr. Chairman, I yield back.

1959 *Mr. Huntsman. Thank you.

1960 *Mr. Johnson. The gentleman yields back. I thank the
1961 gentleman for his comments. The chair now recognizes the
1962 gentleman from Texas, Mr. Pfluger, for five minutes.

1963 *Mr. Pfluger. Thank you, Mr. Chairman. This has been a
1964 great hearing. What an important topic here. So much at
1965 stake. A lot of discussions on ethylene oxide and what that
1966 impact is.

1967 And so I know a lot of those questions have been asked
1968 so, Mr. Whitaker, please understand I am going to diverge
1969 into a couple other areas here, but I appreciate knowing, and
1970 after my colleague here talked about the advances in the
1971 medical industry and how chemistry plays such an important
1972 role in that.

1973 You know, the reality is that we wouldn't have to have
1974 this hearing if the EPA did not have a track record of
1975 overreach. That is really the reality that we are in. And I

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1976 love the discussion on a non-science-based approach. We
1977 can't have a non-science-based approach to regulations, it
1978 has to be science-based. Nobody understands that better than
1979 folks that are experts in the chemistry industry.

1980 I am worried about, and have had conversations with Mr.
1981 Huntsman in Houston before, about the offshoring, the impact
1982 to our national security, the impact to our economic
1983 security, the impact to emboldening our adversaries to do
1984 more of the things that we used to do. And the manufacturing
1985 that we have seen bleed out of western Europe is at risk of
1986 happening in the United States of America if we don't act
1987 now, and that is why we are here.

1988 So I will start by asking a couple of questions. My
1989 staff has done a good job, Mr. Jahn. They said, for example,
1990 there are over 500 chemical -- different chemicals needed to
1991 develop computer chips. You just mentioned that. That is an
1992 effort that this administration has touted, but can you just
1993 kind of elaborate on how these regulations will speed up the
1994 offshoring to places like China?

1995 *Mr. Jahn. So the United States is the second biggest
1996 chemical manufacturer in the world. China is three times
1997 bigger than we are and they are growing. We have expanded in

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1998 this country over the past decades, investing over 200
1999 billion dollars because of the availability of shale gas,
2000 that we are cost-competitive on an energy basis.

2001 We have a 24 billion dollar trade surplus in chemistry.
2002 However, our trade deficit with China on chemistry is five
2003 billion dollars. So if we go in the wrong direction, again,
2004 on so many regulations, I just talked about that, the
2005 tremendous amount of unprecedented regulatory activity on our
2006 industry, we are going to fumble the opportunity that we have
2007 right now to continue to grow and provide the innovation that
2008 we need to achieve our national goals.

2009 And so we are very concerned that this is going to drive
2010 innovation and investment to places like China. We have
2011 already seen that happen in Europe. The European share of
2012 the chemical industry over the past two decades has been cut
2013 in half, and they have -- and so we do not want to follow
2014 that path.

2015 *Mr. Pfluger. Thank you for that, and fumbling the ball
2016 is exactly what -- the path that we are on right now. You
2017 mentioned the DoD report, I have that report right here. As
2018 a former military member, I worked in an area with weapon
2019 systems in a very a critical part of the Department of

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2020 Defense that used PFAS. So, Mr. Chairman, without objection,
2021 I would like to enter this report into the record, and I will
2022 halt on the questions because --

2023 *Mr. Johnson. Without objection, so ordered.

2024

2025 [The information follows:]

2026

2027 *****COMMITTEE INSERT*****

2028

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2029 *Mr. Pfluger. Mr. Huntsman, let's go to the Permian
2030 Basin. You mentioned something very interesting about the
2031 economic impact that should be considered. And when EPA is
2032 doing their regulations and when they are looking at
2033 implementing things, and they have, you know, to date at
2034 least a dozen regulatory efforts that would hurt the chemical
2035 manufacturing sector if not looked at appropriately.

2036 I am very interested in your thoughts on that economic
2037 impact in the Permian Basin for the feedstock that companies
2038 like yours and others in this country depend on and what that
2039 impact would be if we continue down the path of implementing
2040 overburdensome regulations.

2041 *Mr. Huntsman. Well, we are either going to be in a
2042 position where we export natural gas around the world or we
2043 actually export automobiles and semiconductors and we
2044 actually export the finished materials that are derived from
2045 natural gas. Natural gas is not only a form of electricity,
2046 it is also a major natural raw material that comes with
2047 ethane, propane, the various raw materials that come out of
2048 the ground when you take methane out of the ground. Those
2049 are all critical raw materials for our industry.

2050 So I am not opposed to exporting methane or natural gas

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2051 around the world, but I do believe we can be doing a better
2052 job as a country exporting the downstream derivative
2053 materials that come from the petrol chemical industry and the
2054 jobs that are created therein.

2055 *Mr. Pfluger. Thank you. Lastly, I will stick with
2056 you, Mr. Huntsman. There has been a lot of talk on the
2057 current administration bringing the EV and battery supply
2058 chain to the U.S. What would it take to do that, to develop
2059 it here?

2060 *Mr. Huntsman. You are going to have to change about
2061 180 degrees when it comes to your mining policies. Many of
2062 your -- again, it is about speed, it is about competing with
2063 China. It is not that China is starting, they are already
2064 there, they are producing more batteries, they are producing
2065 more electric cars than the rest of the world combined times
2066 a multiple.

2067 And we -- if we are really serious about this, we have
2068 got to get after it and it has got to start with minerals, it
2069 has got to start with chemicals, and it has got to start with
2070 an expedited priority about jobs and economic opportunity.

2071 *Mr. Pfluger. 180-degree change in policy. I like
2072 that.

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2073 I will yield back. Thank you, Mr. Chairman.

2074 *Mr. Johnson. The gentleman yields back. The chair now
2075 recognizes the gentlelady, Dr. Miller-Meeks, from Iowa.

2076 *Mrs. Miller-Meeks. Thank you very much.

2077 And I think it was Mr. Jahn who wanted to say something.
2078 Do you want to add some follow-up?

2079 *Mr. Jahn. I was just going to chime in and say that
2080 the administration is looking at five different chemistries
2081 that goes into automobile manufacturing.

2082 *Mrs. Miller-Meeks. Thank you.

2083 *Mr. Jahn. Thank you.

2084 *Mrs. Miller-Meeks. I want to thank the chair, my
2085 colleagues, and also our witnesses here today. The chemical
2086 industry plays a significant role in the U.S. supply chain --
2087 manufacturing supply chain. Nationwide, the chemical
2088 industry generates 639 billion in annual revenue, and the
2089 U.S. is the second largest global producer producing 11
2090 percent of the world's chemicals.

2091 Specifically in my district in Southeast Iowa, the
2092 chemical industry provides 2,250 direct jobs, generates an
2093 additional 5,480 jobs in plastics and rubber products, and
2094 pays 179 million in wages. The current regulatory

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2095 environment of the environmental protection agency would put
2096 thousands of jobs in my district.

2097 And when people sneer at that, let me say that as a
2098 country when we build wealth, we clean up our environment.
2099 Every nation that has created more wealth has had a cleaner
2100 functioning environment, and just exporting environmental
2101 risk to China or other countries does not absolve us of any
2102 responsibility towards cleaning the environment, a better
2103 environment, or better health for the people in the United
2104 States or the world.

2105 We had last month a hearing on the EPA's proposed
2106 particulate matter 2.5 standard that would decimate
2107 manufacturing in our state. Now we are looking at the EPA's
2108 concerning regulatory actions in the chemical industry that
2109 would ultimately lead to prohibiting the domestic
2110 manufacturing of chemicals. These chemicals are in essential
2111 everyday products we use today, including your cellphone,
2112 your car, your electronics, medical devices, as already been
2113 alluded.

2114 Specifically, the overregulation of ethylene oxide in
2115 formaldehyde would have significant impacts on our Nation.
2116 The FDA estimates that 20 billion medical devices are

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2117 sterilized using ethylene oxide. This includes surgical
2118 kits, IVs, anesthesia masks, heart valves, pacemakers. How
2119 many people would die from not having access to medical care
2120 because we don't have the devices that they need? These
2121 aren't just my concerns. In fact, the FDA stated in public
2122 comments to EPA that ethylene oxide may be the only method to
2123 date that effectively sterilizes and does not change the
2124 device during the sterilization process.

2125 I am a former operating room nurse. I know all about
2126 sterilization and the sterilization methods that we have.
2127 The FDA went on to state, "Without ethylene oxide, there
2128 would be significant sterilization shortfall with no
2129 commensurate sterilization alternative.'" Shortages stemming
2130 from a lack of ethylene oxide would have significant impacts
2131 on patient health and access to critical medical devices and
2132 patient care. How many people would die? How many people
2133 would die?

2134 Now I am also an ophthalmologist, and as you know,
2135 devices such as intraocular lenses used to treat cataracts in
2136 seniors and other populations is not only sterilized by
2137 ethylene oxide, it can only be sterilized with ethylene oxide
2138 given the delicate materials it is made of. How

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2139 irresponsible is it to put forward a rule or regulation when
2140 there is no alternative to the sterilization method now?

2141 And absolutely we want to prevent cancers. Absolutely
2142 we want to clean the environment. But there is a risk to
2143 that, and what we are talking about is that risk and that
2144 benefit.

2145 So I understand that cataract surgery utilizing
2146 intraocular lenses is the most performed surgery in the
2147 United States today with more than 8,000 surgeries to -- per
2148 day. So what would be the impact on America's seniors if
2149 ethylene oxide were no longer produced in the United States?
2150 Mr. Whitaker?

2151 *Mr. Whitaker. It would be devastating. You mentioned
2152 intraocular lenses. That is one and very -- a very important
2153 one. It would essentially shut that down. But that is not
2154 limited to that type of surgery, it would be across the board
2155 for everyone in surgery, as I mentioned earlier, about 40 to
2156 50 million surgeries a year. And the vast majority of
2157 products, 95 percent of products and surgical kits, are
2158 sterilized using ethylene oxide. I think the numbers speak
2159 for themselves.

2160 The hospital system could not operate with that level of

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2161 impact, and it is not worth that risk. We are not opposed to
2162 a regulation. We think you can do it right and we could work
2163 with the EPA to get there, but you have to be thoughtful, and
2164 you have to be science-based, and you have to be focused on
2165 the patients as well as the rule itself, and that is why it
2166 is so critical, and I thank you for raising it.

2167 *Mrs. Miller-Meeks. And I think both parties, both
2168 Republicans and Democrats, through the pandemic have realized
2169 that we need to diversify our supply chain from China. So in
2170 doing this, what would this mean for the capacity and
2171 supplies of critical medical technology needed for patient
2172 care?

2173 *Mr. Whitaker. Yeah, if the rule goes into effect as it
2174 is today, it would be very difficult from a supply chain
2175 standpoint as well. Shortages are almost certain to happen
2176 and happen quickly, and companies would have to relocate
2177 facilities overseas in order to sterilize at the level they
2178 need to. When you have to do that, then you have to ship
2179 product back into the country and the supply chain challenges
2180 are more complicated.

2181 *Mrs. Miller-Meeks. Or maybe patients would have to go
2182 abroad for their cancer treatment?

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2183 *Mr. Whitaker. Or would go elsewhere to get -- yeah.

2184 *Mrs. Miller-Meeks. Thank you very much.

2185 With that, I yield back.

2186 *Mr. Johnson. The gentlelady yields back. Seeing no
2187 other members seeking time to ask questions, I ask unanimous
2188 consent to insert in the record the documents included on the
2189 staff hearing documents list.

2190 Without objection, that will be the order.

2191 [The information follows:]

2192

2193 *****COMMITTEE INSERT*****

2194

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2195 *Mr. Johnson. I remind members that they have 10
2196 business days to submit questions for the record, and I ask
2197 the witnesses to please respond to those questions promptly.
2198 I want to thank our witnesses again. This has been a
2199 very insightful hearing. Thank you all for taking your time
2200 to be with us today.
2201 And with that, our witnesses are excused and the
2202 subcommittee is adjourned.
2203 [Whereupon, at 3:02 p.m., the subcommittee was
2204 adjourned.]