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6 INVESTING IN PUBLIC HEALTH:

7 LEGISLATION TO SUPPORT PARENTS, WORKERS, AND RESEARCH

8 WEDNESDAY, JUNE 29, 2022

9 House of Representatives,

10 Subcommittee on Health,

11 Committee on Energy and Commerce,

12 Washington, D.C.

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15 The subcommittee met, pursuant to call, at 11:00 a.m.
16 in the John D. Dingell Room, 2123 of the Rayburn House Office
17 Building, Hon. Anna Eshoo [chairwoman of the subcommittee],
18 presiding.

19 Present: Representatives Eshoo, Butterfield, Matsui,
20 Welch, Schrader, Cardenas, Ruiz, Dingell, Kuster, Kelly,
21 Craig, Schrier, Trahan, Fletcher, Pallone (ex officio);
22 Guthrie, Burgess, Griffith, Bilirakis, Bucshon, Carter, Dunn,
23 Curtis, Crenshaw, Joyce, and Rodgers (ex officio).

24 Also present: Representatives Clarke and Pence.

25

26 Staff Present: Lydia Abma, Policy Analyst; Hannah
27 Anton, Staff Assistant; Waverly Gordon, Deputy Staff Director

28 and General Counsel; Tiffany Guarascio, Staff Director;
29 Mackenzie Kuhl, Digital Assistant; Una Lee, Chief Health
30 Counsel; Aisling McDonough, Policy Coordinator; Meghan
31 Mullon, Senior Policy Analyst; Juan Negrete, Junior
32 Professional Staff Member; Kaitlyn Peel, Digital Director;
33 Chloe Rodriguez, Clerk; Charlton Wilson, Fellow; Alec
34 Aramanda, Minority Professional Staff Member, Health; Kate
35 Arey, Minority Content Manager and Digital Assistant; Sarah
36 Burke, Minority Deputy Staff Director; Seth Gold, Minority
37 Professional Staff Member, Health; Grace Graham, Minority
38 Chief Counsel, Health; Brittany Havens, Minority Professional
39 Staff Member, O&I; Jack Heretik, Minority Press Secretary;
40 Nate Hodson, Minority Staff Director; Peter Kielty, Minority
41 General Counsel; Emily King, Minority Member Services
42 Director; Clare Paoletta, Minority Policy Analyst, Health;
43 Kristin Seum, Minority Counsel, Health; Kristen Shatynski,
44 Minority Professional Staff Member, Health; and Olivia
45 Shields, Minority Communications Director; and Michael
46 Taggart, Minority Policy Director.

47

48 *Ms. Eshoo. The Subcommittee on Health will now come to
49 order.

50 Due to COVID-19, today's hearing is being held remotely,
51 as well as in person.

52 For members and witnesses taking part remotely,
53 microphones will be set on mute to eliminate background
54 noise. Members and witnesses, you will need to unmute your
55 microphone when you wish to speak.

56 Since members are participating from different locations
57 at today's hearing, recognition of members for questions will
58 be in order of subcommittee seniority.

59 Documents for the record should be sent to Meghan Mullon
60 at the email address we have provided to your staff. All
61 documents will be entered into the record at the conclusion
62 of the hearing.

63 The chair now recognizes herself for five minutes for an
64 opening statement.

65 Today our subcommittee is examined -- examining 11
66 public health bills that support patients, health workers,
67 and biomedical research. Seven bills are reducing
68 disparities or increasing access to health care services for
69 medically under-served populations. About 20 percent of
70 Americans live in rural areas, and are less likely to have
71 health insurance, live farther away from health care
72 facilities, have limited access to health care specialists,

73 and face higher risks of death from heart disease, cancer,
74 diabetes, and stroke.

75 To address these inequities, we are examining
76 Representative Ruiz's bill, H.R. 8151, the Building a
77 Sustainable Workforce for Healthy Communities Act, which
78 invests in community health workers to address workforce
79 shortages in under-served communities.

80 H.R. 5141, the Mobile Health Act, introduced by
81 Representatives Lee and Hudson, and H.R. 8169, the Rural
82 Telehealth Access Task Force Act, introduced by
83 Representatives Pence and Craig, bring services to hard-to-
84 reach populations through mobile medical clinics and expanded
85 access to reliable broadband capabilities.

86 H.R. 8163, the Improving Trauma Systems and Emergency
87 Care Act, introduced by Representative O'Halleran, invests in
88 trauma centers to increase access for the rural Americans who
89 do live near a trauma center currently.

90 Race also affects outcomes. That is why I am pleased we
91 are considering H.R. 2007, the Stephanie Tubbs Jones Uterine
92 Fibroid and Research Act, sponsored by Representative Clark;
93 H.R. 7565 the NIH Improve Act, sponsored by Representative
94 Underwood; and H.R. 7845, the NIH Clinical Trial Diversity
95 Act, sponsored by Representative Kelly. These bills increase
96 research into diseases and populations that have been ignored
97 for too long.

98 I look forward to Dr. Bibbins-Domingo's expert
99 testimony. She chairs the National Academies Committee
100 focused on fair representation in clinical trials, and can
101 explain NIH's vital role in increasing diversity in trials.

102 Ms. Tanika Gray Valbrun will testify about her patient
103 advocacy work on behalf of African American women
104 disproportionately affected by uterine fibroids, including
105 our late colleague, Congresswoman Stephanie Tubbs Jones.

106 Another research bill is H.R. 3773, the -- Pediatricians
107 Accelerate Childhood Therapies, the PACT Act. This is
108 bipartisan and bicameral legislation introduced by two
109 doctors on our Health Subcommittee, Drs. Joyce and Schrier.
110 The PACT Act invests in pediatric physician scientists and
111 researchers with a focus on opportunities for historically
112 under-represented biomedical researchers.

113 Finally, our hearing includes three bills authored by
114 Representatives Curtis, Bilirakis, Hudson, and Trone intended
115 to protect the integrity and security of the U.S. research --
116 biomedical research enterprise from foreign adversaries.

117 Taken together, this is a diverse slate of impactful
118 bills that will improve American health care from early
119 research to patient care, with a focus on reducing
120 disparities and protecting American ingenuity.

121

122

123 [The prepared statement of Ms. Eshoo follows:]

124

125 *****COMMITTEE INSERT*****

126

127 *Ms. Eshoo. The Chair is now pleased to recognize Mr.
128 Guthrie, the ranking member of our subcommittee, for five
129 minutes for his opening statement.

130 *Mr. Guthrie. Thank you, Madam Chair. I appreciate the
131 recognition. I hope everybody is doing well home working for
132 a few days, and I look forward to being back together.

133 Today's hearing includes an examination of the ongoing
134 work at the National Institutes of Health, and ensuring the
135 U.S. remains the leader in biomedical research. A few of the
136 proposals included in today's legislative hearing are
137 designed to promote greater oversight over how U.S. taxpayer
138 dollars are spent on federally-funded biomedical research.

139 It is important to protect U.S. biomedical intellectual
140 property from being stolen by foreign governments. Some
141 adversarial governments such as the Communist Party of China
142 are using their own research programs to recruit researchers
143 in the United States who also receive U.S. taxpayer-funded
144 research dollars and take U.S.-funded IP back to China. This
145 scheme poses a very real threat to U.S. biomedical
146 intellectual property.

147 Perhaps the most widely reported example of this
148 alarming trend is Dr. Charles Lieber, a world renowned
149 researcher and former chair of Harvard's Chemistry and --
150 Chemical Biology Department. Dr. Lieber was charged with
151 lying to Federal investigators about his connection to the

152 Chinese Communist Party's Thousand Talents program, and about
153 income he received from Chinese Communist Party's aligned
154 [sic] Wuhan University of Technology.

155 This continues to be a problem. A watchdog agency
156 published a reported -- a report earlier this month showing
157 there are still lingering research integrity issues that
158 could significantly undermine U.S. biomedical research if
159 they are not appropriately addressed. After concerns were
160 raised regarding NIH guarantees failing to make disclosure
161 about ties to foreign countries, the IG at the HHS surveyed
162 over 770 grantees that were collectively rewarded -- that
163 were collectively awarded over \$20 billion in grant funding
164 from NIH in fiscal year 2020.

165 The findings were alarming. Of the 716 entities that
166 responded, the IG found that over two-thirds of those
167 surveyed failed to meet certain disclosure requirements set
168 forth by the NIH as a condition for receiving Federal
169 funding. These disclosure requirements are designed to
170 protect the type of activity that Charles -- Dr. Charles
171 Lieber was engaged in. These include requiring entities to
172 report all types of foreign financial interests and support,
173 training researchers about their responsibilities, and how to
174 make these disclosures and performing reviews -- to make
175 determinations about whether existing foreign financial
176 interests could compromise the federally-funded research.

177 The IG report came at the heels of a years-long
178 investigation undertaken by top NIH officials to ensure U.S.
179 taxpayer research dollars were being spent appropriately. In
180 fact, the top oversight official at NIH charged with
181 overseeing the department's extramural grants program, Dr.
182 Michael Lauer, even confirmed these concerning -- this
183 concerning trend dating back to 2016.

184 In one of the most egregious examples -- Dr. Lauer
185 himself characterized it -- an NIH-funded researcher failed
186 to disclose a \$5 million startup package from the -- a
187 Chinese university to both the NIH and to the American
188 university employing this researcher.

189 To the credit of NIH, in addition to the existing HHS
190 requirements, the agency issued guidance in 2019 expressly
191 stating grantees must report participation in a foreign
192 talents program like China's Thousand Talents program. The
193 Trump Administration Department of Justice even launched a
194 China initiative to combat malign foreign influence in U.S.
195 research.

196 Despite of all this, more oversight is clearly needed to
197 protect the integrity of U.S. research dollars. I am glad we
198 are here today to finally discuss these issues. Taken
199 together, Mr. Curtis's, Mr. Hudson's, and Mr. Bilirakis's
200 bills before us today would help address the issues
201 highlighted in the OIG's report.

202 The bills would specifically require NIH to
203 transparently report to Congress the number of grantees
204 investigated for non-compliance with grant disclosure
205 requirements; require HHS to develop tools to effectively
206 protect U.S. biomedical research; and to explicitly require
207 NIH grantees to disclose participation in foreign talent
208 programs as a condition of funding, which is currently
209 required by HHS, but not by Federal law.

210 Above all, NIH can and should remain a primary vessel
211 for fundamental scientific research. We can ultimately
212 unleash the agency's full potential without stifling future
213 research if we effectively increase transparency on how these
214 research dollars are spent. I look forward to advancing
215 these critical pieces of legislation toward that end.

216 I look forward to addressing the other bills before the
217 committee this morning. I appreciate the witnesses for being
218 here.

219 [The prepared statement of Mr. Guthrie follows:]

220

221 *****COMMITTEE INSERT*****

222

223 *Mr. Guthrie. And I will yield back, Madam Chair.

224 *Ms. Eshoo. The gentleman yields back.

225 The chair now is pleased to recognize Mr. Pallone, the
226 chairman of the full committee, for your five minutes for an
227 opening statement.

228 *The Chairman. Thank you, Chairwoman Eshoo. Today the
229 committee continues its critical work to improve our public
230 health systems, advance access to care, and enhance the
231 capacity, quality, and integrity of our country's biomedical
232 research system. And we will discuss 11 bills that
233 collectively address critical aspects of these public health
234 issues.

235 Already this year we have passed legislation to
236 reauthorize the Food and Drug Administration's user fees, and
237 to enhance its ability to bring safe and effective treatments
238 and devices to market. We have authorized ARPA, the Advanced
239 -- ARPA-H, the Advanced Research Projects Agency for Health
240 to transform how we detect, treat, and cure the deadliest
241 diseases affecting Americans. And last week the House
242 overwhelmingly passed bipartisan legislation to respond to
243 the mental health and drug overdose crisis.

244 And our bipartisan work to improve the health of all
245 Americans continues today. So we have four bills that
246 address the health needs of our rural and under-served
247 communities.

248 One bill would allow federally-qualified health centers
249 to use New Access Points Grants for establishing mobile
250 health units in order to increase access to health care in
251 rural and under-served areas.

252 Other bills will establish a task force to study
253 barriers to the adoption of telehealth technology in rural
254 areas; promote positive, healthy behaviors and outcomes for
255 populations in medically under-served communities through the
256 use of community health workers; and reauthorize grants for
257 trauma care to support the improvement of emergency medical
258 services and trauma care readiness and coordination -- again,
259 particularly in rural areas.

260 We will also examine legislation that would continue to
261 fund the IMPROVE initiative through the Eunice Kennedy
262 Shriver National Institute of Child Health and Human
263 Development. This initiative reflects our shared bipartisan
264 interests in improving maternal health by advancing research
265 that reduces maternal mortality and morbidity, addresses
266 disparities in maternal health outcomes, and improves health
267 for pregnant and postpartum women before, during, and after
268 pregnancy.

269 And we have legislation that will support and expand
270 research and awareness of uterine fibroids, a condition that
271 impacts as many as 80 percent of women.

272 Now, shortcomings in clinical trial diversity have

273 created knowledge gaps in our understanding of diseases,
274 conditions, treatments, and prevention. And these gaps
275 impact health care decision-making, risk reduction, our
276 knowledge of treatment outcomes, and the development of
277 interventions and medications. So we will also discuss
278 bipartisan legislation that will address these shortcomings
279 by supporting and increasing diversity in NIH-funded clinical
280 trials.

281 Another bipartisan bill supports pediatric research
282 awards for early career pediatric researchers, and
283 prioritizes researchers who have been historically under-
284 represented in the field of pediatric medical research.

285 And we have three bills focused on security in
286 biomedical research. As we look to secure the integrity of
287 our research enterprise, we have to do so in a way that does
288 not impede global collaboration and scientific discovery.
289 But many of us will agree that the United States cannot and
290 will not remain a leader in medical research without
291 attracting the brightest minds across the world and working
292 with the best institutions. And we can both protect our
293 national interests and remain a world leader in biomedical
294 research, in my opinion.

295 And I look forward to working with my Republican
296 colleagues on these bills.

297 So to the witnesses, thank you for joining us. A bunch

298 of bills, but these are all very important.

299 [The prepared statement of The Chairman follows:]

300

301 *****COMMITTEE INSERT*****

302

303 *The Chairman. And I appreciate, Chairwoman Eshoo, the
304 fact that we are having this legislative hearing today, and
305 then can move these because they are bipartisan. So I yield
306 back. Thank you.

307 *Ms. Eshoo. The gentleman yields back.

308 The chair is now pleased to recognize the ranking member
309 of the full committee, Representative Cathy McMorris Rodgers,
310 for your five minutes of -- for an opening statement.

311 *Mrs. Rodgers. Thank you, Madam Chair. The bills
312 before us today reflect the importance of the committee's
313 authorizing responsibilities over key public health programs.

314 We are discussing today about the threat to biomedical
315 research posed by our adversaries, and examining a few steps
316 we could take to address those threats. In the last few
317 years there has been numerous reports of FBI investigations
318 into researchers taking U.S. taxpayer-supported intellectual
319 property to China, not disclosing foreign connections, or
320 tampering with peer review process. We must address those
321 concerns and hold China accountable.

322 Mr. Curtis's bill, H.R. 5442, the Fix Non-Disclosure of
323 Influence in Health Research Act, which requires HHS to
324 report on how they address non-compliance with disclosure
325 requirements or research misconduct related to foreign
326 influence.

327 Mr. Hudson's H.R. 6305, the Protect America's Biomedical

328 Research Enterprise Act, requires the Administration to
329 identify ways to improve intellectual property protection,
330 and develops strategies to prevent national security threats
331 in biomedical research.

332 Mr. Bilirakis's H.R. 5478, the Protecting the Integrity
333 of our Biomedical Research Act, requires NIH grantees to
334 disclose their participation in foreign talent programs.

335 I look forward to examining these bills to address and
336 understand what more NIH can be doing to address these
337 threats, and who has the responsibility -- NIH or the
338 grantees -- for protecting this information. These are
339 common-sense bills, and critical to protecting our national
340 security. They also complement work done in ARPA-H related
341 to research security, which just passed the House, to stop
342 the Chinese Communist Party's influence in our biomedical
343 research.

344 If we don't do a better job of safeguarding our
345 research, both America's national security and our global
346 leadership will be at risk.

347 The pandemic has only made the need for action more
348 urgent, and I want to thank my colleagues on the Energy and
349 Commerce Committee for solutions to hold NIH and HHS
350 accountable for their responsibilities to protect national
351 security.

352 In addition to provisions related to research integrity,

353 there are a number of other NIH bills we are considering
354 today.

355 I have not been shy about my concerns with NIH. I am
356 concerned about a lack of accountability and response to
357 congressional oversight. Their authorization has expired.
358 There is no permanent director. And I think we need to have
359 NIH testify to do more of our oversight of how NIH is
360 functioning as a whole, before providing new authorizations
361 for -- of funding of NIH. I have spoken with the chair of
362 the subcommittee about that, and hope we can work in a
363 bipartisan way to look at NIH and rebuild trust that the NIH
364 has broken.

365 And in addition to NIH, we will also be considering
366 solutions that increase access to health care services in
367 under-served and rural communities like my district.

368 Mr. Pence's Rural Telehealth Access Task Force Act will
369 help identify barriers to telehealth services in rural areas,
370 and better understand how to make telehealth more widely
371 available.

372 We are also considering the Mobile Health Care Act,
373 which allows community health centers to use their funding to
374 purchase mobile health clinics, as well as conduct facility
375 renovations and construction projects.

376 I understand the need for increased access to health
377 services, and appreciate how helpful mobile units have proven

378 to be in rural areas. However, I want to note that I am
379 concerned about permanently allowing funds to be used for
380 construction, instead of health care delivery. Community
381 health centers are an integral part of the health care safety
382 net and have received almost \$38 billion over the last 5
383 years. This includes supplemental funding provided through
384 the public health emergency. I am hopeful that we can come
385 to a consensus on this legislation, and work together to
386 conduct oversight in advance of the funding expiring next
387 year.

388 I want to thank our witnesses for testifying. A special
389 thanks goes out to Desiree Sweeney. She is the CEO of NEW
390 Health in my district, based in Colville, Washington. It is
391 great to have her join us today.

392 I also want to emphasize the importance of oversight and
393 the topical hearings before legislating, including having
394 Federal agencies come before this committee to comment,
395 discuss programs and other related initiatives. I look
396 forward to that happening.

397 Just a big thank you to all the members for putting
398 forward such thoughtful solutions to these important public
399 health issues. Thank you, and I yield back.

400

401

402

403 [The prepared statement of Mrs. Rodgers follows:]

404

405 *****COMMITTEE INSERT*****

406

407 *Ms. Eshoo. The gentlewoman yields back.

408 Pursuant to committee rules, all members' written
409 opening statements shall be made part of the record.

410 I now would like to introduce our witnesses. We have a
411 superb panel of witnesses.

412 Dr. Kirsten Bibbins-Domingo is a professor of
413 epidemiology and biostatistics and the Lee Goldman, M.D.
414 endowed professor of medicine at the University of
415 California, San Francisco.

416 Welcome to you.

417 Dr. Kevin Croston is the chief executive officer of
418 North Memorial Health. He is testifying today on behalf of
419 the Trauma Center Association of America.

420 Ms. Tanika Gray Valbrun is the founder and president of
421 the White Dress Project.

422 Mr. Michael Shannon is the executive and president of
423 the Government Solutions at IP Talents, Incorporated. He is
424 also the former director of the Office of Management
425 Assessment for the National Institutes of Health.

426 Ms. Desiree Sweeney is the chief executive officer of
427 NEW Health.

428 Dr. Leslie Walker-Harding is the Ford/Morgan endowed
429 professor and chair of the department of pediatrics at the
430 University of Washington. She is also the chief academic
431 officer and senior vice president at Seattle Children's

432 Hospital.

433 Thank you to each one of you. It is an honor to have
434 you with us today, and we look forward to your testimony.

435 For witnesses testifying in person, you are probably
436 familiar with the lights in front of you. You have one
437 minute remaining when the light turns yellow. Please stop
438 when the light turns red.

439 Dr. Bibbins-Domingo, you are now recognized for five
440 minutes, and thank you again for joining us.

441

442 STATEMENT OF KIRSTEN BIBBINS-DOMINGO, PH.D., M.D., M.A.S.,
443 PROFESSOR OF EPIDEMIOLOGY AND BIostatISTICS AND THE LEE
444 GOLDMAN, M.D. PROFESSOR OF MEDICINE, UNIVERSITY OF
445 CALIFORNIA, SAN FRANCISCO; KEVIN CROSTON, M.D., CEO, NORTH
446 MEMORIAL HEALTH; TANIKA GRAY VALBRUN, FOUNDER AND PRESIDENT,
447 THE WHITE DRESS PROJECT; MICHAEL D. SHANNON,
448 EXECUTIVE/PRESIDENT OF GOVERNMENT SOLUTIONS, IPTALONS, INC.;
449 DESIREE SWEENEY, CEO, NEW HEALTH; AND LESLIE R.
450 WALKER-HARDING, M.D., F.A.A.P., F.S.A.H.M., FORD/MORGAN
451 ENDOWED PROFESSOR, CHAIR DEPARTMENT OF PEDIATRICS/ASSOCIATE
452 DEAN, UNIVERSITY OF WASHINGTON, CHIEF ACADEMIC OFFICER/SENIOR
453 VICE PRESIDENT, SEATTLE CHILDREN'S HOSPITAL

454

455 STATEMENT OF KIRSTEN BIBBINS-DOMINGO

456

457 *Dr. Bibbins-Domingo. Thank you very much. Chairwoman
458 Eshoo, Ranking Member Guthrie, and members of the committee,
459 thank you for the opportunity to testify today.

460 I am a general internist and a professor at the
461 University of California, San Francisco. I am here today
462 speaking in my capacity as a physician scientist, and as
463 someone who has personally faced the importance of
464 diversifying clinical research.

465 Two thousand seventeen was the year that the issues
466 before this committee became urgent for me. I was then the

467 chair of the U.S. Preventive Services Task Force, an
468 independent body charged by Congress with generating
469 evidence-based guidelines on the use of preventive services.
470 During my tenure we issued recommendations on diabetes,
471 breast cancer, colorectal cancer, lung and prostate cancer.

472 In my discussion with patients and clinicians on our
473 recommendations, I inevitably encountered a similar pattern
474 of questions: How confident are you that these
475 recommendations apply to me and to patients like me? Were
476 these studies conducted in clinics like mine? You are
477 recommending screening for diabetes and those who are
478 overweight and obese, but my Asian patients seem to develop
479 diabetes at lower weight. What about them? What about my
480 Latino patients who develop diabetes at younger ages, or my
481 Black patients, who develop colorectal cancer at younger
482 ages? Shouldn't we start screening them earlier?

483 My recurring response was, unfortunately, we just don't
484 have the studies in these populations that allow us to say
485 with certainty whether or how to adapt our guidelines.

486 In 2017, this was also the year my father lost his
487 battle with prostate cancer. My father was a career Army
488 officer, a veteran, and a strong supporter of science and
489 medicine. He had even served as a lay reviewer for a
490 committee on Federal funding for prostate cancer research.

491

492 He had had excellent medical care, but as his journey with
493 prostate cancer came to an end, the stark absence of Black
494 men like my father in prostate cancer research became acutely
495 distressing to me.

496 Prostate cancer is the most common cancer in all men in
497 the U.S. Black men, who make up 13 percent of the population
498 of men, are nearly twice as likely to get prostate cancer,
499 and are more than twice as likely to die once diagnosed. Yet
500 Black men make up only 5 percent of the participants in
501 prevention studies, and a strikingly low 2.4 percent of
502 participants in late-stage treatment studies.

503 I recently chaired a National Academies report on
504 improving representation in clinical trials and clinical
505 research. I would like to leave this committee with the
506 three main takeaways from that report.

507 Number one, failing to achieve a more diverse clinical
508 research ecosystem is costly. It costs us in terms of
509 scientific innovation and the generalizability of our
510 research. It costs us because it deprives patients of state-
511 of-the-art treatments that are often only available through
512 clinical trials. It costs us in the trust we seek to build
513 in the medical and scientific enterprise across all
514 communities in the U.S.

515 The data is clear that many want to participate in
516 clinical studies but are simply never asked. And it costs us

517 in dollars. Our economic analysis demonstrated that the
518 financial and social costs of health disparities in the U.S.
519 are in the range of hundreds of billions of dollars over the
520 next three decades. Addressing health disparities is
521 complex, but better representation in clinical studies may
522 help address this issue. And if only modestly so, the value
523 would be worth billions.

524 Number two, despite more than three decades of stated
525 commitment to this issue across Federal agencies, very little
526 progress has been made. This is an issue that seemingly
527 everyone supports, but no one is held accountable for its
528 progress. And yet Federal agencies operating in a
529 coordinated fashion could have immense power to improve
530 representation. The Federal Government is the largest funder
531 of research. It is the regulator of processes of scientific
532 research. It is the gatekeeper to monetizing scientific
533 discovery. And it is the purchaser of new drugs and devices.
534 More coherence in Federal policy to align investment and
535 accountability could achieve the goals of inclusive science.

536 Number three, Congress has a particularly important role
537 right now to move us beyond the status quo, to ensure a
538 coordinated Federal response to this issue across Federal
539 agencies, to increase accountability towards stated goals, to
540 ensure that we have adequate data collection so that we can
541 mark our progress in a transparent and open manner, and to

542 align incentives for all in the research ecosystem to enable
543 progress be made more quickly.

544 Whether you are motivated by the goal of producing the
545 highest quality science, or by pursuit of fairness and equity
546 in how science translates to better health for our patients,
547 or by the enormous economic toll of health disparities in the
548 U.S., I urge the committee to approach the issue of improving
549 representation and inclusion in clinical research with the
550 urgency it deserves.

551 Thank you very much.

552 [The prepared statement of Dr. Bibbins-Domingo follows:]

553

554 *****COMMITTEE INSERT*****

555

556 *Ms. Eshoo. The -- thank you, Dr. Bibbins-Domingo.

557 The chair now recognizes Dr. Croston for five minutes.

558

559 STATEMENT OF KEVIN CROSTON

560

561 *Dr. Croston. Chairman Pallone, Ranking Member McMorris
562 Rodgers, Chairwoman Eshoo, Ranking Member Guthrie, members of
563 the subcommittee, thank you for holding this hearing on the
564 Improving Trauma Systems and Emergency Care Act, H.R. 8163.

565 My name is Dr. Kevin Croston, I am the chair-elect of
566 the Trauma Center Association of America, also called TCAA.
567 I am the chief executive officer of North Memorial Health, a
568 health system in the Minneapolis/St. Paul area of Minnesota,
569 and a practicing general surgeon. Thank you for inviting me
570 to speak.

571 TCAA is a non-profit, 501(c)(6) association representing
572 trauma centers and systems across the country, and is
573 committed to ensuring access to lifesaving trauma services
574 and the financial health of our trauma centers.

575 For a little background, let me walk through a couple of
576 quick definitions.

577 Traumatic injury is the leading cause of death for
578 people under the age of 44, and the fourth leading cause of
579 death of all age groups in the United States, claiming more
580 than 270,000 lives annually. And in 1920 and 1921 [sic],
581 incidentally, COVID-19 surpassed traumatic injury as the
582 third leading cause of death.

583 According to the World Health Organization, the leading

584 causes of traumatic injury and death, including traffic
585 accidents, murder, and suicide, are expected to increase
586 substantially in the coming years, placing all three among
587 the top 20 causes of death in the world by 2030.

588 Trauma centers play a key role in reducing these
589 numbers. Care at a level 1 trauma center lowers by 25
590 percent the risk of death for injured patients, compared to
591 treatment received at non-traumatic centers. In other words,
592 the routine hospital emergency departments. This is because
593 trauma centers are uniquely qualified to provide
594 comprehensive, high-level acute care for patients with the
595 most extreme injuries, regardless of the -- a patient's
596 ability to pay. We have people waiting for their arrival,
597 and we have specialists, a panel of specialists, available at
598 all times.

599 Trauma systems are -- by contrast, they represent
600 comprehensive networks and infrastructure to provide optimal
601 care for injured patients, encompassing a wide spectrum, from
602 injury prevention efforts, coordinated pre-hospital care,
603 integrated networks of trauma centers for acute and
604 rehabilitative care, to a concerted research agenda.

605 Regarding patient access and trauma center financing,
606 there remains a significant geographic variation in the
607 availability and accessibility of trauma care. A little over
608 46 million Americans lacked access to a level 1 trauma center

609 within the golden hour, the 60-minute period following
610 traumatic injury during which there is the highest likelihood
611 that prompt medical procedures will prevent death.

612 This deficiency is particularly acute in our nation's
613 rural areas, as well as among some traditionally vulnerable
614 populations -- for example, minorities, recent immigrants, et
615 cetera, and trauma center closures disproportionately affect
616 communities with higher proportions of minorities, the
617 uninsured, and people living in poverty.

618 According to the -- an Avalere study commissioned by the
619 Trauma Center Association of America, trauma centers report
620 numerous financial pressures, including Federal payment
621 reductions; increased trauma care demands, particularly among
622 the geriatric population and from opioid-related trauma
623 cases; the need to cover vast geographic regions; difficulty
624 attracting and maintaining high-quality trauma physicians and
625 other staff due to the strains of the 24-hour trauma service
626 availability and the staffing crisis that resulted from
627 COVID-19.

628 The Improving Trauma Systems and Emergency Care Act,
629 H.R. 8163 -- in history, in 2010 Congress authorized hundreds
630 of millions of dollars per year in Federal grants to support
631 and sustain trauma care and systems nationwide. However,
632 Congress has not appropriated any of the funding authorized
633 for these programs. The Improving Trauma Systems and

634 Emergency Care Act would reauthorize, reorganize, and
635 modernize Federal grant programs for the purposes of awarding
636 pilot grants for trauma centers, supporting trauma care
637 readiness and coordination, and awarding grants to improve
638 trauma care in rural areas.

639 There are three areas of the Act. The pilot grants for
640 trauma centers requires the Assistant Secretary for
641 Preparedness and Response to award 10 multi-year contracts or
642 competitive grants to states, tribes, or tribal
643 organizations, or level 1, 2, or 3 trauma centers, or other
644 eligible entities or consortia. These strengthen the trauma
645 system coordination and communication. They improve
646 situational awareness, develop and disseminate evidence-based
647 practices across facilities, and conduct activities to
648 facilitate research.

649 It also lowers the barrier for entry by providing -- by
650 lowering awardees the current requirement in -- statutory for
651 Federal -- non-Federal matches from 1 for each \$3 of Federal
652 funds to 1 for every 5.

653 Grants to improve trauma care in rural areas
654 reauthorizes the Secretary of Health and Human Services to
655 improve trauma care in rural areas, and by supporting
656 research and demonstration projects.

657 And lastly, the trauma care readiness and coordination
658 piece of this legislation requires ASPR again to support

659 states and consortia to coordinate and improve emergency
660 services and trauma care during a public health emergency by
661 disseminating information in a more friendly way.

662 *Ms. Eshoo. Doctor --

663 *Dr. Croston. So, in conclusion --

664 *Ms. Eshoo. Your time has expired. You want to just
665 offer another sentence to close?

666 *Dr. Croston. Yes, thank you. Sorry about that.

667 Thank you again for your consideration of this important
668 legislation, and for the opportunity to testify before you
669 today. I am happy to answer any questions the subcommittee
670 may have. Thank you for your time.

671 [The prepared statement of Dr. Croston follows:]

672

673 *****COMMITTEE INSERT*****

674

675 *Ms. Eshoo. Thank you.

676 The chair now recognizes Ms. Gray Valbrun for your five
677 minutes of testimony.

678

679 STATEMENT OF TANIKA GRAY VALBRUN

680

681 *Ms. Valbrun. Chairman Pallone, Ranking Member McMorris
682 Rodgers, Subcommittee Chairwoman Eshoo, Subcommittee Ranking
683 Member Guthrie, and members of the committee, my name is
684 Tanika Gray Valbrun, president and founder of the White Dress
685 Project.

686 The mission of the White Dress Project is to raise
687 global awareness about the uterine fibroid epidemic through
688 education, research, community, and advocacy. It is my
689 absolute honor to testify in support of H.R. 2007, the
690 Stephanie Tubbs Jones Uterine Fibroids Research and Education
691 Act of 2021.

692 H.R. 2007 is named in honor of the late Congresswoman
693 Tubbs Jones, who not only championed women's health issues,
694 but also suffered from uterine fibroids herself. I am proud
695 to call her son, Mervyn Jones, who is here with us today, a
696 dear friend and supporter of the White Dress Project.

697 H.R. 2007 is a critical step to improve research into
698 this public health crisis, to garner data, and improve health
699 outcomes for those living with fibroids. The critical need
700 to address fibroids is neither a Democratic or Republican
701 issue, as demonstrated by the Senate companion bill, but it
702 is a health issue that impacts many women, whether they live
703 in rural or urban America.

704 According to NIH, the U.S. economic burden of fibroids
705 is estimated at \$34 billion annually. Yet scientists know
706 very little about the genomics that underlie uterine
707 fibroids.

708 As the only surviving child of a mother who lost twins
709 due to fibroids, my personal struggle with fibroids has been
710 debilitating, and gravely impacted my quality of life. Since
711 age 14, I have experienced heavy menstrual bleeding. I have
712 had more than six blood transfusions due to severe anemia. I
713 have had excessive cramping and bloating for much of my life,
714 and many times appearing to be more than four months
715 pregnant. I have missed out on social functions, time with
716 my family, days off work. I was nicknamed Bag Lady because I
717 would always have a bag of clothes with me, just in case I
718 had an accident. I have never bought a car with cloth seats,
719 only leather to easily remove stains; multiple days in the
720 month calling out sick from work because I was just too tired
721 to go; and never, ever wearing white.

722 I decided to seek treatment for my fibroids, and I was
723 told that I needed a hysterectomy the first time I saw a
724 doctor. I had to find more options, because I knew I wanted
725 to be a mother. In July of 2013 I had 27 grapefruit-sized
726 fibroids removed in an emergency surgery. In 2018 I had to
727 have another surgery for fibroids. And today, as I speak
728 before you, I still have fibroids. And it has impacted my

729 journey to be a mother.

730 After my surgery I knew that I wanted to be a champion,
731 so I started the White Dress Project. In research conducted
732 by our organization and Healthy Women, we found that race
733 plays a significant role in fibroid outcomes and quality of
734 life among women living with fibroids. They are more common
735 in Black women than White, Hispanic, or Asian women. And
736 fibroids typically develop in Black women at a younger age,
737 grow larger, and cause more severe symptoms than for women of
738 all other races.

739 Black women are more likely to be hospitalized, more
740 likely to have fibroids surgically removed, seven times more
741 likely to have a myomectomy, and two-and-one-half times more
742 likely to have a hysterectomy, compared to White women.

743 Fibroids also tend to have a disproportionate impact on
744 women living in rural areas. Typically in rural areas,
745 access to trained OB-GYNs who feel comfortable performing
746 certain procedures and appropriate testing is severely
747 limited.

748 I would also like to address the lack of diversity in
749 clinical trials. Genetic studies on fibroids, particularly
750 for Black women, have been limited for a variety of factors,
751 leaning toward a mistrust of the medical community as a
752 result of Tuskegee syphilis studies and the Henrietta Lacks
753 cancer cells processing. Thus I fully support H.R. 7845.

754 In conclusion, almost 20 years ago, in a 2007 op ed, the
755 late Congresswoman Tubbs Jones wrote, "Women deserve
756 better," and I absolutely believe they still do. By passing
757 H.R. 2007, Congress would be taking a step toward
758 prioritizing the health care and quality of life for women
759 across the United States.

760 A special, special thank you to Congresswoman Yvette D.
761 Clarke for her unwavering advocacy of this issue, and for
762 serving as a congressional champion.

763 To the committee, I sincerely thank you for listening to
764 my testimony today and your support of H.R. 2007 to improve
765 the lives of millions of women who are dealing with uterine
766 fibroids.

767 And thank you to everyone who has shared their story.
768 We must continue to share.

769 [The prepared statement of Ms. Valbrun follows:]

770

771 *****COMMITTEE INSERT*****

772

773 *Ms. Eshoo. Ms. Valbrun, thank you for your superb
774 testimony. You really honor our late colleague, Tubbs Jones,
775 and I want to welcome her son to our hearing today, as well.
776 So a very special thanks to you.

777 Mr. Shannon, you are recognized for your five minutes of
778 testimony.

779

780 STATEMENT OF MICHAEL D. SHANNON

781

782 *Mr. Shannon. Good morning, Chairman Pallone, Ranking
783 Member McMorris Rodgers, Ranking Member Guthrie, and
784 Chairwoman Eshoo, and members of the subcommittee. I am
785 speaking today as an expert witness on oversight and internal
786 controls reinforcing research security associated with
787 federally-funded research and development.

788 I am president of the Government Solutions for IPTalons,
789 Inc., which is a managed service risk and research security
790 company. I am formerly a member of the Senior Executive
791 Service and Director of the Office of Management Assessment
792 for the National Institutes of Health. I thank you for the
793 opportunity to appear before you, and discuss three pieces of
794 legislation related to disclosure requirements, participation
795 in foreign talent programs, and protecting America's
796 biomedical research enterprise.

797 I am not representing the NIH or the Federal Government,
798 but rather appear before you as a citizen with unique
799 knowledge of government oversight and expertise in the
800 subject matter at hand. Any comments I may make related to
801 operations in my statement here or during questions are
802 limited to my experience up to the time that I left my
803 position in January of 2021.

804 I left Federal service to engage more directly in the

805 protection of the U.S. research enterprise from risk
806 associated with non-compliant actions and malign foreign
807 activity intended to take advantage of those actions. I
808 joined my business partner, Allen Phelps, in building
809 IPTalons to provide specialized research security services,
810 training, and tools in support of this aim, as recognized
811 thought leaders in this area were regularly asked to assist
812 in identifying solutions balancing the burden on awardees
813 with the need for stewardship and accountable due diligence.

814 International collaboration is absolutely essential for
815 innovation, discovery, and the benefit of science to all
816 humankind. Transparency and reciprocity are the glue holding
817 mutually beneficial research relationships together. As with
818 any endeavor, trust and due diligence protects efforts and
819 promotes best outcomes.

820 I have provided an extended review of the legislation in
821 my written response, but would like to speak to some specific
822 points here.

823 We have all heard FBI Director Wray correctly say we
824 cannot arrest our way out of this issue. The rest of that
825 statement could be because the issue of conflicts of
826 interest, commitment, and foreign influence are often
827 primarily compliance issues. Early emphasis on criminality
828 rather than compliance resulted in many missed opportunities
829 and -- to remediate risk, and contributed to an inaccurate

830 perception of the actual scope and scale of the problem, by
831 pointing to just a few high profile events as indicia of a
832 smaller problem.

833 We have heard some tout resignations and terminations as
834 a sign of activity and success. However, a loss of a
835 researcher is not a win for anyone. Focus on terminations
836 and resignations often fails to address compliance, can lead
837 to a lost opportunity to understand the full impact of the
838 risk, and foments distrust among researchers and research
839 administrations. We advise a restorative approach. Focus
840 should be on restoring and maintaining compliance whenever
841 possible and appropriate among federally-funded research
842 programs and persons.

843 Unreported affiliations and support have been a
844 persistent problem for over two decades because of a lack of
845 consistent oversight and internal controls. Individuals and
846 nation state actors have exploited the open and collaborative
847 environment. The issue is one of individuals making
848 decisions, wittingly or unwittingly, influenced or
849 independently, leading to non-compliance.

850 Research security programs must be a part of the pre-
851 award process and periodic reporting cycle to identify
852 potential risk of unreported affiliations and support.
853 Applicant organizations and awarding agencies must better
854 validate certifications of complete and accurate submissions

855 at the application and throughout the life of the award.

856 There is concern about discriminatory activity targeting
857 specific persons and ethnicities. Avoiding prejudice is
858 essential, and focus on conduct is the only valid indicator
859 of misconduct. Unfortunately, these allegations have also
860 been used to deflect attention from exploitive activity. It
861 is important to understand that this issue is about conduct,
862 not culture. Allen and I have conducted thousands of
863 investigations on these issues. And although one state is,
864 by far -- nation state is, by far, the most prolific
865 offender, offenders are of all stripes.

866 Legislation, policy, and guidelines should focus on
867 requiring and enabling authorities to fix and find issues --
868 find and fix issues. Where violations of law is found,
869 proper referral is made. However, in most cases, restoration
870 to a compliant posture is possible.

871 As much as possible we must focus on the elimination of
872 risk, rather than people, because it is more appropriate to
873 the threat and essential to U.S. research, innovation to
874 retain those persons and their contributions mindfully and
875 accountably. Congress should demand stewardship and due
876 diligence on behalf of the U.S. taxpayer as a requirement for
877 an awarding agency and a condition for award recipients. The
878 bills before you take steps in the right direction.

879 I thank you for the opportunity to appear before you,

880 and I am happy to answer any questions you may have.

881 [The prepared statement of Mr. Shannon follows:]

882

883 *****COMMITTEE INSERT*****

884

885 *Ms. Eshoo. Thank you, Mr. Shannon.

886 I am now pleased to recognize Ms. Sweeney for your five
887 minutes of testimony.

888

889 STATEMENT OF DESIREE SWEENEY

890

891 *Ms. Sweeney. Thank you. First of all, I want to say
892 thank you, Chairman Eshoo, Ranking Member Guthrie, Chairman
893 Pallone, Ranking Member McMorris Rodgers, and members of the
894 committee. Thank you for the opportunity to testify today.

895 My name is Desiree Sweeney, and I am the chief executive
896 officer at NEW Health. We are a community health center
897 serving rural northeast Washington State. We were founded in
898 1978, and today we provide primary medical, dental,
899 behavioral health, and pharmacy services to more than 16,000
900 patients annually, and employ over 150 staff members. Three-
901 quarters of our patients are insured through Medicaid and
902 Medicare, or are uninsured. With -- 80 percent of our total
903 patients are low income. We operate seven medical and three
904 dental locations within our three rural counties, which are
905 connected by three mountain passes. One of our counties we
906 serve meets the frontier definition of fewer than seven
907 people per square mile.

908 NEW Health is part of a system of 1,400 community health
909 centers that make up the largest primary care network in the
910 nation, serving nearly 29 million patients.

911 Health centers have been able to thrive because of the
912 incredible support this committee has shown over the 50-year
913 history of the program. In the spring of 2020, NEW Health

914 purchased a mobile clinic that is equipped to provide both
915 medical and dental services. While we are rural, our
916 population is rapidly increasing, and we are at capacity and
917 utilizing the space of all of our locations, and are quickly
918 working to expand physical space.

919 As a health center serving communities in rural and
920 frontier communities, we have to also recognize that not all
921 of these communities can support a full time brick-and-mortar
922 site. Our new mobile clinic is a cost-effective alternative
923 that breaks down transportation and access barriers for our
924 patients by going beyond the traditional four walls of the
925 clinic. The communities that we serve are home to a high
926 number of older adults. Bringing health care services closer
927 to our patients' homes is essential to help patients gain
928 access to care.

929 While some of our communities have access to fiber
930 internet, the vast majority of our service area have
931 historically lacked internet and adequate cell phone signal.
932 Broadband infrastructure development is a high priority in
933 northeast Washington, but until we have better infrastructure
934 many residents have limited access to telehealth and must
935 access health care services in person. The mobile clinic
936 expands our ability to connect patients with health care.

937 Importantly, the mobile clinic allows for services to be
938 tailored to specific populations. When we evaluated our

939 community gathering locations in our rural communities to
940 evaluate where to -- we could take the mobile clinic, the
941 most common public locations included our K through 12
942 schools, our libraries, and our VFW halls.

943 With nearly 10 percent of our population residing in our
944 service area being veterans, some individuals are mistrustful
945 of a brick-and-mortar clinic, and we are hoping to reach
946 these patients through the mobile clinic when it is parked at
947 their local VFW.

948 Every year our region in Washington State is impacted by
949 wildfires. These camps are often set up in remote locations.
950 And if we could have that mobile clinic closer to that, then
951 we could ensure the safety of the firefighters.

952 I want to thank the committee for considering H.R. 5141,
953 the Mobile Health Care Act. I, along with National Health
954 Service, National Association and Community Health Centers
955 support this bill because it will authorize mobile units
956 specifically as part of HRSA's New Access Points Grant
957 authority. The bill will facilitate more mobile units and
958 provide greater care in the community.

959 I would also like to speak to the Building a Sustainable
960 Workforce for Healthy Communities Act. In 2023 we will bring
961 in community health workers in the role of a patient
962 navigator. Our navigators will focus on social determinants
963 of health by connecting patients with food, housing, and

964 other resources. It is important for these positions to
965 understand local needs and be a trusted resource.

966 Many of our patients rely on firewood in the winter
967 months, and we have even had patients who have run out of
968 firewood, and we were able to connect them to local
969 resources. Developing funding mechanisms to increase the
970 utilization of community health workers would help health
971 centers and other organizations in serving low-income and
972 vulnerable patients.

973 H.R. 8151 will ensure continued resources for the
974 important work of community health workers and support
975 primary care at 1,400 health centers across the country.

976 Again, I appreciate the opportunity to share my thoughts
977 and experiences from NEW Health as the committee debates
978 these pieces of legislation. I know our patients will
979 benefit from the new mobile clinic, and believe health
980 centers across the nation will also benefit with the mobile
981 act passed.

982 Additionally, H. 151 [sic] would able increased
983 utilization of community health workers.

984 Thank you, and I welcome any questions.

985 [The prepared statement of Ms. Sweeney follows:]

986

987 *****COMMITTEE INSERT*****

988

989 *Ms. Eshoo. Thank you, Ms. Sweeney.

990 The chair is now pleased to recognize Dr. Walker-Harding
991 for your five minutes of testimony.

992

993 STATEMENT OF LESLIE R. WALKER-HARDING

994

995 *Dr. Walker-Harding. Wonderful. Good morning, Chairman
996 Eshoo, Ranking Member Guthrie, and members of the
997 subcommittee. And thank you for convening this hearing on
998 this most important topic, and for inviting me as a witness.

999 My name is Leslie Walker-Harding, and I serve as chair
1000 of pediatrics at the University of Washington School of
1001 Medicine, and as senior vice president and chief academic
1002 officer at Seattle Children's Hospital. I am a practicing
1003 adolescent medicine pediatrician. I serve as an executive
1004 committee member of the Pediatric Scientists Development
1005 Program, run by the Association of Medical School Pediatric
1006 Department Chairs. And I serve as a member of the Steering
1007 Committee on the Coalition of Pediatric Medical Research.

1008 I will focus my testimony primarily on H.R. 3773, the
1009 Pediatricians Accelerate Childhood Therapies Act, which is
1010 led by Dr. John Joyce and my good friend -- and the only
1011 pediatrician serving in Congress today -- Dr. Kim Schrier.
1012 And that was co-led by another health policy leader from
1013 Washington State's delegation, Ranking Member McMorris
1014 Rodgers in the last Congress.

1015 The PACT act, as well as the NIH Clinical Trial
1016 Diversity Act, which is also on the agenda, focuses on three
1017 core principles that are needed to achieve more research

1018 breakthroughs for children and other populations.

1019 First, the PACT Act recognizes that a robust pediatric
1020 research workforce, including a pipeline that produces early
1021 career researchers, is fundamental to achieving breakthroughs
1022 that will lead us to new therapies and cures for children.
1023 Simply put, if we don't attract and retain the next
1024 generation of pediatric scientists to the field, children and
1025 adolescents will continue to suffer the effects of diseases
1026 and syndromes that impact them through adulthood.

1027 The PACT Act also recognizes that our pediatric research
1028 workforce needs to better reflect the diversity of our
1029 nation's children. The lack of diverse representation in
1030 pediatric researchers limits the diversity of questions asked
1031 and studied, resulting in fewer solutions to be applied to
1032 improve the health of all children.

1033 And the NIH Clinical Trial Diversity Act recognizes that
1034 our clinical trials need to better reflect our nation's
1035 population, particularly when it comes to the very patients
1036 that candidate therapies are intended to treat. The core of
1037 the PACT Act would authorize the National Institutes of
1038 Health to create a career development award that focuses on
1039 developing early career researchers who are focused on
1040 pediatrics, particularly those researchers from populations
1041 that have been historically under-represented in the field.

1042 Supported by the American Academy of Pediatrics and the

1043 Children's Hospital Association, let me briefly describe the
1044 challenges that we are navigating. Developing our next
1045 generation of researchers is a top priority of my
1046 institution. We have several programs focused on this
1047 initiative.

1048 To attract a wide range of early career scientists with
1049 diverse lived experience at Seattle Children's, we created
1050 three-year awards to support MDs and PhDs just after the
1051 completion of their post-graduate training, so they can
1052 benefit from mentorship and funded need -- needed to be
1053 successful in acquiring NIH funding. Unfortunately, programs
1054 developing promising pediatric researchers into impactful
1055 scientists are not sustainable or feasible for most academic
1056 or children's hospital programs to fund indefinitely. We
1057 need the PACT Act to supplement what our institution and
1058 others are doing.

1059 Pediatric research faces a number of particular
1060 challenges that are unique or more pronounced compared to
1061 other fields. Children are a smaller proportion of the
1062 overall population, and thus pediatrics has a more
1063 challenging time competing against fields focused on adults.
1064 Children's hospitals are more heavily reliant on public
1065 programs, notably Medicaid and CHIP, which pay less than
1066 commercial payers and Medicare, and often do not cover the
1067 full cost of clinical care, leaving less revenue to devote to

1068 research activities.

1069 To fix these challenges, I urge Congress to enact the
1070 PACT Act, which would create a career development award
1071 program to support outstanding early career researchers
1072 focusing on pediatric research. Awards would go to
1073 individual researchers, and could also support training
1074 programs involved -- involving research entities and
1075 minority-serving institutions to help develop more
1076 researchers from under-represented populations. By focusing
1077 awards on individual researchers, the program would favor --
1078 not favor only those in largest institutions, but cast a
1079 broad net for talent.

1080 You might ask, "Why now?" Not acting now to create
1081 this opportunity that builds upon the 21st Centuries Act
1082 [sic] would only set us further back in the overall health of
1083 the nation. Science is at a crossroads with technological
1084 advances and with ARPA-H passing the House last week. The
1085 country is poised to leap ahead with biomedical innovation,
1086 as we did in technology with DARPA. A shortage of pediatric
1087 researchers to engage in this scientific renaissance will
1088 prevent us from realizing our potential to discover major
1089 breakthroughs and cures for children that result in advances
1090 over the lifespan.

1091 I thank you for including the PACT Act on this agenda,
1092 and I look forward to answering any questions on the bill.

1093 [The prepared statement of Dr. Walker-Harding follows:]

1094

1095 *****COMMITTEE INSERT*****

1096

1097 *Ms. Eshoo. Thank you, Dr. Walker-Harding.

1098 And to each of our witnesses today, you have more than
1099 enhanced this hearing with your expertise.

1100 We will now move to members' questions. I recognize
1101 myself for five minutes, first to Dr. Bibbins-Domingo on
1102 clinical trial diversity.

1103 Doctor, the House recently passed the DEPICT Act
1104 legislation that I wrote to increase clinical trials
1105 diversity by requiring drug sponsors to submit to the FDA a
1106 diversity action plan for later-stage pivotal trials. Would
1107 you share for a moment why it is important for researchers to
1108 also consider and plan for diverse participants in earlier
1109 trials, including trials funded by the NIH?

1110 And do you support 7845 and 6586 becoming law? And if
1111 you don't, why?

1112 *Dr. Bibbins-Domingo. Thank you very much for those
1113 questions.

1114 I am really pleased that there -- at the efforts to spur
1115 the type of diversity and inclusion in trials from the drug
1116 companies that are seeking approval from the FDA. To really
1117 achieve our goal, though, we have to have diversity and
1118 inclusion at all phases of research. And that is why it is
1119 very important that there be a focus on the NIH. The NIH is
1120 the largest funder of the research that really underlies all
1121 of our drug discovery. It is the basis on which we know

1122 information that goes into how we develop drug trials.

1123 Quite simply, we need to have studies in the populations
1124 for whom our drugs, our devices, all of our innovations are
1125 intended. And so from purely a standpoint of
1126 generalizability, we should be including the populations who
1127 are affected by the diseases and the conditions that we are
1128 seeking to try to understand, and then develop drugs,
1129 devices, other interventions to be able to do. So a focus on
1130 the NIH is very appropriate.

1131 Simple things like genetic diversity, which one of the
1132 speakers talked about, our genetic studies are mostly in
1133 White populations. And so just on that basis alone, we are
1134 often times not considering the full diversity and
1135 heterogeneity that might underlie genetic basis for some
1136 types of conditions --

1137 *Ms. Eshoo. Great, thank you very much.

1138 To Dr. Walker-Harding on pediatric research, I was
1139 really taken aback to learn from your testimony that, despite
1140 being several years into recruitment of the NIH's precision
1141 medicine All of Us program, that the program has yet to
1142 implement a child recruitment strategy. After the delay of
1143 the COVID vaccine for the pediatric population, I think that
1144 there are many Americans that are fed up with kids being a
1145 second thought when it comes to medical research.

1146 What should the NIH be doing to include more children in

1147 All of Us?

1148 And how will the PACT Act improve pediatric research?

1149 *Dr. Walker-Harding. Wonderful. Thank you. Yes, I
1150 share some of the same feelings.

1151 I think one of the things is to think about kids. A lot
1152 of times, as I mentioned, there are so many more adult
1153 illnesses and people working in adult medicine that
1154 pediatrics sometimes is thought of second, and especially in
1155 research. Even in the IRB, people worry, should we be
1156 looking at kids first? Shouldn't we look at adults? It is
1157 safer. It -- you know, it is just different. It is not
1158 safer.

1159 *Ms. Eshoo. But what should the --

1160 *Dr. Walker-Harding. And I --

1161 *Ms. Eshoo. -- NIH -- excuse me --

1162 *Dr. Walker-Harding. Yes.

1163 *Ms. Eshoo. What should the NIH be doing to include
1164 more children in this program, which is called All of Us?

1165 *Dr. Walker-Harding. I think we have to start putting
1166 the plans together to actually have them start being
1167 recruited, doing the actual work.

1168 I think there has been a lot of time in planning, and
1169 less in doing -- actually just signing people up and getting
1170 them there. The people are there. People want to enroll
1171 their kids. We just have to start doing it.

1172 *Ms. Eshoo. Okay, well --

1173 *Dr. Walker-Harding. And I think the PACT Act -- what I
1174 would say, too -- the PACT Act is important because we need
1175 the researchers who are interested in pediatric research
1176 ready, and standing ready to interpret and make sense out of
1177 the data that is collected.

1178 *Ms. Eshoo. Okay. Thank you very much.

1179 I will yield back and recognize the ranking member of
1180 the -- of our health subcommittee, Mr. Guthrie, for your five
1181 minutes of questions.

1182 *Mr. Guthrie. Thank you, Madam Chair. What a great
1183 hearing, and what wonderful testimony: pediatric research;
1184 focusing on women's health; diversity in our studies to make
1185 sure we get our studies that reflect the makeup of America is
1186 absolutely important. So thanks for doing that.

1187 I am going to focus on the security of our intellectual
1188 property and NIH in my questions. And these are to Mr.
1189 Shannon.

1190 You know, there was an IG study that looked at 770
1191 grantees, 617 responded. Two-thirds of the respondents found
1192 certain issues with disclosure about investment in foreign --
1193 of the proper disclosures. That means 153 didn't even
1194 respond. And I think, being a statistics person myself, you
1195 can probably figure that population is biased by people who,
1196 if you didn't respond, either you just didn't make the effort

1197 or you have something to hide for not responding. So I think
1198 we could even assume it is a higher number than two-thirds.

1199 So the question is, why isn't the NIH taking this more
1200 important -- making it more important to them? It just --
1201 are they willfully turning their eye? Is it -- or are they
1202 just indifferent, and why is this such an issue that we
1203 [inaudible] before?

1204 And also, I think, as we move these bills forward, if
1205 153 grantees just don't respond to the IG, maybe we should
1206 look at banning them from future research if they don't
1207 respond to the IG as we move forward.

1208 But -- so Mr. Shannon, why is the NIH so lax in this
1209 area?

1210 *Mr. Shannon. Well, there are a couple of thoughts to
1211 that.

1212 I don't think it is a willful -- necessarily, in all
1213 cases, a willful desire to avoid answering the question. I
1214 think, first, the question has not been asked for quite some
1215 time.

1216 I also think that it is difficult to have a cohesive
1217 plan when there is no specific cohesive strategy to address
1218 this.

1219 Awardee compliance absolutely should be -- they should
1220 be held accountable for compliance. And they have
1221 requirements under the grants policy statement and the grant

1222 agreement that they have signed to receive those funds. And
1223 the --

1224 *Mr. Guthrie. Well, let me just -- I am going to
1225 interrupt.

1226 *Mr. Shannon. Yes, sir.

1227 *Mr. Guthrie. But you said that this question hasn't
1228 been asked in quite some time. It is asked in every grant,
1229 isn't it?

1230 *Mr. Shannon. Oh, that is correct.

1231 *Mr. Guthrie. Okay.

1232 *Mr. Shannon. I was specifically thinking of the
1233 question of conflicts of interest and the like that -- those
1234 questions are asked in general in every grant. And some of
1235 the legislative efforts here today get more specific,
1236 although I caution against specific titles for various
1237 programs, because, on a wider perspective, to avoid that, you
1238 just change the title.

1239 But awardees struggle from everything from the increased
1240 burden of being able to provide this oversight. Their sense
1241 that I am hearing from them often times is, well, this hasn't
1242 been something that has been paid attention to. And that is,
1243 quite frankly, true. There has not been an initiative to
1244 provide the type of in-depth oversight or accountable process
1245 to audit whether or not -- and validate and verify whether or
1246 not those certifications are complete and accurate when they

1247 are answering that question.

1248 So -- and we see the numbers even larger, perhaps, that
1249 -- based on our company's investigative research, just our
1250 data alone, indicate that up to 85 percent of U.S.-based
1251 researchers with federally-funded research have some type of
1252 foreign affiliation that is -- may not be reported. Now, not
1253 all of those are -- that is not an indictment of anyone. Not
1254 all of those are bad. But those all indicate the potential
1255 for non-compliance. And that is why my emphasis was on
1256 compliance.

1257 *Mr. Guthrie. Thank you. I think -- yes, I was going
1258 to ask you that next. Just because it has foreign
1259 connections doesn't make it necessarily bad research.

1260 What do you think the risk is of -- out there, since we
1261 are not getting the disclosure we are supposed to be
1262 receiving? And hopefully these bills will actually force NIH
1263 to do that.

1264 What do you think the risk is out there that, if
1265 researcher A is working with researcher B that has -- in a
1266 common interest to solve a problem for humanity that is --
1267 from a foreign country, that is fine. But if researcher A is
1268 working with researcher B, who is from an antagonistic
1269 country, or a country that is an adversary for ours, that is
1270 an issue and risk. What do you think is the actual risk out
1271 there?

1272 I have about a minute left, less than a minute. If you
1273 would just talk about the actual risk that we are facing, and
1274 I will yield back after you finish.

1275 *Mr. Shannon. Certainly. The risk is substantial,
1276 particularly from non-compliance. The key is transparent and
1277 reciprocal relationships. Everybody wants international
1278 collaborations. We all benefit from that, and that is the
1279 way it should be. But when that relationship is not
1280 transparent or reciprocal, or an individual is seeking to
1281 benefit themselves as a result of that, that is where you
1282 fall into problems. So the risk is --

1283 *Mr. Guthrie. And how common do you think that is? I
1284 am sorry. How common do you think that is -- the second
1285 version you just said.

1286 *Mr. Shannon. As I said, our data suggests 85 percent
1287 have some type of foreign affiliation. The percentage of
1288 those who are doing that intentionally to enrich themselves
1289 is probably at about five percent, based on our investigative
1290 data.

1291 *Mr. Guthrie. Okay. Thank you. Thank you, you
1292 finished right on time.

1293 My time is up and I yield back. Thank you, Madam Chair.

1294 Thanks for your testimony, and all of the other
1295 witnesses, as well.

1296 *Ms. Eshoo. The gentleman yields back. The chair is

1297 now pleased to recognize the chairman of the full committee,
1298 Mr. Pallone, for your five minutes of questions.

1299 *The Chairman. Thank you, Chairwoman Eshoo. My
1300 questions are related to the NIH Clinical Trial Diversity Act
1301 of 2022.

1302 Earlier this year we considered clinical trial diversity
1303 policies in the FDA user fee package. And without clinical
1304 trial diversity, we lack robust data on the very groups that
1305 the drug device or biological product was intended to help,
1306 and the populations most impacted by certain diseases. So I
1307 wanted to ask Dr. Bibbins-Domingo.

1308 In your testimony you say that Congress has a particular
1309 role right now to move us beyond the status quo. And I
1310 wanted to ask, what is the role that Congress has, in your
1311 opinion?

1312 And then what is the cost of not improving diversity in
1313 clinical trials, economically and otherwise, if you would?

1314 *Dr. Bibbins-Domingo. Yes, thanks for that question. I
1315 think what is lacking is coordination across the various
1316 agencies, Federal agencies, that have a responsibility for
1317 funding, for regulating, and for oversight of our clinical
1318 research enterprise.

1319 Right now, one of the most shocking things in our report
1320 was that we couldn't find the information. You can't find
1321 the information right now today on how many -- on the

1322 demographics of people who participate in clinical research
1323 in the U.S. You can find from the FDA those drugs that have
1324 been approved, and the demographics of those, but we don't
1325 know anything about all of the studies that are out there.
1326 It is very hard to find those things, even with
1327 clinicaltrials.gov reporting.

1328 And so I would urge there be an annual report to
1329 Congress. That is one of the recommendations in our report
1330 that has -- across these agencies can really highlight across
1331 various characteristics, demographic characteristics,
1332 regional characteristics, participation in the clinical
1333 research enterprise, the progress that is made over time
1334 because that is what is needed. The data, the
1335 accountability, and the reporting is needed in order for
1336 these Federal agencies to work together to achieve these
1337 goals.

1338 *The Chairman. All right. Thanks a lot. I wanted to
1339 shift gears and speak briefly about some of the barriers to
1340 care that low-income populations face, and how H.R. 5141 --
1341 that is Representative Lee's Mobile Health Care Act -- may
1342 help to improve access.

1343 So, Ms. Sweeney, in your testimony you mentioned that
1344 NEW Health serves -- or N-E-W Health service -- serves a
1345 rural area where transportation is a problem. And given the
1346 low-income population you serve, I assume a lot of your

1347 clients don't have access to reliable transportation. Is
1348 that right?

1349 I mean, you can just say yes or no, but is that correct?

1350 *Ms. Sweeney. Yes, that is correct.

1351 *The Chairman. Okay.

1352 *Ms. Sweeney. We do not have public transportation.

1353 *The Chairman. All right. So can you describe how you
1354 have been able to use your new mobile health unit to increase
1355 access to care?

1356 *Ms. Sweeney. So we received our mobile unit. We
1357 ordered it in 2020. And because of manufacturing we received
1358 it just recently this year. And so we are currently using
1359 that programing. So we haven't rolled it out to date, but
1360 when we do that programing, then we will definitely address
1361 that. So we have already done the planning and the
1362 conversations.

1363 And you know, food banks are one area that we have
1364 really identified that patients can access. And so we have
1365 already talked to our stakeholders and partners at food
1366 banks, the K-through-12 schools, and the VFWs to get that
1367 programing. So that will be one way that we have -- you
1368 know, we will be able to address those barriers.

1369 And then the second way, as we learned during the
1370 pandemic, when we really needed to get out into hot spots and
1371 hot zones, we can definitely deploy that out into our units.

1372 And so we have already worked with our local health district
1373 to identify future opportunities to support health needs as
1374 they arrive.

1375 *The Chairman. All right, then. Let me ask you one
1376 more -- one last question.

1377 Your clinic used Federal COVID funds to set up the
1378 mobile clinic, but the Mobile Health Care Act, you know,
1379 Representative Lee's bill, would allow the New Access Points
1380 funds to be used to establish similar mobile clinics.

1381 So how important was this Federal funding in helping NEW
1382 Health to set up a mobile clinic? I mean, would you have
1383 been able to do it without it?

1384 *Ms. Sweeney. We would not. We had been watching and
1385 had internal strategy conversations to how would we be able
1386 to afford a mobile unit. We identified a need, but we just
1387 weren't able to bring it on with the funding that we had.

1388 And so, with the opportunity of the COVID funding, we
1389 were actually able to bring that need and that service line
1390 into our communities.

1391 *The Chairman. I am just asking you, because I think,
1392 you know, we want to highlight that, you know, Federal
1393 support is critical to help, you know, that that is really
1394 important, you know, in order for you to get up and running,
1395 and others that would be similarly affected. So thanks
1396 again.

1397 Thank you, Madam Chair.

1398 *Ms. Sweeney. Thank you.

1399 *Ms. Eshoo. The gentleman yields back.

1400 The chair now recognizes the ranking member of the full
1401 committee, Mrs. McMorris Rodgers, for your five minutes of
1402 questions.

1403 *Mrs. Rodgers. Thank you, Madam Chair. I join in
1404 thanking all the witnesses for your testimony today. Very
1405 helpful and insightful. I wanted to start with Mr. Shannon.

1406 The Protect America's Biomedical Research Enterprise Act
1407 requires the Department of Health and Human Services to
1408 evaluate ways to better protect intellectual property and
1409 sensitive medical information used in biomedical research
1410 from national security risk and related threats. Would you
1411 explain the differences between compliance research and
1412 security and research as it relates to foreign influence and
1413 other conflicts?

1414 And do you think that there needs to be more awareness
1415 in the research community about these differences?

1416 And what are the roles of the individual research
1417 institutions and academia versus the role of Federal agencies
1418 in these matters?

1419 *Mr. Shannon. Certainly. Thank you for the question.

1420 So there is a difference between research integrity and
1421 research security, and that is kind of a distinction that I

1422 think your question gets after.

1423 Research integrity. I had a conversation with Dr.
1424 Nakamura when I first joined NIH. He was the director of the
1425 Center for Scientific Review, and he was concerned about
1426 misconduct among scientists. And I said, "What kind of
1427 misconduct, like data manipulation or plagiarism?"`

1428 He said, "No, that is research integrity.`" And so he
1429 explained that we were talking about scientist -- non-
1430 scientific misconduct.

1431 Well, fortunately, we came up with a much easier way to
1432 say that: research security. Research security focuses on
1433 the protection of the information, the -- ensuring that the
1434 access to information is not abused, and that the process has
1435 integrity, but for the purpose of ensuring that it is a
1436 closed system.

1437 So when you -- when an awardee or an applicant submits a
1438 grant application to the peer review, for example, that they
1439 know that their intellectual property is going to be
1440 protected by the agency they have submitted it to, and trusts
1441 that they will get a fair hearing, and there will be a fair
1442 playing field. We know that that has not always been the
1443 case. Peer review is an amazing process, but it has some
1444 vulnerabilities.

1445 Similarly, at the university level or at the awardee
1446 level, whether it is lab or university, the integration of a

1447 security review into the pre-award process is almost never
1448 done. It is starting to be done. But prior to recent
1449 events, it has not been.

1450 And so why is that important? Well, there are
1451 implications when you receive certain types of awards that
1452 can affect the cost on that award. And research security is
1453 one of those, depending on the level and sensitivity of the
1454 award to be granted.

1455 So it also encompasses things like ITARs and CFIUS
1456 protection of information that might be limited or restricted
1457 by Commerce or the State Department.

1458 *Mrs. Rodgers. Okay.

1459 *Mr. Shannon. So all of those things, rolled in,
1460 contribute to the security posture.

1461 *Mrs. Rodgers. Thank you. I -- as you know, the Fix
1462 Nondisclosure of Influence in Health Research Act, H.R. 5442,
1463 requires NIH to report actions taken to ensure compliance
1464 with foreign influence disclosure requirements. However,
1465 there are many non-compliance cases which do not include
1466 questions of undisclosed conflicts.

1467 Are there other areas vulnerable to conflicts that would
1468 benefit from increased transparency and disclosure, such as
1469 the peer review process?

1470 *Mr. Shannon. Definitely the peer review process, and
1471 certainly, at the awardee level, those persons submitting

1472 those applications need to -- there needs to be a way -- and
1473 there is -- to vet and identify or verify what is disclosed.
1474 Right now it is an honor system. And most people are
1475 honorable within that system. However, when it is purely an
1476 honor system, those who are dishonorable tend to be able to
1477 take advantage of that.

1478 I would also say it is important that not just at the
1479 award level do you need to have that kind of protection, but
1480 also intramural programs. NIH, for example, has a very large
1481 intramural program. They are faced with the same challenges
1482 as the research awardee community. So that is --

1483 *Mrs. Rodgers. Thank you.

1484 *Mr. Shannon. -- another area that I would point out.

1485 *Mrs. Rodgers. Good, good. I appreciate your insights
1486 there. I just have some other questions I want to ask, too.

1487 *Mr. Shannon. Certainly.

1488 *Mrs. Rodgers. Ms. Sweeney from my district, the Rural
1489 Telehealth Access Task Force Act will create an inter-agency
1490 task force to help identify barriers to telehealth services
1491 in rural areas. I wanted to ask if you would speak to how
1492 NEW Health has utilized telehealth, and any barriers that you
1493 have faced along the way.

1494 *Ms. Sweeney. Yes. I think one of the most important
1495 things is to recognize, as you know, being in our district,
1496 many of our constituents still have dial-up internet and cell

1497 phone service is not 5G, it is 3G at best, if we have
1498 service. So thank you for that question.

1499 Broadband investments are critically needed for how --
1500 for our service area. And I support this bill because it
1501 would look at how we address barriers to adoption of
1502 telehealth. So even at the height of our pandemic, our
1503 telehealth was about four percent of our patient population,
1504 at best, and the majority of those were telephonic because
1505 our patients just did not have access to that. And so, you
1506 know, we really understand those challenges, and broadband is
1507 just such a challenge.

1508 One thing I want to address, too, is the lack of
1509 infrastructure. And so --

1510 *Ms. Eshoo. The gentlewoman's time has expired. This
1511 is an important area. Maybe someone else can continue
1512 pulling this thread. So we need --

1513 *Mrs. Rodgers. Thank you.

1514 *Ms. Eshoo. -- to go to -- yes.

1515 *Mrs. Rodgers. I yield back.

1516 *Ms. Eshoo. The gentlewoman yields back to -- the chair
1517 recognizes the gentleman from North Carolina, Mr.
1518 Butterfield, for your five minutes of questions.

1519 *Mr. Butterfield. Thank you, and good morning, Madam
1520 Chair. It is good to see all of you this morning. And thank
1521 you to the chair for your leadership. And thank you for

1522 convening us, and just leading this subcommittee into great,
1523 great destinations. You have done great work during this
1524 session, and we thank you so very much.

1525 And to the chairman of the full committee, and to both
1526 of the ranking members, thank you as well for your service.

1527 This committee -- let me just say to the witnesses --
1528 and thank you for your testimony. I heard all of your
1529 testimonies, and they were very powerful and very relevant.
1530 And just thank you for your resource and for your intellect.

1531 Let me just start with Dr. Bibbins-Domingo.

1532 Dr. Domingo, this committee has a very, very strong
1533 record of supporting clinical trial diversity measures. And
1534 I am so glad to see the NIH Clinical Trial Diversity Act's
1535 inclusion in today's hearing is now before us.

1536 I have worked with Dr. Francis Collins over the years,
1537 and we are going to miss him dearly. But every time we met
1538 with Dr. Collins he would always stress the importance of
1539 including minorities -- African Americans, if you will -- in
1540 clinical trials. And so this bill that we have today will
1541 help move the needle on health disparities by building on
1542 NIH's current work to strengthen participation in clinical
1543 trials by unrepresented populations.

1544 And so my question to you is, in your testimony you
1545 stated that lack of representation may compound low accrual
1546 that causes many trials to fail. You also stated that under-

1547 represented populations are just as likely to want to
1548 participate in clinical trials as other groups, if they are
1549 given that opportunity. And so I am interested in the
1550 connection, if you will, between these two statements.

1551 *Dr. Bibbins-Domingo. Yes, thank you very much. It is
1552 often times a misunderstanding to say that we face the state
1553 of under-representation because these communities and these
1554 populations don't want to participate in studies. And we
1555 often talk about the past wrongs. Those are really important
1556 issues, and we have to do everything to build trust.

1557 But the data on this is quite clear, that when people
1558 are asked, minority populations are no more likely or less
1559 likely to want to participate in studies. And in fact, in
1560 many cases for conditions that they are affected by, they are
1561 more likely to want to participate. We do --

1562 *Mr. Butterfield. Well, can you explain --

1563 *Dr. Bibbins-Domingo. -- have to address many of the
1564 barriers --

1565 *Mr. Butterfield. Yes, that is --

1566 *Dr. Bibbins-Domingo. Go ahead.

1567 *Mr. Butterfield. Yes. Can you explain how NIH
1568 Clinical Trials Diversity Act will encourage participation in
1569 early-stage clinical trials, and how that participation will
1570 help solve the problem?

1571 *Dr. Bibbins-Domingo. Yes. I think that we have to

1572 basically not put the burden on the communities that are not
1573 participating, but rather put those processes in place at the
1574 funding level at the NIH, and then with the investigators to
1575 say this is a priority, and therefore we need to invest and
1576 enroll these populations and, as funders, need to hold those
1577 accountable who have received NIH funding.

1578 And I think, by --

1579 *Mr. Butterfield. Thank you.

1580 *Dr. Bibbins-Domingo. -- setting the clear targets,
1581 this will achieve those goals.

1582 And I do think this is also an issue of accrual for
1583 trials. As you probably know, many trials don't reach their
1584 accrual targets. And it is important that, if we build the
1585 infrastructure to enroll the populations that should be
1586 represented, we likely will have more of an opportunity to
1587 actually reach those targets.

1588 *Mr. Butterfield. Thank you. Let me now move over to
1589 Dr. Walker-Harding.

1590 Dr. Harding, I would like to pivot, if I can, to the
1591 research security policies before us today. Research
1592 security. The contributions of immigrants to the American
1593 scientific landscape cannot be understated. Since the year
1594 2000, American immigrants have won 39 percent of U.S. Nobel
1595 Prizes in physics and chemistry and medicine. It is clear
1596 that our nation's institutions and universities benefit

1597 greatly from foreign biomedical workers.

1598 And so the bills before us seek to promote the security
1599 of federally-funded biomedical research by evaluating better
1600 ways to protect intellectual property and sensitive medical
1601 information and other biomedical research and development of
1602 products from national security risk and threats. And so I
1603 agree that we must protect our research enterprise, but we
1604 must do so with a balanced approach that does not impede
1605 America's position as a trustworthy global partner and
1606 leader.

1607 It looks like I am running out of time. I am not going
1608 to be able to get through my question, Madam Chair. I am
1609 very respectful of time, and so thank you so very much. I
1610 yield back.

1611 *Ms. Eshoo. The gentleman yields back. And thank you,
1612 Mr. Butterfield. We are just going to so miss you. I don't
1613 know how else to say it. You are such a --

1614 *Mr. Butterfield. Thank you.

1615 *Ms. Eshoo. -- really a high-value member of our
1616 subcommittee. Thank you to you.

1617 *Mr. Butterfield. Thank you so much.

1618 *Ms. Eshoo. The chair is pleased to recognize one of
1619 the doctors on our subcommittee, Dr. Burgess of Texas, for
1620 your five minutes of questions.

1621 *Mr. Burgess. Thank you, Chair Eshoo. Thank you for

1622 having this hearing today.

1623 Every one of these witnesses today is fascinating.
1624 There won't be enough time to get to all the questions that I
1625 have in front of me. And I would just tell each of you, you
1626 can expect questions for the record to be coming your way.

1627 I just want to underscore something that our ranking
1628 member, Cathy McMorris Rodgers, said at the outset of this
1629 hearing. We are -- we have got 11 public health bills in
1630 front of us. Most of them will concern the Department of
1631 Health and Human Services, the National Institute of Health,
1632 and we have no Administration witnesses in front of us. And
1633 in fact, over the term of this Congress we have had very
1634 little in the way of participation of Administration
1635 witnesses at a time when we are in a once-in-a-century
1636 pandemic.

1637 And Chairman Pallone, I have written to you several
1638 times about what appears to be the passivity of this
1639 committee -- which is unfortunate, because we are one of the
1640 premiere research committees in the United States House of
1641 Representatives. But we -- I don't feel we have done our
1642 work.

1643 Today we had an opportunity to perhaps hear from some of
1644 those agencies. But again, we are not. We do have good
1645 witnesses, and I don't want to diminish what they are
1646 bringing to the discussion, but there is a lot of work that

1647 is left undone.

1648 And so let me just point out that Chairwoman DeGette, in
1649 an Oversight and Investigations Subcommittee hearing a year
1650 ago promised a hearing -- promised to me, individually -- a
1651 hearing on the originations of the coronavirus, the COVID
1652 origination hearing. And to the best of my knowledge, we
1653 have not had such a hearing. And again, we desperately need
1654 it.

1655 Mr. Shannon, who is with us here today, certainly your
1656 expertise is one that we value. I think you bring a lot to
1657 the discussion. Let me just ask you, since you worked at the
1658 NIH until January of 2021, do you think the NIH considers
1659 itself to be a leader in global health research?

1660 *Mr. Shannon. I do. NIH is a global collaborator, and
1661 rightfully so.

1662 I think the -- although I think the U.S. is more
1663 innovative than most, it doesn't have a corner on the market
1664 of good ideas. So I think that is an important
1665 consideration, that we must have international collaboration.
1666 But we have got to do our due diligence to protect that
1667 collaborative relationship, and make sure that it is
1668 transparent and reciprocal.

1669 And there are some -- there are solutions. You know, a
1670 national research security standard, for example, would be
1671 very helpful to help NIH have a cohesive strategy, and even

1672 consideration of expansion of the IG opportunity. So there
1673 are things that can be done to help NIH be even more diligent
1674 in their global activities, which are absolutely necessary to
1675 the benefit of our research and development enterprise.

1676 *Mr. Burgess. Well, thank you. You actually
1677 anticipated and answered my next question, but it just
1678 underscores the point: the NIH is going to be collaborating
1679 with foreign entities and researchers, and we have to have
1680 the proper measures and procedures in place to -- certainly
1681 to protect Americans. But as we have seen in the global
1682 pandemic, we want to be certain we protect the world at
1683 large.

1684 Let me just ask you this. To your knowledge -- and I
1685 realize that you concluded your term in January 2021 with the
1686 NIH, but did the United States federally fund gain of
1687 function research?

1688 *Mr. Shannon. I -- sir, I have no idea. I am not -- I
1689 wasn't privy to any of the discussions on the scientific side
1690 of things. I was oversight and compliance.

1691 A question on whether or not a grant was appropriately
1692 used on any type of deliberative research would be brought
1693 through the extramural research compliance arena.

1694 *Mr. Burgess. Well, let me -- my time is going to run
1695 out, so let me ask you this question. Would it have been
1696 appropriate to engage in this type of research in an

1697 adversarial country?

1698 And I think we have to agree that China, Russia, and
1699 Iran would be adversarial countries. Would that be
1700 problematic, if research was conducted in one of those labs?

1701 *Mr. Shannon. Again, sir, I think there are
1702 circumstances where international collaboration may include
1703 countries that are adversarial or not.

1704 You know, again, the decision and discussion process
1705 through the peer review and the laws and requirements that
1706 allow what type of research to be done, I don't have
1707 knowledge on whether or not --

1708 *Mr. Burgess. Let me --

1709 *Mr. Shannon. -- that grant in particular, the focus --

1710 *Mr. Burgess. -- because it was two years ago the city
1711 of Houston, where the Chinese consulate -- they had to call
1712 the fire department, because they were burning records in
1713 open trash barrels. And apparently, the fire was so large
1714 that it attracted attention.

1715 *Ms. Eshoo. The gentleman's time has expired.

1716 *Mr. Burgess. Well, I will follow up, Mr. Shannon, in
1717 writing.

1718 [The information follows:]

1719

1720 *****COMMITTEE INSERT*****

1721

1722 *Mr. Burgess. But I mean, it is this type of activity
1723 that leads the casual observer to be suspicious of some of
1724 these actions.

1725 And I thank our witnesses, all of our witnesses.

1726 *Ms. Eshoo. The gentleman yields back.

1727 It is a pleasure to recognize the gentlewoman from
1728 California, Ms. Matsui, for your five minutes of questions.

1729 *Ms. Matsui. Thank you very much, Madam Chair, for
1730 holding this hearing. And thank you for the witnesses for
1731 your testimonies today. I know five minutes goes quite
1732 quickly, so I will just jump into the questions.

1733 Ms. Sweeney, this is for you. A growing number of
1734 health care organizations have hired community health workers
1735 to provide social support, care coordination, and advocacy
1736 for high-risk patients. These workers are often trusted
1737 individuals from local communities who understand how people
1738 live and work.

1739 Ms. Sweeney, why is this local perspective important for
1740 the work of your patient navigators?

1741 And does having a workforce that reflects the community
1742 impact your health center's ability to provide whole-person
1743 care?

1744 *Ms. Sweeney. Yes. So I do believe that the community
1745 health workers can better facilitate improved health outcomes
1746 because it is a natural trust within many of our communities,

1747 whether they are rural patients -- you know, we talk about
1748 equity for our immigrant patients, people of color. Everyone
1749 can really talk about their journey.

1750 And so helping them support and identify resources --
1751 because sometimes it is really challenging. People are
1752 prideful, and they don't want to say, "I need help with food,
1753 I don't need -- I need help with resources.'" And so someone
1754 that can be in that role that is not telling them take their
1755 medications for their A1C, but just saying, you know, "How
1756 can I help you with things that are outside of health care,"
1757 is really going to be a very important component.

1758 Some of our patient navigator work will also be to
1759 support patients in navigating the health exchanges and
1760 understanding things, whether it is identifying -- literacy
1761 is a barrier to it, whether it is digital literacy -- that is
1762 a big thing in our area. So our geriatric population doesn't
1763 know how to use a computer.

1764 *Ms. Matsui. Thank you very much. Health centers in my
1765 district also continue to really face workforce challenges.
1766 Can you describe the shortcomings in reimbursement for
1767 community health workers, and how Congress might help address
1768 these obstacles?

1769 *Ms. Sweeney. Yes, I think that is a great question.
1770 Currently, to my knowledge, in Washington State we don't have
1771 a reimbursement mechanism for that. So it is something that,

1772 you know, we are having to self-fund.

1773 *Ms. Matsui. Okay.

1774 *Ms. Sweeney. And so those gaps are always challenging
1775 to try to fill.

1776 *Ms. Matsui. Okay --

1777 *Ms. Sweeney. So you can recognize the need, but you
1778 need to figure out how to sustain the program financially.

1779 *Ms. Matsui. Sure. Thank you very much. This question
1780 is for Dr. Bibbins-Domingo.

1781 I am pleased that today's hearing continues this
1782 committee's work to promote clinical trial diversity. You
1783 know, clinical research is no exception to the rapid pace of
1784 health care innovation, as trial sponsors look for new ways
1785 to improve the speed and experience of clinical trials for
1786 patients and providers.

1787 During the pandemic we have seen an uptick in adoption
1788 of decentralized clinical trials, as longstanding regulatory
1789 barriers to telehealth and conducting trial activities
1790 remotely [inaudible] way for the duration of the public
1791 health emergency.

1792 Dr. Bibbins-Domingo, in your view, how might telehealth
1793 fit into the conversation around what Congress can do to
1794 better coordinate Federal efforts that promote equitable
1795 clinical research?

1796 Post-pandemic, do you see telehealth continuing to play

1797 an increasingly important role in recruiting and retaining
1798 diverse participants for clinical trials?

1799 *Dr. Bibbins-Domingo. Thank you very much for that
1800 question. I actually think that the pandemic, in its way
1801 that it was disruptive, allowed new innovations to actually
1802 flourish, and telehealth is certainly one of them.

1803 I can -- speaking as a clinician, I can say telehealth
1804 has been remarkable in allowing us to increase our access.

1805 I will also say that new technologies also have to be
1806 adapted to the goals that we are trying to achieve. For me
1807 and my population -- I serve in an urban safety net setting
1808 -- we don't -- most of my patients don't use telehealth.
1809 They use the telephone, unfortunately. And so we always have
1810 to be ensuring that our new technologies also work for all of
1811 the populations that we are trying to have them achieve.
1812 They increase access. We can reach rural populations, people
1813 who can't come in, in much better ways. That is remarkable.
1814 But then also making -- we have to build in the types of
1815 investment that ensures that new technologies are actually
1816 available to all of those that we want to include in care and
1817 in our studies.

1818 So I am all in favor of technologies. I think that they
1819 are remarkable and increase access, but we also have to make
1820 them equitable, as well.

1821 *Ms. Matsui. Well, absolutely. And that is part of the

1822 challenge, because, as we have more access, we know that
1823 there are disparities in all of the access, too. So thank
1824 you very much. I do look forward to Congress advancing
1825 legislation that really supports leveraging telehealth in an
1826 equitable manner as a tool across the health care sector.

1827 Thank you, Madam Chair. My time has disappeared. I
1828 yield back.

1829 *Ms. Eshoo. It goes by quickly. The gentlewoman yields
1830 back.

1831 The chair is pleased to recognize the gentleman from
1832 Virginia, Mr. Griffith, for your five minutes of questions.

1833 *Mr. Griffith. Thank you, Madam Chair. And I just want
1834 to say I agree with the questions and the answers just given
1835 to -- by Ms. Matsui, and then the answers that were given.
1836 Both Ms. Bibbins-Domingo and Ms. Sweeney have mentioned that
1837 a lot of folks in their areas -- and in my area, as well --
1838 use telephonic forms of telehealth. And we have to figure
1839 out how to make reimbursement for both the computer version
1840 and continue to reimburse or do better ways of reimbursing
1841 for telephonic.

1842 All right, let me move on to Mr. Shannon.

1843 Mr. Shannon, EcoHealth Alliance, an NIH grantee during
1844 the time that you were there -- at least it started then --
1845 recently acknowledged that it is waiting for its sub-grantee,
1846 the Wuhan Institute of Virology, to release electronic files

1847 and lab notebooks associated with a key experiment on
1848 coronavirus and doing coronavirus research prior to 2020,
1849 which was supported by the NIH grant. It seems weird and
1850 perverse to me that an NIH grantee cannot or will not produce
1851 the substantiating materials from an experiment paid for by
1852 the United States. Wouldn't you agree, yes or no?

1853 *Mr. Shannon. Yes, I would agree.

1854 *Mr. Griffith. Shouldn't NIH grantees be required to
1855 retain a copy of all research records? And when I say
1856 "grantees," I mean grantees and sub-grantees. Shouldn't
1857 they be required to retain a copy of all research records,
1858 electronic files, and laboratory notebooks generated by a
1859 foreign sub-grantee, and be required to make such data
1860 available upon request to the NIH and/or from Congress, yes
1861 or no?

1862 *Mr. Shannon. Yes, and the requirement exists.

1863 *Mr. Griffith. Then how come we can't get these records
1864 from the Wuhan lab?

1865 *Mr. Shannon. I don't know the answer to that, sir. I
1866 can tell you that the NIH grants policy statement -- section
1867 8.4.2, specifically -- requires that any record reasonably
1868 considered to be pertinent to the grant must be retained and
1869 available.

1870 And in fact, the grantee and -- or the awarding
1871 recipient and -- is responsible for compliance across the

1872 board. They have -- they actually have to --

1873 *Mr. Griffith. Okay.

1874 *Mr. Shannon. -- keep their people available

1875 [inaudible] --

1876 *Mr. Griffith. Let me move on. We have had a number of
1877 issues with this type of thing with EcoHealth Alliance. And
1878 at one point they were banned from getting new money on that
1879 grant, but then the NIH gave them a grant for something else.

1880 When we have somebody who is not complying or not making
1881 their sub-grantees comply, shouldn't we ban them from getting
1882 new grants in the future?

1883 *Mr. Shannon. Well, I think there is absolutely a case
1884 to be made that stewardship should be a --

1885 *Mr. Griffith. I take that as a yes, and I apologize.

1886 *Mr. Shannon. Okay.

1887 *Mr. Griffith. I would love to talk to you for hours,
1888 but I only have five minutes.

1889 Also, as a former director at the NIH, and an NIH
1890 advisor to the FBI, how big of a problem is non-disclosure of
1891 foreign interests?

1892 Under current requirements, should it have been
1893 disclosed when EcoHealth Alliance received their NIH grant
1894 that they had a partnership with the Wuhan Institute of
1895 Virology?

1896 *Mr. Shannon. Generally, all disclosures of support or

1897 activity and location of performance are supposed to be
1898 disclosed. That is a requirement of the grant in the grant's
1899 policy --

1900 *Mr. Griffith. Since you were there at that time -- and
1901 I know you may not remember, but do you know if that was
1902 disclosed at the time of the grant on coronavirus to
1903 EcoHealth Alliance?

1904 *Mr. Shannon. I do not. Those grant compliance areas
1905 fall under the auspices of [inaudible] --

1906 *Mr. Griffith. Yes, I heard your answer to Dr. Burgess,
1907 and I thought that was fine. Again, I hate to cut you off,
1908 but I have got to move on.

1909 What is the China military civil fusion strategy, and
1910 how is it relevant to the threats facing biomedical research
1911 by the U.S. in China?

1912 *Mr. Shannon. It is a -- the MCF for military civil
1913 fusion strategy is a major driver of the Chinese Communist
1914 Party in their efforts to create a technologically advanced
1915 military to promote economic benefit beyond, and replace the
1916 U.S. as a premier economic powerhouse. So the focus is on
1917 targeting critical infrastructure, including biomedical, and
1918 there is a purposeful attempt to do that, to gather
1919 information that way.

1920 And the focus is also recognizing that the way we look
1921 at the right and wrong of it is probably not the way they do.

1922 They don't see it as their job to comply --

1923 *Mr. Griffith. Yes, I mean, let me --

1924 *Mr. Shannon. -- but for us to --

1925 *Mr. Griffith. Let me -- hang on. Let me finish up,
1926 and I do apologize. I could talk to you for hours.

1927 But do you think, looking at Wuhan Institute of
1928 Virology, that they are, in fact, a part of this strategy? I
1929 do. Do you?

1930 *Mr. Shannon. I don't have any knowledge to demonstrate
1931 that that is the case. But I know, if you --

1932 *Mr. Griffith. But you would -- yes or no, you would be
1933 surprised if they were not a part of it, wouldn't you?

1934 *Mr. Shannon. I would be surprised if they were not
1935 part of the -- both the military and party.

1936 *Ms. Eshoo. The gentleman's time has expired.

1937 *Mr. Griffith. Thank you.

1938 *Mr. Shannon. Yes.

1939 *Mr. Griffith. I appreciate it.

1940 *Ms. Eshoo. The gentleman's time has expired.

1941 The chair is pleased to recognize the gentleman from
1942 California, Mr. Cardenas, for your five minutes of questions.

1943 *Mr. Cardenas. Thank you very much, Chairwoman Eshoo,
1944 and also Ranking Member Guthrie, for holding this important
1945 hearing, and I really appreciate this opportunity to discuss
1946 these matters with these experts on their expert opinions and

1947 their experience that collectively goes far beyond many, many
1948 communities.

1949 So we are very fortunate to have all of you witnesses.
1950 So thank you so much.

1951 I am thrilled to see that the NIH Clinical Trial
1952 Diversity Act is being considered today. And I want to thank
1953 committee leadership, as well as the bill's lead author,
1954 Representative Robin Kelly, for ensuring this bill's
1955 inclusion at today's hearing.

1956 If we are serious about demanding that clinical trials
1957 are reflective of all communities served, we need to
1958 implement policy that impacts each of the relevant agencies,
1959 including those that provide resource for trials. The NIH
1960 funds clinical trials, including those in phase one, as well
1961 as those that will not apply for FDA approval, which would
1962 include studies on potential behavioral health interventions,
1963 for example.

1964 As a clinical cog in the broader clinical trial system,
1965 NIH must also hold to certain standards to ensure diversity
1966 and representation for all. Not only would the bill require
1967 NIH to develop measurable recruitment and retention goals
1968 based on disease prevalence, it would also ensure less
1969 burdensome follow-ups and launch a public awareness campaign
1970 across Federal agencies related to research participation
1971 opportunities.

1972 I am going to be asking my first question to Dr.
1973 Bibbins-Domingo.

1974 Given that context, I want to ask you, as a witness, as
1975 -- a bit about the importance of clinical trial diversity
1976 broadly, and the focus on NIH specifically. Dr.
1977 Bibbins-Domingo, thank you for joining us today. I
1978 understand that clinical trial diversity is a personal issue
1979 with you, as we heard in your testimony. And I am grateful
1980 that you are willing to share the story with us and all of
1981 America.

1982 Failing to diversify clinical trials has a serious cost,
1983 both in terms of people, in livelihoods, and in dollars and
1984 cents. In your testimony you note that an economic analysis
1985 by the National Academies found that "lack of representation
1986 may cost the U.S. hundreds of billions" -- that is billions,
1987 with a B -- "of dollars over the next three decades as a
1988 consequence of U.S. health disparities."

1989 My question to you is, can you explain this connection
1990 between clinical trial diversity and cost?

1991 And why is the NIH a key player in addressing the
1992 shortfalls in the diversity of clinical trials?

1993 *Dr. Bibbins-Domingo. Thank you very much. Yes. So
1994 our analysis that we commissioned for this report examined
1995 the three common conditions -- heart disease, hypertension,
1996 diabetes -- and asked what does the disparities, the big gaps

1997 that we have in the U.S. across White, Black, and Latino
1998 populations for these conditions, and how much does it cost
1999 us in terms of life years lost, people with disability, and
2000 work loss -- people who are not productive members of
2001 society? These are now costs that, over a 30-year period,
2002 approach \$1 trillion, frankly.

2003 Now, disparities in health outcomes like that are
2004 actually multi-factorial. They are not all going to be
2005 addressed by improving diversity in clinical trials. But if
2006 clinical trials and clinical research, which is important,
2007 only addressed a small fraction, let's say one percent, the
2008 benefits to society in terms of life years gained, productive
2009 life years gained, would be on the order of hundreds of
2010 billions of dollars. This is an analysis restricted to a few
2011 conditions and a few disparities, but it does highlight how
2012 big an economic toll that is, and does suggest that research,
2013 which we do think is important in this country -- that is why
2014 we fund it -- for improving health is important for
2015 addressing this, even if it only plays a small role in that.

2016 *Mr. Cardenas. What are the dangers of prolonged
2017 mistrust in our scientific processes?

2018 And how can proposals like the NIH Clinical Trial
2019 Diversity Act help to close that gap?

2020 *Dr. Bibbins-Domingo. Yes. We have a very important
2021 gap in trust, mistrust, distrust that we have seen really

2022 highlighted through the pandemic.

2023 A lot -- this is actually reinforced by the fact that we
2024 are not engaging communities in the participation in our
2025 scientific and medical enterprise. People don't accept a new
2026 vaccine because it really hasn't been studied in people like
2027 them. And I think that we -- often times we miss the
2028 opportunity to reinforce trust by engaging communities in all
2029 aspects of our medical and scientific enterprise. And this
2030 is just one aspect that I think is -- and an important
2031 feature of why representation is important.

2032 *Mr. Cardenas. Thank you. It is clear that we need to
2033 take a holistic approach in making clinical trials more
2034 diverse. It is an urgent issue, and I appreciate all of your
2035 thoughtful responses.

2036 Madam Chair, my time has expired, and I yield back.

2037 *Ms. Eshoo. The gentleman yields back.

2038 The chair is pleased to recognize the gentleman from
2039 Florida, Mr. Bilirakis, for your five minutes of questions.

2040 *Mr. Bilirakis. Thank you, Madam Chair. I appreciate
2041 it very much. This is a great hearing, as always. And I
2042 really do want to talk about this particular issue, and I
2043 thank the witnesses for their testimony today. So this is a
2044 bipartisan hearing, and I appreciate the witnesses again
2045 being here today. In particular, Madam Chair, I want to
2046 thank you for putting up for consideration my bill, H.R.

2047 5478, the Protecting the Integrity of our Biomedical Research
2048 Act, which will provide transparency and accountability at
2049 the NIH -- so very important.

2050 American taxpayers deserve to know when their money is
2051 being used improperly, when it is being used to benefit
2052 foreign governments. My legislation would provide an extra
2053 layer of protection and increased transparency for our
2054 Federal research grants by requiring full disclosure of
2055 foreign talent programs as a condition of receiving
2056 extramural biomedical research grant funds.

2057 In fact, GAO has been warning research institutions over
2058 the past few years with the concerns about inappropriate
2059 influence of foreign entities on NIH researchers. That is
2060 why I am grateful to have Mr. Mike Shannon, an expert in this
2061 field who previously worked as a senior executive at NIH.

2062 And thank you for being here, Mike, today. I have a
2063 couple of questions for you, Mr. Shannon. Thank you for your
2064 testimony, again, and for providing specific feedback on how
2065 to better improve the three bills who have -- who were on the
2066 docket today. So we really appreciate it with regard to
2067 research integrity.

2068 Can you expand more on the need to ensure we are
2069 capturing the full gambit of bad actors in this space,
2070 particularly those looking to subvert potential new
2071 requirements under the bill?

2072 And that is why we have these hearings, to even improve
2073 our bills that were filed. So, please, if you can answer
2074 that question, Mike, I would appreciate it.

2075 *Mr. Shannon. Certainly. There are a great many types
2076 of influence that can be wielded, and that can include
2077 financial remuneration, additional payments. And those are
2078 often understood that they need to be reported. What is not
2079 clear, and what has been not universally done is the complete
2080 and accurate reporting of all support.

2081 So we know that the Health Education Act section 117
2082 requires the reporting of gifts, and we know that my
2083 colleague there who heads that arena recognizes the vast
2084 under-reporting that has been happening there. But that is
2085 another indicator of where support can be used to influence.

2086 We have also seen in investigations where individuals
2087 who are -- who may have family members in the foreign nation,
2088 they may be coerced. They may be encouraged, either with
2089 threats to that family or just an honor threat, that you are
2090 embarrassing our family, that sort of thing.

2091 So it really spans the gamut of what is going to inspire
2092 and influence someone to be willing to take that step, and
2093 whether it is for self-enrichment or some type of
2094 reputational self-preservation, it is a large issue. Again,
2095 we see it as primarily a compliance issue. There are law
2096 enforcement instances. We have got to make sure we charge

2097 the appropriate charges when there is a law enforcement
2098 incident. It is much more of an espionage kind of effort
2099 than it is, you know, the common criminal.

2100 But on the compliance side there is a solution, and
2101 there is a mechanism to restore, rather than remove
2102 individuals and then put in place due diligence to observe
2103 and ensure that that conduct does not continue.

2104 *Mr. Bilirakis. Thank you very much. I didn't want to
2105 interrupt you, because this is such good information for us.

2106 You also rightly point out that this issue may be
2107 addressed in the American -- the America COMPETES Act. And I
2108 want to reiterate that H.R. 5478 builds on bipartisan
2109 provisions included in the original USICA bill sponsored by
2110 Senator Schumer.

2111 I also helped lead a bipartisan letter to NIH, with some
2112 of my fellow colleagues on this committee, addressing this
2113 topic in response to specific incidents regarding
2114 inappropriate influence. You addressed that to a certain
2115 extent, inappropriate influence from the Chinese Communist
2116 Party within our biomedical research grants. We must better
2117 address this.

2118 I am not sure if we have time for this, but I am going
2119 to give you the question.

2120 And then, Madam Chair, if you want to cut me off, that
2121 is okay, because he will respond to me.

2122 Can you discuss the importance of internal buy-in within
2123 NIH and HHS, which we know is traditionally resistant to
2124 change?

2125 And can you tell me how we can provide better oversight
2126 of compliance in this area?

2127 *Ms. Eshoo. The gentleman's time --

2128 *Mr. Bilirakis. Yes.

2129 *Ms. Eshoo. -- has expired.

2130 *Mr. Bilirakis. Yes, I will yield back --

2131 *Ms. Eshoo. But I think that your question --

2132 *Mr. Bilirakis. -- so we can get a response --

2133 *Ms. Eshoo. -- can be submitted to the witness to --

2134 *Mr. Bilirakis. Absolutely.

2135 *Ms. Eshoo. -- respond in writing.

2136 [The information follows:]

2137

2138 *****COMMITTEE INSERT*****

2139

2140 *Voice. Welch is back.

2141 *Ms. Eshoo. Pardon me?

2142 *Voice. Welch is back.

2143 *Mr. Bilirakis. Thank you.

2144 *Ms. Eshoo. The chair is now pleased to recognize the
2145 gentleman from Vermont, Mr. Welch, for your five minutes of
2146 questions.

2147 [Pause.]

2148 *Ms. Eshoo. Mr. Welch?

2149 *Mr. Welch. I thank you very much, Madam Chair. I
2150 appreciate the hearing, but I actually do not have any
2151 additional questions. Thank you very much.

2152 *Ms. Eshoo. Okay, then we -- the chair now recognizes
2153 the gentleman from California, Dr. Ruiz, for your five
2154 minutes of questions.

2155 *Mr. Ruiz. Thank you for holding this important
2156 hearing. Just real quickly, I will take the personal
2157 privilege of sending a shout out to the multitude of interns
2158 in my office watching live on screen right now. Thanks for
2159 being here.

2160 As we have seen throughout the pandemic, there are
2161 critical gaps in our public health infrastructure. We are
2162 presented with an opportunity at this moment, as we move
2163 forward, to learn from this experience. I truly believe that
2164 we are at a critical juncture as a country. If we don't

2165 course correct now, even after everything we have seen and
2166 experienced throughout the past two years, then I fear we
2167 won't ever have the will to do it. And yes, to do it right,
2168 we will have to invest in our public health infrastructure.

2169 But inaction costs more than action, and we end up with
2170 sicker communities. As a doctor and a public health expert,
2171 it is hard for me to even narrow down priorities in the
2172 public health space because there are so many critical issues
2173 to address, like the need for a better public health
2174 education system, especially for our harder-to-reach
2175 communities, to empower them to make better decisions to
2176 protect their health, or even the ever-worsening provider
2177 shortage, or generally the way our health care system focuses
2178 on curing severe, expensive sickness, but not preventing it,
2179 or how we balk at spending money on things that will prevent
2180 disease, even if it saves us money down the road.

2181 What I would like to talk about today, the utilization
2182 of community health workers, or promotoras, helps address a
2183 number of these critical issues. Greater utilization of
2184 community health workers is not a silver bullet to solve our
2185 public's health system. There is no one silver bullet here,
2186 but they can go a long way to keeping our communities
2187 healthier.

2188 As you know, community health workers understand local
2189 needs and can give people tools and resources to achieve

2190 better health and well-being. This may include helping
2191 patients manage chronic diseases, connecting them with social
2192 services organizations, or making sure a patient has a proper
2193 storage for their medication.

2194 Proactively addressing root causes of poor health is not
2195 only better for the health of our communities, but it
2196 actually saves money. In fact, research has shown that
2197 utilization of community health workers saves \$2.47 for every
2198 dollar spent.

2199 So if community health workers saves us money and
2200 improves health, I think that investing in policies that
2201 increase utilization of them is a no-brainer. My bill, H.R.
2202 8151, the Building a Sustainable Workforce for Healthy
2203 Communities Act, will reauthorize a competitive grant program
2204 to support state and local governments, tribal organizations,
2205 and community-based organizations, and expanding community
2206 health worker programs in under-served areas. The grants are
2207 intended to serve communities that experience higher rates of
2208 chronic disease, infant mortality, maternal morbidity and
2209 mortality, and health professional shortage areas.

2210 The bill also expands the services that community health
2211 workers can provide under this grant, such as using community
2212 health workers to educate, guide, and provide home visitation
2213 services for chronic diseases and postpartum care.

2214 Under my bill, the community health workers will also be

2215 able to conduct outreach and education to communities that
2216 require additional support during public health emergencies.

2217 Ms. Sweeney, what are some services that you intend for
2218 the patient navigators, as described in your testimony, to
2219 provide into the future as NEW Health works to get their
2220 community health worker programs off the ground?

2221 *Ms. Sweeney. Thank you. So I think, for us, really,
2222 you know, everyone's barriers are different, and they are all
2223 the same at the -- at many community health centers. So for
2224 us to identify those social determinants of health and what
2225 are the barriers to patient, whether it is compliance,
2226 comprehension, health care, access, trust -- and so we will
2227 really utilize these patient navigators to help build the
2228 trust within the community to eliminate barriers to care,
2229 whichever barrier that is.

2230 And so I think, really, for them to identify those
2231 social determinants of health and non-compliance -- you, as a
2232 clinician, recognize non-compliance doesn't always mean
2233 obstinance. It could be financial barrier, or a
2234 comprehension barrier.

2235 *Mr. Ruiz. Or a failure and non-compliance of a system
2236 that doesn't give -- take into consideration those barriers,
2237 which is their responsibility to do so.

2238 *Ms. Sweeney. Right.

2239 *Mr. Ruiz. So I -- you know, before we leave I would

2240 also like to thank the committee for including H.R. 5141, the
2241 Mobile Health Care Act, in this hearing, and for my
2242 colleague, Congresswoman Lee, on her leadership on this
2243 important issue.

2244 Giving health centers the ability to invest in mobile
2245 clinics will help them reach the most under-served areas by
2246 taking health care directly to the communities. I have
2247 participated multiple times in these mobile health clinics,
2248 and have even driven some of these RVs out into our most
2249 under-served areas in my district throughout my medical
2250 career.

2251 And with that, I yield back.

2252 *Ms. Eshoo. The gentleman's time has expired.

2253 The chair is pleased to recognize the gentleman from
2254 Indiana, Dr. Bucshon, for your five minutes of questions.

2255 *Mr. Bucshon. Well, thank you, Chairwoman Eshoo and
2256 Ranking Member Guthrie. Today's hearing covers a variety of
2257 important issues, many of which are particularly relevant,
2258 given that we have experienced and learned -- what we have
2259 experienced and learned over the last couple of years.

2260 The COVID-19 pandemic has taught us a lot about what our
2261 public health agencies and our health care systems can do
2262 well. But it has also provided some startling examples of
2263 deficiencies Congress needs to address. The bills before us
2264 today represent just a small portion of that work.

2265 I appreciate that my colleagues, Representatives
2266 Bilirakis, Curtis, and Hudson, have introduced bills to
2267 address some of the issues we are seeing with oversight of
2268 Federal funding for scientific research.

2269 To be clear, I strongly support Federal funding for
2270 research. I learned in my early days of Congress, leading
2271 the Science, Space, and Technology Subcommittee responsible
2272 for the National Science Foundation, that we cannot rely on
2273 the private sector for all such work. But when taxpayer
2274 dollars are being used, we must pay close attention to the
2275 quality of the work being done, and we must have adequate and
2276 frequent oversight of all Federal agencies funding scientific
2277 research.

2278 Mr. Shannon, your written testimony provides many solid
2279 observations about how we can improve that quality,
2280 particularly when it comes to foreign influence. Do you
2281 believe that, if we enact the proper guardrails, the United
2282 States can continue to safely and responsibly fund biomedical
2283 research projects, not only in the U.S., but internationally?

2284 *Mr. Shannon. Yes, I do. I think, though, that the --
2285 although the reporting requirements that are in the bills are
2286 absolutely essential and important for accountability and
2287 oversight, I think you also need to look at the IG axiom of
2288 what gets checked gets done. And so, if there aren't
2289 periodic audits for compliance and looking at all of those

2290 conditions for award, then those will fall by the wayside,
2291 and we may find ourselves with a similar problem in the
2292 future.

2293 *Mr. Bucshon. Yes. I mean, I, in general, have been,
2294 you know, shocked by the revelations of the lack of
2295 compliance and reporting that we have seen across the United
2296 States and academic institutions, particularly as some of
2297 those cases were mentioned, and the lack of oversight
2298 potentially that we have had.

2299 And it does amaze me in Congress, I mean, how many
2300 things that in hearings like this you hear have happened, and
2301 you just can't understand why the law hasn't been followed.
2302 And primarily, I think a lot of that is, you know, it is
2303 Congress's responsibility to occasionally provide adequate
2304 oversight of basically everything that we do, particularly
2305 when taxpayer dollars are involved.

2306 I am also grateful for the legislation like H.R. 7565,
2307 the IMPROVE Act, which provides authorization for a research
2308 initiative designed to mitigate preventable maternal
2309 morbidity and mortality. We have heard it, this
2310 subcommittee, the shocking data coming out across the country
2311 about the increasing maternal mortality, particularly in
2312 certain areas of our country, and the racial and ethnic
2313 disparities in that issue -- on that issue, and I know we are
2314 all trying to address that.

2315 My state of Indiana has one of the highest rates of
2316 maternal mortality in the country, and it led me to advocate
2317 for the TRIUMPH for New Moms Act, a piece of legislation that
2318 Representative Barragan and I were able to pass in the House,
2319 that was included in the mental health package last week.
2320 That bill focused specifically on mental health challenges
2321 that often plague pregnant and postpartum women.

2322 The IMPROVE Act would further build on efforts to
2323 support them.

2324 Dr. Bibbins-Domingo, I don't have a specific question,
2325 but I want to comment on some things you have said. You have
2326 advocated for broader participation of women in clinical
2327 studies, and your testimony makes many critical points about
2328 the need for greater clinical trial diversity. Dr. Ruiz, who
2329 just recently asked questions, and I introduced H.R. 5030,
2330 the DIVERSE Trials Act, to improve diversity in clinical
2331 trials and a couple of other things. And the Senate actually
2332 has a companion bill, S. 2706, introduced by Senators
2333 Menendez and Tim Scott.

2334 So I do agree also that telemedicine gives us a
2335 potential opportunity to increase the diversity in clinical
2336 trials, as you pointed out. And I know, as a medical doctor
2337 myself, different populations of people respond differently
2338 to medications, and they have different health issues that
2339 cannot be adequately assessed unless you actually study those

2340 populations.

2341 So with that, Madam Chairwoman, I yield back the balance
2342 of my time.

2343 *Ms. Eshoo. The doctor yields back.

2344 The chair is pleased to recognize the gentlewoman from
2345 Michigan, Mrs. Dingell, for your five minutes of questions.

2346 *Mrs. Dingell. Thank you, Chairman Eshoo and Ranking
2347 Member Guthrie, for convening today's bipartisan legislative
2348 hearing, with so many important bills that support our
2349 nation's health care system, the workforce, and research
2350 enterprise.

2351 The issues that today's witnesses and my colleagues on
2352 committee have discussed are so critical to addressing gaps
2353 in care and ensuring traditionally under-served groups are
2354 able to access quality, affordable health care in a timely
2355 manner. There are issues that are critically important to
2356 communities in my district, which has a very large Middle
2357 East and North African population. We have heard from
2358 concerned residents and community groups that the lack of
2359 such services are barriers to quality health and health
2360 equity for MENA residents.

2361 Ms. Sweeney, community health centers play a critical
2362 role in addressing health equity, both in my district but
2363 across the country. Could you speak to the importance and
2364 effectiveness of culturally and linguistically appropriate

2365 services, particularly for immigrants, refugees, and
2366 individuals with limited English proficiency?

2367 *Ms. Sweeney. Yes, that is a great question, and I
2368 think that health centers have done a really great job of,
2369 you know, working towards that and addressing that by being
2370 community driven. And so we can better adapt to our
2371 patients' needs because you can't always understand what
2372 someone is going to need until they come and seek care with
2373 you. And so community health centers have really been known
2374 to build that trust within our patients, and to be community
2375 focused. And I think that is really a benefit to help
2376 support equity within our health center network, no matter
2377 where we are located in the U.S.

2378 *Mrs. Dingell. Thank you for that. It is important to
2379 note that MENA Americans, like those in my district, are not
2380 currently recognized as a distinct community under the Public
2381 Health Service Act. This is why I have joined my colleagues,
2382 Representative Tlaib, Eshoo, and Kelly, to introduce the
2383 Health Equity in MENA Community Inclusion Act of 2022, which
2384 would amend the Public Health Service Act to address this
2385 issue.

2386 But I would also like to highlight the 340B drug pricing
2387 program, which is critically important to ensuring community
2388 health centers in my district -- and again, across the
2389 country -- that they are able to provide quality health

2390 access to be able to provide quality care to my constituents.

2391 Ms. Sweeney, how has the 340B program helped NEW Health
2392 provide quality care to the beneficiary it serves?

2393 And can you talk about the program's impact on
2394 under-served communities specifically?

2395 *Ms. Sweeney. Yes, thank you. That is a great
2396 question.

2397 The 340B program is incredibly important to health
2398 centers across the country. You know, by law and mission we
2399 must reinvest all savings of the 340B program back into the
2400 patient care.

2401 So I think a couple of examples we could do is
2402 telehealth. When the pandemic first broke out, we just
2403 really didn't even know how it was going to be reimbursed,
2404 how that was going to be paid. And so having that
2405 opportunity to utilize that cost savings to do right by the
2406 patients in that time of need was essential.

2407 And those needs for the under-served and vulnerable
2408 populations will always continue. And so being able to have
2409 that opportunity to reinvest that, and protect that savings
2410 for our most vulnerable patients is essential. And it is the
2411 mission of everything we do. And we -- it is really
2412 extremely important to the health center sustainability.

2413 *Mrs. Dingell. I thank you, and I thank you for all
2414 that you do.

2415 One thing that is important to note is that a number of
2416 major prescription drug manufacturers have arbitrarily
2417 decided to restrict their participation in the 340B program
2418 since the summer of 2020. It is an issue I am hearing about
2419 from my constituents who receive health care through the
2420 community health care centers, which have faced cutbacks in
2421 services as a result of the pharmaceutical companies
2422 overcharging these very, very, very critical safety net
2423 providers. It has a real impact on the access to care and
2424 pharmacy actions here need to be addressed moving forward.

2425 Thank you, Madam Chair. And with that I yield back.

2426 *Ms. Eshoo. The gentlewoman yields back.

2427 The chair is pleased to recognize the pharmacist on our
2428 committee, the gentleman from Georgia, Mr. Carter, for your
2429 five minutes of questions.

2430 [Pause.]

2431 *Ms. Eshoo. Are you there, Mr. Carter?

2432 *Voice. [Inaudible] Curtis.

2433 *Ms. Eshoo. Pardon me?

2434 *Voice. Curtis is next.

2435 *Ms. Eshoo. Who?

2436 [Pause.]

2437 *Ms. Eshoo. Mr. Curtis of Utah, you are recognized for
2438 your five minutes of questions.

2439 *Mr. Curtis. Thank you, Madam Chair.

2440 *Ms. Eshoo. I don't know what happened to Carter.

2441 *Mr. Curtis. Thank you, Madam Chair.

2442 I am, like many of my colleagues here, deeply concerned
2443 by the foreign influence in our research institutions through
2444 China's Thousand Talents program. My bill before us today,
2445 which I am grateful that many have acknowledged, the Fix
2446 Nondisclosure of Influence in Health Research Act, or Fix NIH
2447 Research Act, would shine a light on these [inaudible]
2448 influence operations. The Fix NIH Research Act is currently
2449 in the China package, and I urge my colleagues on the
2450 conference to maintain its inclusion and pass it into law in
2451 the coming months.

2452 I served on a GOP China task force in 2020. I lived in
2453 Asia. I have a great appreciation for the language, the
2454 culture, and the people. But that being said, the final
2455 report of the China task force found that the CCP has a
2456 coordinated global campaign to recruit overseas science and
2457 technology experts through talent programs like Thousand
2458 Talents and other efforts to obtain knowledge and IP through
2459 coercive and fraudulent means. The CCP's talent programs,
2460 rather, require participants to operate in secrecy and, in
2461 some cases, contractually obligate participants to legally --
2462 illegally transfer information and property.

2463 In 2019, a massive espionage campaign to steal advanced
2464 biomedical research was exposed at a prominent and cutting-

2465 edge research facility in Houston. Multiple scientists were
2466 caught sending research back to the CCP's government, or
2467 plotting to do so. This brazen act is just the tip of the
2468 iceberg of the CCP's wide-scale espionage efforts here in the
2469 United States, especially through their talents -- Thousand
2470 Talents program.

2471 In December 2021, the chair of Harvard's Department of
2472 Chemistry and Chemical Biology was convicted by a Federal
2473 jury in connection with lying to Federal authorities about
2474 his affiliation with the People's Republic of China's
2475 Thousand Talents program and the Wuhan University of
2476 Technology in Wuhan, as well as failing to report large sums
2477 of money he received from Wuhan University of Technology,
2478 while simultaneously receiving Federal grants from NIH and
2479 DoD.

2480 Mr. Shannon, can you explain why it does matter that
2481 researchers who are working for Chinese-affiliated entities
2482 are also getting grants from the United States?

2483 And why does this compromise the integrity of research,
2484 or how does it compromise national security?

2485 *Mr. Shannon. Yes, it certainly matters. When
2486 scientific information is submitted for potential award to
2487 advance our research and development capabilities, the intent
2488 is for the benefit of all, from a U.S. perspective. When you
2489 have individuals who either work in a dual funding capacity,

2490 or have a conflict of interest or a conflict of commitment,
2491 that can result in less effort being given to the U.S.
2492 research.

2493 It can also cost in the way of the training and
2494 mentorship, where a scientist who may be deciding to work in
2495 this capacity and be -- enrich themselves, their effort is
2496 focused elsewhere, not on the primary effort here. And that
2497 is not the agreement that they entered into when they
2498 received that grant award.

2499 From a national security perspective, it absolutely
2500 matters because not -- in most of these cases it is not a
2501 transparent or reciprocal arrangement. And so it is not to
2502 the benefit of the global health, or to the benefit of the
2503 U.S., who is funding the effort often times. It inures to
2504 the benefit of another nation. In many cases -- in our
2505 investigative statistics we see that is primarily the
2506 Communist Party in China. That effort directly impacts our
2507 ability to be innovative, our ability to be ahead of the
2508 curve, and to seek that innovation and commitment from the
2509 funds that we invest.

2510 *Mr. Curtis. Thanks, Mr. Shannon.

2511 I would also like to just re-emphasize my appreciation
2512 to my colleagues who have supported this bill. And, Madam
2513 Chair, I yield my time.

2514 *Ms. Eshoo. The gentleman yields back.

2515 The chair is pleased to recognize the gentlewoman from
2516 New Hampshire, Ms. Kuster, for your five minutes of
2517 questions.

2518 *Ms. Kuster. Great. Thank you so much, Madam Chair.

2519 Creative approaches to delivering care are essential to
2520 reach all communities and vulnerable populations, including
2521 those who are experiencing inconsistent housing, who may live
2522 far from medical facilities, and who don't have access to
2523 transportation, or may lack connection to a medical provider.
2524 That is why legislation such as the Mobile Health Care Act is
2525 so key to improving health.

2526 As the founder and co-chair of the Bipartisan Addiction
2527 and Mental Health Task Force, I am proud to say that we
2528 included the Mobile Health Care Act as part of our
2529 legislative agenda for the 117th Congress. Providing
2530 financial support to health centers, establishing mobile
2531 health units in rural and under-served communities is an
2532 evidence-based approach to close significant gaps in physical
2533 and mental health care.

2534 In my home district, Lamprey Health Care in Nashua, New
2535 Hampshire uses a mobile van to meet patients where they are,
2536 helping to remove barriers to establish primary care, provide
2537 behavioral health care, and respond to COVID-related
2538 concerns. Some days this means providing services to school
2539 children on site to ensure minimal disruption of their school

2540 day, and other times this means leveraging the unit and
2541 expanded telehealth flexibilities to connect patients with
2542 substance use disorder to proper support.

2543 At a time when workforce recruitment and retention is
2544 such a challenge, folks at Lamprey have expressed greater job
2545 satisfaction with the opportunity to work directly with
2546 patients through the mobile health unit. The Mobile Health
2547 Care Act will empower other health centers to follow
2548 organizations like Lamprey to expand their services.

2549 Ms. Sweeney, what populations would benefit most from
2550 more health centers being able to use a mobile unit to
2551 deliver public health and health care services?

2552 *Ms. Sweeney. Thank you. That is a great question.

2553 So we are going to be able to provide dental exams,
2554 extractions, fillings, and sealants for patients perhaps who
2555 cannot access those. So when you talk about that K-through-
2556 12 group who have to miss school to go to a dental exam, or
2557 their parents have to take time away from work, so that is
2558 one specific population.

2559 And then, when we really talk about 10 percent of our
2560 total population being veteran population, and their needs
2561 being in -- you know, where they are apprehensive to come
2562 into an institution or a brick and mortar, so we really think
2563 bridging that VFW with the veterans population are two very
2564 strong populations.

2565 And then, of course, anyone that has transportation or
2566 mobility issues.

2567 So also, we also talk about in our area we have
2568 wildfires. And so when those camps are deployed, they are
2569 often times not close to an urban area. And so those
2570 firefighters are charged to have to leave the area for health
2571 care. And so we will be able to target specific populations
2572 and respond to various needs, not just health care or
2573 pandemic, but also natural disasters or anything that could
2574 be impacting us.

2575 And I think that is really going to be beneficial for
2576 all community health centers, to have access through a mobile
2577 unit, to really deploy resources to where it is most needed
2578 in the short term, and then long term for our youth and
2579 veterans.

2580 *Ms. Kuster. Great. And could you speak to how mobile
2581 health units will improve mental health care in rural
2582 communities, as well as addiction treatment?

2583 *Ms. Sweeney. Yes. So as we know in -- the increasing
2584 mental health needs and lack of resources, if we could deploy
2585 those to people where they are at on their journey -- and I
2586 think you had made that comment -- you know, we want to meet
2587 people where they are at in their journey in crisis, because
2588 it doesn't always happen Monday through Friday, 8:00 to 5:00.
2589 And so, if we can, deploy those resources where our patients

2590 are.

2591 And then addiction resources, if there is an area in our
2592 service area that has a higher-than-normal resource
2593 allocation needed, we could deploy that more cost effectively
2594 and more timely than trying to install a brick-and-mortar
2595 rapidly.

2596 *Ms. Kuster. Do you use the medically-assisted
2597 treatment? Is that something that you have deployed for
2598 addiction, for substance use disorder?

2599 *Ms. Sweeney. We have medication-assisted treatment
2600 support services, and we utilize our referral network in our
2601 critical access hospital in the county. So we participate in
2602 the substance use disorder health care system in our region
2603 with our health department, our critical access hospital, and
2604 our rural health clinics.

2605 *Ms. Kuster. Great. Well, I will just say from
2606 personal experience here and elsewhere, that that would be
2607 really, really helpful. And I urge my colleagues to support
2608 the bill, and I thank the chair for including it in the
2609 package.

2610 And with that I yield back.

2611 *Ms. Eshoo. The gentlewoman yields back.

2612 The chair is pleased to recognize the gentleman from
2613 Pennsylvania, Dr. Joyce, for your five minutes of questions.

2614 *Mr. Joyce. Thank you for convening this important

2615 legislative hearing, Chair Eshoo and Ranking Member Guthrie.

2616 I would also like to thank the committee for including
2617 legislation that I introduced along with my colleague, Dr.
2618 Schrier, H.R. 3773, the Pediatricians Accelerated Childhood
2619 Therapies, or PACT. [Inaudible] legislation will codify
2620 efforts to coordinate pediatric research [inaudible] NIH
2621 research institutes, and will invest in supporting early
2622 career researchers to help ensure a health pipeline of new
2623 individuals working in this critical field.

2624 As we saw during the debate of H.R. 7666 last week,
2625 pediatric populations have borne the brunt of the upheaval in
2626 our daily lives during the COVID-19 pandemic, and we will be
2627 dealing with the aftermath of this for years going forward.
2628 When speaking to hospitals in Philadelphia, specifically the
2629 Children's Hospital of Philadelphia, we hear this confirmed,
2630 particularly in the space of behavioral health.

2631 Ensuring a strong supply of pediatric researchers,
2632 including physician scientists who focus on clinical,
2633 translational, pharmaceutical, these areas of research are so
2634 absolutely important.

2635 [Audio malfunction.]

2636 *Mr. Joyce. -- that emphasis at this point in time.

2637 My first question is for Dr. Walker-Harding.

2638 Would you please speak a bit more to the challenges that
2639 you are seeing in the field, particularly when it comes to

2640 retaining researchers in pediatric academic research areas?

2641 And what are the stressors that you are seeing from
2642 people that they are experiencing in this field that often
2643 force them to leave the field?

2644 *Dr. Walker-Harding. Thank you so much for that
2645 question.

2646 Yes, we are seeing a lot, especially -- some of the same
2647 things you are seeing in Children's Hospital, Philadelphia we
2648 see at the University of Washington and across the country.

2649 It is -- first of all, less people go into pediatric
2650 research to begin with. And if they don't have the funding,
2651 if you are talking about a physician scientist who also wants
2652 to see patients, being able to balance seeing patients,
2653 trying to get funding -- and if you are a woman, trying to
2654 take care of your kids at home, especially during COVID --
2655 this has been a stress. It is really hard to get that
2656 support.

2657 Universities, children's hospitals don't have the same
2658 kind of funding to support early-career researchers. And so
2659 what happens is they start out with great ideas, trying to
2660 work on it, have difficulty finding funding for pediatric
2661 research, have difficulty supporting their time to do that
2662 work. And they slowly move out of that space, and we lose
2663 the critical people who are seeing patients who can answer
2664 the questions that they are seeing because they are trained

2665 to do so. But without the funding --

2666 *Mr. Joyce. Thank you for your insight --

2667 *Dr. Walker-Harding. -- without -- we can't take care
2668 of them.

2669 *Mr. Joyce. Thank you. I would now like to turn the
2670 issue to NIH research vulnerability, and what could be done
2671 to address the threats presented by the Chinese Communist
2672 Party.

2673 In the last few years we have seen an alarming uptick in
2674 malign foreign influence in our nation's biomedical research.
2675 I am pleased to see that we are taking up bills related to
2676 fixing this problem today. And I would urge that we also
2677 look at legislation like H.R. 5626, the Safe Biomedical
2678 Research Act, which I introduced aimed at this issue, as
2679 well.

2680 Mr. Shannon, in your experience, how important is it for
2681 the NIH to have strong standards on cyber and technology
2682 practices to safeguard sensitive information?

2683 *Mr. Shannon. It is very important, and I think they
2684 have taken some great steps towards working in that direction
2685 on the cyber side.

2686 But we are also -- you know, the large portion of this
2687 problem is behavioral-based. And so there is a nexus between
2688 cyber activity and behaviors, because a lot of those
2689 behaviors happen in the cyber space. So being able to

2690 observe that and react to it is critically important.

2691 *Mr. Joyce. [Inaudible] that the NIH has those strong
2692 standards on cyber and technology practices to safeguard the
2693 sensitive information?

2694 And do you believe that those standards exist today, and
2695 are properly enforced?

2696 *Mr. Shannon. I am not an expert in the NIH cyber
2697 policies. I worked very closely with them on investigations
2698 and audits. But I can tell you that they have a strong,
2699 committed team that does a great job in that regard. So I
2700 can't speak to the specifics of their cyber policies, but I
2701 know that they have been continually working to address that.
2702 And after the GAO audit that occurred a couple of years ago,
2703 I think they are in an even stronger position today.

2704 *Mr. Joyce. I think we need that strong position.

2705 Madam Chair, I see my time has expired, and I yield.

2706 *Ms. Eshoo. The gentleman yields back.

2707 The chair is pleased to recognize the gentlewoman from
2708 Illinois, Ms. Kelly, for your five minutes of questions.

2709 *Ms. Kelly. Thank you, Madam Chair. I am so thankful
2710 for this committee's leadership in advancing important
2711 clinical trial diversity policy with the Food and Drug
2712 Administration of 2022. However, real progress on clinical
2713 trial diversity will require a multi-faceted approach across
2714 Federal agencies, as you know well.

2715 While the DEPICT Act focuses on FDA policy to increase
2716 clinical trial diversity, there is a need for similar
2717 policies to be implemented at the NIH. The NIH is the
2718 largest funder of biomedical research in the world, investing
2719 \$41.7 billion annually on biomedical research.

2720 I am proud to have introduced the NIH Clinical Trial
2721 Diversity Act with Representative Fitzpatrick and my E&C
2722 colleagues, Representatives Cardenas, Butterfield, and
2723 Clarke. This bipartisan bill builds on current NIH policy,
2724 and provides a framework for NIH to work with sponsors so
2725 they can meet their clinical trial diversity goals. This
2726 bill would ensure that NIH-sponsored clinical research
2727 develops effective treatments for diseases and conditions
2728 across diverse populations.

2729 Dr. Bibbins-Domingo, in your testimony you discuss the
2730 importance of including diverse populations at the outset of
2731 clinical trial research to ensure that all communities have
2732 access to innovative treatments. Could you please speak to
2733 the importance of including diverse populations in phases one
2734 and two of clinical trials?

2735 *Dr. Bibbins-Domingo. Thank you for that question. It
2736 is important that we create an infrastructure that includes
2737 diverse populations at all phases of our research, including
2738 the formative phases and the -- all of the early phases of
2739 clinical trials for -- the reason is that this research

2740 should be generalizable to the populations for whom it is
2741 intended.

2742 Focusing on the earlier phases, especially by focusing
2743 on the NIH and the types of research that it funds, will
2744 actually reinforce the institutions that actually enroll
2745 individuals in research to create that types of
2746 infrastructure locally to make enrollment in studies easier.

2747 It is true that in early phases of research, when the
2748 numbers are small, you don't -- they are not often powered to
2749 look for differences between groups. But looking for
2750 differences between groups is not the only reason we want to
2751 include diverse populations in research. We want to do them
2752 at the discovery phases, at the genetic phases, at the
2753 mechanistic phases, and at all phases to think about
2754 generalizability. And investing in the infrastructure at all
2755 phases actually will enhance our ability to recruit in those
2756 late-phase clinical trials, where we sometimes do want to
2757 explore differences in drug efficacy across populations.

2758 So I really applaud the focus on FDA and NIH, and think
2759 that they can work in synergy.

2760 *Ms. Kelly. Why is it important for NIH-funded trials
2761 investigating behavioral intervention for mental health and
2762 substance abuse use disorders will also be required to
2763 develop clear and measurable clinical trial diversity goals?

2764 *Dr. Bibbins-Domingo. Thank you. For the same reason.

2765 A focus simply on just the drugs and devices really ignores
2766 the fact that so much of what we do in clinical medicine to
2767 improve health is informed by funding that the NIH gives to
2768 investigators for things like mental health interventions,
2769 for things like implementation science, for things like
2770 substance use. All of those that may not have a
2771 pharmaceutical at the end of the pipeline, but are just as
2772 critically important that we use evidence-based practices to
2773 inform our care.

2774 For those things that you mentioned -- mental health,
2775 behavioral health, substance use -- we know that there are
2776 huge disparities in those arenas, as well. And having
2777 research that addresses these issues in the populations that
2778 are affected are hugely important for addressing the health
2779 needs in those populations.

2780 *Ms. Kelly. Thank you.

2781 Dr. Walker-Harding, can you please elaborate on the need
2782 for alternative follow-ups to increase clinical trial
2783 participation of rural and linguistically diverse
2784 individuals?

2785 *Dr. Walker-Harding. Sure, it -- different from adult
2786 medicine, pediatric specialists, pediatric researchers are
2787 not in rural areas. They have to travel sometimes for hours,
2788 especially where I am at, two to three hours a week for
2789 essential care. If you have to do that, you really need to

2790 have other ways of having them engage in research, because it
2791 is an extraordinary burden to have to keep coming back and
2792 forth from rural and remote areas.

2793 If you are linguistically diverse, you need to be able
2794 to understand in your own language and culturally what a
2795 research project --

2796 *Ms. Eshoo. The gentlewoman's time has expired.

2797 *Dr. Walker-Harding. -- would be doing to help your
2798 child.

2799 *Ms. Eshoo. The gentlewoman's --

2800 *Dr. Walker-Harding. So --

2801 *Ms. Eshoo. -- time has expired.

2802 *Ms. Kelly. Thank you.

2803 *Ms. Eshoo. The chair now recognizes the gentleman from
2804 -- is Mr. Carter with us?

2805 There you are. The gentleman from Georgia, Mr. Carter,
2806 for your five minutes of questions.

2807 *Mr. Carter. Thank you, Madam Chair, and thank all of
2808 the witnesses for being here. We appreciate your
2809 participation.

2810 Full disclosure, I am a pharmacist by profession. And
2811 as a health care professional, I know that accessibility and
2812 affordability in health care are extremely important to our
2813 country. If we are going to talk about public health, we
2814 have to make sure that patients continue to have access to

2815 pharmacies.

2816 You know, pharmacists are the most accessible health
2817 care professionals in America. Ninety-five percent of all
2818 Americans live within five miles of a pharmacy. And that is
2819 extremely important to make sure that we have accessibility
2820 to health care professionals. That is why I was happy and
2821 pleased to introduce H.R. 7213, the Equitable Community
2822 Access to Pharmacist Services Act, a bipartisan piece of
2823 legislation introduced in our committee. And I look forward
2824 to making sure that this legislation gets a hearing, and that
2825 it gets passed, because it will continue to give us access to
2826 pharmacies, and that is very important. And I am looking
2827 forward, as I say, to working with this committee to try to
2828 do that.

2829 Mr. Shannon, I want to ask you. First of all, it was
2830 revealed in April that recently disclosed documents that the
2831 Wuhan Institute of Virology had an agreement with the
2832 University of Texas's Medical Branch's Galveston National
2833 Laboratory to collaborate on scientific research with the
2834 Chinese lab, and that it entitled the Chinese to ask the
2835 Texas lab to destroy any secret files.

2836 It also -- in addition to that, EcoHealth disclosed to
2837 the NIH that the NIH-funded research files under their grant
2838 were in the custody of the Wuhan lab, and that EcoHealth
2839 would need to get permission from the Wuhan lab in order to

2840 turn over the records to the NIH. Again, this is EcoHealth,
2841 who got a grant from NIH. NIH wants some information, and
2842 now EcoHealth tells them they got to get permission from
2843 Wuhan in order to get that information.

2844 Mr. Shannon, my question for you is are you concerned
2845 about these side agreements between the NIH grantees -- that
2846 is, those who are getting money from the NIH, the National
2847 Institutes of Health, a federally-funded program -- are you
2848 concerned about those side agreements between them and the
2849 Chinese research partners that preclude the NIH from getting
2850 access to NIH-funded data?

2851 *Mr. Shannon. Yes, that is in conflict with the
2852 regulations, the grants policy statement that requires that
2853 those records be available if they are considered pertinent
2854 to the grant. And so if there is a nexus between the grant
2855 funding that the one entity received, and they sub-award
2856 something out of that, then that requirement extends. That
2857 is -- so yes, I would be very concerned with that.

2858 But it does go to the whole question of persons
2859 accepting risk at a level beyond their authorities, or
2860 unbeknownst to their organization, and not being able to
2861 account for those things. So that is part of the broader
2862 issue of these agreements, not only between organizations,
2863 but individuals, as well.

2864 *Mr. Carter. Do you think there are any national

2865 security concerns with an agreement like this?

2866 And if there are, how can that be addressed?

2867 *Mr. Shannon. Well, I think when you are talking about
2868 research that is funded for critical infrastructure
2869 technologies, that certainly falls into the realm of a
2870 national security concern.

2871 The compliance aspect of this is absolutely something
2872 that needs to be addressed to ensure that there is
2873 compliance. And as I have said, the rules have been there
2874 for a long time. And NIH is not incorrect when they say,
2875 "Nothing has changed, the rules have been there," although
2876 they put out clarifying guidance to those rules, which is
2877 important to make sure it is clear.

2878 But -- and you have got great people doing great things
2879 trying to get after this. But what gets checked gets done.
2880 And if it is not checked, it is not getting done. So
2881 periodic audits, periodic reviews, some type of stewardship
2882 score perhaps as consideration for an award, not to disrupt
2883 what science is awarded, but to perhaps result in additional
2884 conditions on award, would be helpful.

2885 *Mr. Carter. Right. Well, let me ask you this.
2886 Shouldn't an NIH grantee -- that is, someone who has gotten a
2887 grant from the NIH -- the NIH, of course, being federally
2888 funded by taxpayers' money, shouldn't they be publicly
2889 accountable, especially to a congressional inquiry?

2890 *Mr. Shannon. Well, I think it is -- they are
2891 accountable through their awarding agency. I think it would
2892 be difficult to have direct accountability for reporting from
2893 the vast number of awardees, and then being cognizant also of
2894 Congress's previous priorities of reducing burden on the
2895 grantee.

2896 I think the appropriate mechanism is through the
2897 awarding agency, and that awarding agency being clear on what
2898 Congress wants to know, and making sure they get --

2899 *Ms. Eshoo. The gentleman's time has expired. The
2900 chair is pleased to recognize, if she is available,
2901 Congresswoman Craig of Minnesota.

2902 Are you on?

2903 All right. I don't see or hear her. We will go to
2904 Congresswoman Schrier, Washington State, for your five
2905 minutes of questions.

2906 *Ms. Schrier. Well, thank you, Chairwoman, and thank
2907 you to our witnesses for joining us today and for your
2908 excellent testimonies.

2909 Today I would like to focus on the Pediatricians
2910 Accelerate Childhood Therapies Act of 2021, or the PACT Act,
2911 this bipartisan legislation that I was really happy to
2912 co-lead with my friend and colleague, Dr. Joyce, who you just
2913 heard from. And the PACT Act of 2021 would require NIH to
2914 make awards specifically to early career pediatric

2915 researchers, creating a pipeline of research -- researchers,
2916 as you have heard, to advance childhood therapies.

2917 This bill would also coordinate research at national
2918 health research institutions through the Trans-NIH Pediatric
2919 Research Consortium.

2920 Dr. Walker-Harding. First, it is wonderful to see you
2921 again. Thank you for your devotion to children and families
2922 in Washington State. And thank you for highlighting the PACT
2923 Act in your testimony. You really highlighted how important
2924 it is to support research early in pediatric careers,
2925 especially given the tight timeline that researchers have to
2926 demonstrate that they can win independent research funding.

2927 And in prior conversations, you have also made the case
2928 for supporting pediatric research at children's hospitals and
2929 universities so that we can keep research in academic
2930 institutions, and not lose all of that talent to the private
2931 industry.

2932 Of course, you and I know pediatric research is vital to
2933 finding causes and treatments for conditions that affect
2934 children like pediatric cancer, autism, brain injury,
2935 infectious diseases, metabolic disorders. But even with this
2936 tremendous need and increased investment at NIH, there has
2937 been a decline in pediatric researcher slots at NIH.

2938 Can you talk about how this has affected Seattle
2939 Children's?

2940 *Dr. Walker-Harding. Yes, this has resulted in us
2941 having less ability to recruit people with great minds that
2942 are coming out wanting to do research without the funding.
2943 This is very much restricted, the spaces that people can do
2944 this research. I think that we have to be able to have what
2945 the PACT Act underscores: individual research, funding
2946 support. It gives security to the early researcher early on,
2947 when they are really in that tenuous point of can they do
2948 this work, especially for people who are coming from under-
2949 represented places where they haven't, you know, gotten the
2950 support that they needed to be successful.

2951 *Ms. Schrier. Thank you. And, you know, you noted this
2952 impact of kind of getting people that acceleration, that
2953 boost, early on. Can you talk about some of the challenges
2954 that early career pediatric researchers might face at the
2955 beginning of their careers, and how this legislation helps?

2956 *Dr. Walker-Harding. Yes, we really saw it play out in
2957 COVID.

2958 You know, early on in -- when you are trying to balance
2959 being a clinician, being a researcher, and, you know,
2960 especially if you are a woman and you have to care for the
2961 family, trying to figure out the time that you have to
2962 actually ask a question, do the research, get your partners,
2963 get your mentors in place, it really takes a lot time and
2964 work. And if you don't have the funding to give you that

2965 time, and you don't have the mentors that the funding allows,
2966 you just -- it is really hard for people to keep up.

2967 And so we have seen people want to switch from being a
2968 researcher to being a clinician, which is fine, except we are
2969 losing that mind, and we need all of the minds we can find to
2970 focus on pediatric research.

2971 *Ms. Schrier. Thank you.

2972 And I think about the impact, for example, of autism on
2973 an entire family, like how kids' health affects adult -- all
2974 the adults around them. And I am interested in your comments
2975 about how the diseases and conditions of childhood are often
2976 -- excuse me, of adulthood are often rooted in the pediatric
2977 years, and how this stronger commitment to pediatric research
2978 and the pediatric workforce can help all through life and
2979 into adulthood.

2980 Can you elaborate a little bit on that [inaudible]?

2981 *Dr. Walker-Harding. Absolutely. It is -- most of the
2982 health concerns that we deal with in adults have their
2983 underpinnings, origins, or beginnings in pediatrics. If you
2984 are talking about heart disease, diabetes, obesity, substance
2985 use, depression, cancer, you know, all of those things, if we
2986 are going to pay attention to them in pediatrics, could be
2987 mitigated, decreased, eliminated.

2988 We have to start thinking about how we developmentally
2989 look at how we are going to address health problems in this

2990 country, so that we can prevent and have treatments for them,
2991 instead of just waiting for people to have a disease and work
2992 toward it. That is critical in pediatric research.

2993 *Ms. Schrier. Thank you. I really appreciate it. It
2994 is one of the reasons that I talk so much about, for example,
2995 using our nutrition programs effectively to really channel
2996 kids to liking fruits and vegetables and the things that will
2997 stave off those adult diseases later. So thank you again.

2998 I yield back.

2999 *Ms. Eshoo. The gentlewoman yields back. It would be
3000 good to know how many pediatric researchers we have in the
3001 country today, in comparison to others.

3002 The chair is now pleased to recognize the gentleman from
3003 Texas, Mr. Crenshaw, for your five minutes of questions.

3004 *Mr. Crenshaw. Thank you, Madam Chair. I thank you to
3005 the ranking member for holding this hearing today, and thank
3006 you to the panel of witnesses for being here. My questions
3007 are for Michael Shannon, so I will premise this with these
3008 following facts.

3009 The U.S. Government estimates that every year China
3010 steals \$225 billion worth of things like patents and trade
3011 secrets from American companies. The Chinese consulate in
3012 Houston was shut down because it had become a hotbed of
3013 spying and intellectual property theft in both the energy and
3014 medical sectors. The FBI raided MD Anderson and several of

3015 our other prestigious medical institutions because of
3016 incidents where Chinese spies were physically stealing data
3017 sets and samples from our medical labs.

3018 So my question is, has the U.S. Government been
3019 successful in actually prosecuting these types of cases?

3020 *Mr. Shannon. In some cases, yes. And those have been
3021 widely publicized. Where they have not been successful was
3022 early on focusing on this issue from a counter-intelligence
3023 perspective, when it is much more an espionage type of issue,
3024 when you get beyond the compliance questions, and you get
3025 into the actual action with the intent to do something and to
3026 violate the law.

3027 So they have found success. I think the refocus of the
3028 Federal Bureau of Investigation on the broader spectrum, to
3029 focus on those types of activities that are espionage-like,
3030 or result in a theft of IP, or are foreign agent action is a
3031 much better approach, and I think they will find success that
3032 way, even greater success that way.

3033 *Mr. Crenshaw. Okay. And for the times that they do
3034 have trouble prosecuting, what exactly are the challenges to
3035 prosecuting these cases? Why are they difficult?

3036 *Mr. Shannon. Well, I think early on a couple of
3037 issues.

3038 First, again, the use of the 1001 charge, 18 U.S.C.
3039 1001, lying on a Federal document or something of that

3040 nature, it is not a very strong charge when brought by AUSAs,
3041 as I understand it. It is not a very popular charge for them
3042 to bring. That is one challenge.

3043 The other is the -- that a large portion of this is
3044 compliance and procedural misconduct. So things that were
3045 brought forward criminally might have been better dealt with
3046 administratively. You know, again, as they are refocusing
3047 their efforts and focusing on an espionage and foreign agent-
3048 type focus when the evidence suggests that, I believe they
3049 will find greater success.

3050 *Mr. Crenshaw. Chinese institutions and individuals
3051 gave about \$1 billion to U.S. universities from 2015 to 2019
3052 to incentivize soft collaboration between U.S. institutions
3053 and Chinese research institutions. How is China -- how are
3054 Chinese institutions designing these collaboration activities
3055 to avoid prosecution by the U.S. Government?

3056 *Mr. Shannon. Well, it has been a concerted effort for
3057 a couple of decades, and it has been built over time. It is
3058 a generational issue. So you have got researchers who grew
3059 up being taught how to do this.

3060 There are contract agreements that come into play that
3061 make demands on individuals. And once you have accepted that
3062 remuneration, you are kind of in the trap. And so that --
3063 the -- they are also instructed -- or once we started
3064 identifying these issues, we found instructions that

3065 indicated how they would try to avoid that: first deny that
3066 it is you; say that it is -- you know, it is something other
3067 than what it is, you didn't know; or, where we were somewhat
3068 vulnerable, the policy wasn't clear, or I wasn't told, which
3069 is why training and education is a big part of the solution,
3070 as well.

3071 *Mr. Crenshaw. So is it better distinctions and
3072 disclosure requirements and peer review? Will that help?

3073 *Mr. Shannon. Well, I think the disclosure requirements
3074 are there. It is just there hasn't been, until recently --
3075 and some of the tools that we deploy can rapidly identify
3076 those potential conflicts that are out there with potential
3077 threat actors. And risk rating that, and then addressing
3078 those risks, starting from a compliance perspective -- if you
3079 identify a relationship like that, does -- did the employer
3080 know about it? And if they didn't know about it, are they
3081 okay with it?

3082 Again, it is people accepting risk at a level that is
3083 above their authority to do so on behalf of their
3084 organization that is causing a lot of these problems. So
3085 being able to put internal controls, ensuring that there is
3086 accountability.

3087 I have advocated also for, again, research security or -
3088 - and other considerations as sort of a stewardship
3089 consideration for additional grant conditions.

3090 All of those things will help motivate awardees to take
3091 that step. There is a tuition cliff coming. They are going
3092 to be relying on research to fund their organizations. It is
3093 important for them to be competitive, and those with the best
3094 research security should have the best opportunity to be
3095 those trusted partners for those investments.

3096 *Mr. Crenshaw. I appreciate your time. It looks like I
3097 am -- and I am out of it.

3098 I yield back. Thank you.

3099 *Ms. Eshoo. The gentleman yields back.

3100 The chair is pleased to recognize the gentlewoman from
3101 Minnesota, Ms. Craig, for your five minutes of questions.

3102 *Ms. Craig. Well, thank you so much, Chairwoman, and
3103 thank you for holding this important hearing, as well as to
3104 our witnesses for being here today.

3105 Many of the bills up for discussion today focus on the
3106 health care issues most important to my constituents,
3107 including the unique barriers facing rural communities, and
3108 how we can best address them. Americans living in rural
3109 communities are more likely to travel long distances to
3110 access care. They are more likely to be uninsured or under-
3111 insured. And they face skyrocketing costs that serve to a --
3112 as a barrier to access.

3113 On top of that, health care workforce shortages are
3114 increasingly widespread, and hospitals in rural communities

3115 have been closing at a high rate for decades. But like many
3116 districts, access to broadband has been a significant issue
3117 that only deepens these disparities.

3118 With that, Ms. Sweeney, in your testimony you spoke
3119 about the lack of broadband access in the area that NEW
3120 Health serves. How would better infrastructure and the
3121 adoption of telehealth technology strengthen your ability to
3122 serve your patients?

3123 *Ms. Sweeney. Yes, thank you for that question. I
3124 think it is best illustrated by an experience.

3125 And so every day at 3:30 our internet broadband for my
3126 health care physicians was declining, and our EHRs would
3127 really bog down. So as our IT department further analyzed
3128 what was going on, what happens at 3:30 in most of our areas?
3129 Our students are getting out of school and they are coming
3130 home. So they are jumping on their gaming systems, and
3131 competing for that same broadband that we are trying to do
3132 our health records, and it really became problematic.

3133 And so in rural communities we are competing for that
3134 same broadband. We don't have dedicated lines, we don't have
3135 fiber. Like I mentioned earlier, we have some of our
3136 communities that are still on dial-up internet. And so it is
3137 really just a big challenge for our employee -- or our --
3138 excuse me, our patients as a whole. So it limits our ability
3139 to build out that telehealth.

3140 So we did talk about telephonic as an opportunity we
3141 have utilized. But I think, too, the cost prohibitive nature
3142 of our ISP providers, and so the cost for rural broadband for
3143 our constituents, is much higher than it is for our urban
3144 partners. And so much so we had utilized the USAC funding
3145 historically this last year. Our broadband provider did not
3146 submit a bid. There is nothing we can do about it, so our
3147 cost for broadband will go back up to its original cost,
3148 which is -- takes a significant part of our budget, and takes
3149 away from our primary care resources because we have to fill
3150 that budget shortfall.

3151 *Ms. Craig. Thank you so much, Ms. Sweeney. And I was
3152 sort of chuckling here as you were talking about competing
3153 with kids for broadband coverage. I -- as the mother of four
3154 sons, I certainly can remember those days of competing with
3155 Xbox and other gaming systems. So thank you for that.

3156 Dr. Croston, how can deployment of broadband funding
3157 through Federal programs help improve access to trauma care,
3158 particularly in rural areas?

3159 *Dr. Croston. Thank you, Representative Craig.
3160 Certainly, having visual connections to remote emergency room
3161 sites would provide the opportunity to give better guidance
3162 and help triage more effectively.

3163 The biggest problem rural areas face is getting to
3164 definitive care as quickly as possible, and sometimes that

3165 means a short stay in an emergency room remotely, and
3166 sometimes people would prefer to recover at home if it is at
3167 all possible.

3168 So having access to telehealth or a connection to a
3169 level one trauma center and staff there might provide support
3170 that would be needed to keep people locally, when possible.
3171 So it should work both ways.

3172 *Ms. Craig. Thank you so much for that. I know that
3173 telehealth accessibility is an issue we can all agree should
3174 demand more Federal attention.

3175 And I was proud to introduce H.R. 8169, the Rural
3176 Telehealth Access Task Force Act, with my colleague,
3177 Congressman Pence. This bill will form an HHS-led task force
3178 to study barriers to telehealth access and identify potential
3179 solutions.

3180 I am really proud of the investments most recently that
3181 we are making in many of our states through the bipartisan
3182 infrastructure bill to expand access to broadband, to the
3183 internet, and I look forward to continuing to work with each
3184 of you to make sure that it reaches all Americans.

3185 And with that, Madam Chair, I am going to yield my five
3186 seconds back to you.

3187 *Ms. Eshoo. I appreciate it. The gentlewoman yields
3188 back.

3189 It is a pleasure to recognize the gentlewoman from

3190 Massachusetts -- almost last, but not last at all -- a great
3191 member of our subcommittee, Congresswoman Trahan.

3192 *Mrs. Trahan. Well, thank you, Madam Chairwoman, and
3193 thank you to the witnesses here today.

3194 Throughout the COVID-19 pandemic, community health
3195 centers across the nation have delivered lifesaving care to
3196 the American people. Ms. Sweeney, in your testimony you
3197 recognize that not all communities can support a full-time,
3198 brick-and-mortar health center site, and that your new mobile
3199 unit has been a cost-effective alternative that breaks down
3200 transportation and access barriers to your patients.

3201 In my district few have done more to serve numerous
3202 patient populations before and throughout the pandemic than
3203 the hardworking men and women at the Greater Lawrence Family
3204 Health Center, the Lowell Community Health Center, and
3205 Community Health Connections in Fitchburg, Massachusetts.
3206 And since 2017, the Greater Lawrence Family Health Center has
3207 utilized mobile health units to connect with the homeless
3208 population in Lawrence. This population does not typically
3209 access the brick-and-mortar health center, but instead they
3210 rely on the health centers -- two mobile units to receive
3211 substance use disorder treatment, behavioral health care,
3212 primary care, and acute care.

3213 These mobile units also screen for social determinants
3214 of health to get vulnerable populations access to necessities

3215 like food and housing.

3216 The Lowell CHC currently does not have a formal mobile
3217 health clinic. However, they host numerous preventative
3218 screenings and COVID-19 vaccination clinics in the community,
3219 which have been very successful, and have demonstrated the
3220 ability to close disparities in access to such services.
3221 Lowell CHC is currently exploring expanding this model as a
3222 mobile health clinic.

3223 So the Mobile Health Care Act will achieve the goal of
3224 allowing more health centers the flexibility to acquire and
3225 develop innovative mobile clinic solutions to serve some of
3226 the hardest-to-reach populations such as veterans, homeless
3227 individuals, agricultural workers, and those in remote areas.

3228 So, Ms. Sweeney, if you could, just describe how the
3229 Mobile Health Care Act helps health centers like Lawrence and
3230 Lowell and Fitchburg either build up or establish their
3231 mobile health units.

3232 *Ms. Sweeney. Yes, that is -- thank you for asking that
3233 question. So the legislation enables mobile units to qualify
3234 as a new access point, regardless of whether it is associated
3235 with a permanent site. This designation and funding
3236 flexibility will facilitate more mobile units being utilized
3237 by health centers, and getting our patients access where they
3238 need access.

3239 So it takes a really -- you know, aligning it to a site,

3240 and we can more easily get it to multiple sites within our
3241 service area. Like we mentioned earlier, we are three-county
3242 location, so we can better serve patients more cost
3243 effectively.

3244 *Mrs. Trahan. And Ms. Sweeney, in your testimony you
3245 also discuss the critical workforce shortages and the high
3246 staff turnover health centers grapple with daily. What are
3247 some of the difficulties your health center faces in staffing
3248 your mobile unit?

3249 And then what Federal resources do health centers across
3250 the nation need to overcome these workforce barriers to be
3251 able to continue providing culturally competent and quality
3252 care to their under-served patient populations?

3253 *Ms. Sweeney. Yes, so our mobile unit has actually been
3254 a very positive thing when we are talking about provider
3255 burnout, that people are looking forward to a care model that
3256 is -- you know, more readily meets the patient's needs. And
3257 so our plan for our existing clinical staff is to roll out
3258 our existing staff into the mobile clinic, and then we will
3259 look at evaluating a dedicated mobile clinic staff team
3260 individually.

3261 And so it is important to note that our workforce
3262 challenges predated COVID. And so our workforce challenges
3263 are not just limited to clinical positions. It is across all
3264 things. So we need resources for those capital projects, for

3265 workforce development programs.

3266 And again, community health centers have multiple gaps
3267 that we are trying to do. And in our testimony we did talk
3268 about NEW Health University, our strategic workforce program.
3269 So we are very excited about our initial results with that,
3270 and how we are overcoming not only our mobile staffing, our
3271 behavioral health staffing, and our general staffing
3272 challenges in general.

3273 *Mrs. Trahan. Well, it is such an important time. And
3274 I am thrilled to see this piece of legislation, you know,
3275 move forward with the support -- and also your testimony,
3276 which validates the need for getting beyond the brick-and-
3277 mortar clinic.

3278 Thank you so much, Madam Chair. I yield back.

3279 *Ms. Eshoo. The gentlewoman yields back. That
3280 concludes members of the subcommittee questioning. And I now
3281 would like to recognize a member of the full committee, the
3282 gentlewoman from New York.

3283 And we are very grateful to you, Congresswoman Clarke,
3284 for H.R. 2007, named for our late colleague, Stephanie Tubbs
3285 Jones. So it is a pleasure to have you with us. You can
3286 waive on to this subcommittee any time you would like. You
3287 are recognized for five minutes of questions.

3288 *Ms. Clarke. And I thank you very much, Madam Chair,
3289 for including a piece of legislation in this hearing that not

3290 only holds great personal significance to me, but is
3291 especially important during a time where women's basic
3292 reproductive rights are under attack.

3293 Let me thank the witnesses. This has been a fascinating
3294 hearing, and has really driven home the challenges we face as
3295 a multi-ethnic, multi-racial, multi-religious society.

3296 My legislation, H.R. 2007, the Stephanie Tubbs Jones
3297 Uterine Fibroid Research and Education Act, is named in
3298 tribute to our dear colleague, friend, mentor, the late,
3299 great honorable Congresswoman Stephanie Tubbs Jones. We know
3300 that, during her tenure in Congress, this legislation was one
3301 of her top priorities, as Black women are disproportionately
3302 impacted by uterine fibroids more than any other women. And
3303 she would often say, as has been stated by our witness, that
3304 Black women deserve better.

3305 And myself personally living through my own challenges
3306 with uterine fibroids, I think often times about the millions
3307 of marginalized women who possess little to no means for
3308 treatment, and can -- and cannot access any solutions for
3309 their pain and suffering, and they are suffering in silence.

3310 For my colleagues who may not be as in-tuned, uterine
3311 fibroids are non-cancerous growths on the uterus, and are
3312 among the country's most common gynecological conditions.
3313 About 26 million women and girls in the United States between
3314 the ages of 15 and 50 have fibroids, with more than 15

3315 million experiencing what is classified as severe symptoms.
3316 And no group of women suffer more from fibroids than Black
3317 women, who are at an increased risk compared to their White
3318 counterparts to get fibroids at a younger age, and suffer
3319 with more severe symptoms.

3320 It is estimated that fibroids cost the health care
3321 system between 5.9 billion to \$34.4 million each year [sic]
3322 in productivity.

3323 This issue has not received the attention nor the
3324 funding it deserves. And increasing awareness on uterine
3325 fibroids is critical to our efforts to address the national
3326 maternal mortality crisis and prevent pregnancy-related
3327 deaths. We must allocate funding towards research and
3328 education, so that those being impacted are receiving the
3329 proper care that they deserve. But in doing so, we can close
3330 the gap on this glaring disparity that has been
3331 disproportionately borne out in the lives of Black women.

3332 Lastly, I would like to thank and recognize the work of
3333 the Fibroids Foundation, the White Dress Project, and other
3334 organizations and individuals that continuously and
3335 tirelessly advocate and create awareness about this
3336 condition.

3337 Let me say, Madam Chair, that it is critical that we
3338 look at the whole woman and the health care. These are the
3339 most important reproductive years in the lives of women. And

3340 to be afflicted with such a condition during that time is
3341 devastating in many ways, and dangerous in others.

3342 So I would like to direct my first question to Ms.
3343 Tanika Gray Valbrun.

3344 Tanika, thank you for being here today and sharing with
3345 the committee your personal experiences with fibroids. Why
3346 do you believe we need to research and disseminate public
3347 information on fibroids?

3348 *Ms. Valbrun. Thank you so much, Congresswoman, for
3349 your advocacy and for sharing your story.

3350 It is imperative that we collect data and research so
3351 that we can know what is happening with this condition. On a
3352 very base level, there is so much information that we still
3353 don't know for the general public. A lot of women still
3354 don't know that a lot of times the symptoms they are
3355 experiencing are as a result of uterine fibroids.

3356 So for this condition, there are just base definitions
3357 and clinical studies that need to be done so that we are
3358 aware of what is happening with this condition, and really
3359 that we can educate people. There is really --

3360 *Ms. Clarke. And could you --

3361 *Ms. Valbrun. -- just a lot of lack of awareness.

3362 *Ms. Clarke. And could you elaborate on how disruptive
3363 uterine fibroids can be to a woman's overall workplace
3364 performance and quality of life?

3365 *Ms. Valbrun. Yes, absolutely. Quality of life is one
3366 of the biggest symptoms. The impact on quality of life is
3367 one of the biggest symptoms of uterine fibroids. Taking
3368 multiple days off work, not feeling comfortable, having
3369 stains and embarrassment, as I spoke about in my testimony.

3370 So it really is something that is daunting, and that
3371 many women have to think about when they think of their
3372 social life, when they think of the jobs they are going to
3373 get, even sitting -- standing up from a chair can be a
3374 crucial part in a woman's life when she is dealing with
3375 fibroids.

3376 *Ms. Eshoo. The gentlewoman's --

3377 *Ms. Valbrun. So it is --

3378 *Ms. Craig. Thank you. I have run out of time. I
3379 appreciate it.

3380 *Ms. Valbrun. Yes.

3381 *Ms. Craig. Madam Chair, I yield back. Thank you.

3382 *Ms. Eshoo. The gentlewoman yields back. I wanted to
3383 be a little more generous with your time, because you have
3384 waited since 8:00 a.m. or 11:00 a.m. to join us today.

3385 That now concludes our hearing. I want to thank, on
3386 behalf of all of my colleagues, Dr. Bibbins-Domingo, Dr.
3387 Croston, Ms. Gray Valbrun, Mr. Shannon, Ms. Sweeney, and Dr.
3388 Walker-Harding for your very important and highly instructive
3389 testimony today.

3390 Please know that members have 10 business days to submit
3391 additional questions for the record. And so I ask the
3392 witnesses to please respond promptly to any questions that
3393 you receive.

3394 And I do have a submittal of documents to the record. I
3395 request unanimous consent to enter the following documents
3396 into the record: a letter from the Medical Imaging and
3397 Technology Alliance in support of H.R. 2007; a letter from
3398 the American College of Surgeons regarding H.R. 8163; a
3399 letter from the March of Dimes in support of H.R. 7565 and
3400 H.R. 2007; a statement from the Fibroid Foundation on H.R.
3401 2007.

3402 Does the ranking member join me in the unanimous consent
3403 request?

3404 *Mr. Guthrie. Yes, Madam Chair. We have no objections
3405 on our side.

3406 *Ms. Eshoo. Okay. Without objection, so ordered.

3407 [The information follows:]

3408

3409 *****COMMITTEE INSERT*****

3410

3411 *Ms. Eshoo. Thank you very much, Mr. Guthrie.

3412 And not seeing anything else to come before the
3413 subcommittee this morning, I want to thank all of my
3414 colleagues for your important work. I am so proud of this
3415 subcommittee and what each member brings forward to make a
3416 difference to the people of our country.

3417 So at this time, in gratitude and respect for the rest
3418 of your day, the subcommittee is adjourned.

3419 [Whereupon, at 1:58 p.m., the subcommittee was
3420 adjourned.]