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6 BOOSTER SHOT: ENHANCING PUBLIC HEALTH THROUGH VACCINE

7 LEGISLATION

8 H.R. 550, THE "IMMUNIZATION INFRASTRUCTURE MODERNIZATION

9 ACT'';

10 H.R. 951, THE "MATERNAL VACCINATIONS ACT'';

11 H.R. 979, THE "VACCINE FAIRNESS ACT'';

12 H.R. 1452, TO DIRECT THE SECRETARY OF HEALTH AND HUMAN

13 SERVICES TO PUBLISH THE FORMULA THE SECRETARY USES TO

14 DETERMINE THE ALLOCATION OF COVID-19 VACCINES, AND FOR OTHER

15 PURPOSES;

16 H.R. 1550, THE "PROMOTING RESOURCES TO EXPAND VACCINATION,

17 EDUCATION AND NEW TREATMENTS FOR HPV CANCERS ACT OF 2021'' OR

18 THE "PREVENT HPV CANCERS ACT OF 2021'';

19 H.R. 1978, THE "PROTECTING SENIORS THROUGH IMMUNIZATION ACT

20 OF 2021'';

21 H.R. 2170, THE "HELPING ADULTS PROTECT IMMUNITY ACT,'' OR THE

22 "HAPI ACT'';

23 H.R. 2347, THE "STRENGTHENING THE VACCINES FOR CHILDREN ACT

24 OF 2021'';

25 H.R. 3013, THE "COVID VACCINE TRANSPORTATION ACCESS ACT'';

26 H.R. 3655, THE "VACCINE INJURY COMPENSATION MODERNIZATION

27 ACT'';

28 H.R. 3742, THE "VACCINE INFORMATION FOR NURSING FACILITY
29 OPERATORS ACT'' OR THE "VACCINE INFO ACT''; AND
30 H.R. 3743, THE "SUPPORTING THE FOUNDATION FOR THE NATIONAL
31 INSTITUTES OF HEALTH AND THE REAGAN-UDALL FOUNDATION FOR THE
32 FOOD AND DRUG ADMINISTRATION ACT''

33 TUESDAY, JUNE 15, 2021

34 House of Representatives,
35 Subcommittee on Health,
36 Committee on Energy and Commerce,
37 Washington, D.C.

38

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41 The subcommittee met, pursuant to call, at 10:30 a.m.
42 via Webex, Hon. Anna Eshoo [chairwoman of the subcommittee],
43 presiding.

44 Present: Representatives Eshoo, Butterfield, Matsui,
45 Castor, Sarbanes, Welch, Schrader, Cardenas, Ruiz, Dingell,
46 Kuster, Kelly, Barragan, Blunt Rochester, Craig, Schrier,
47 Trahan, Fletcher, Pallone (ex officio); Guthrie, Upton,
48 Burgess, Griffith, Bilirakis, Long, Bucshon, Mullin, Hudson,
49 Carter, Dunn, Curtis, Crenshaw, Joyce, and Rodgers (ex
50 officio).

51 Also Present: Representative Schakowsky.

52 Staff Present: Jacquelyn Bolen, Health Counsel; Jeff

53 Carroll, Staff Director; Waverly Gordon, General Counsel;
54 Tiffany Guarascio, Deputy Staff Director; Perry Hamilton,
55 Clerk; Stephen Holland, Health Counsel; Mackenzie Kuhl, Press
56 Assistant; Una Lee, Chief Health Counsel; Aisling McDonough,
57 Policy Coordinator; Meghan Mullon, Policy Analyst; Kaitlyn
58 Peel, Digital Director; Tim Robinson, Chief Counsel; Chloe
59 Rodriguez, Clerk; Kylea Rogers, Staff Assistant; Kimberlee
60 Trzeciak, Chief Health Advisor; Rick Van Buren, Health
61 Counsel; C.J. Young, Deputy Communications Director; Alec
62 Aramanda, Minority Professional Staff Member, Health; Sarah
63 Burke, Minority Deputy Staff Director; Theresa Gambo,
64 Minority Financial and Office Administrator; Seth Gold,
65 Minority Professional Staff Member, Health; Grace Graham,
66 Minority Chief Counsel, Health; Nate Hodson, Minority Staff
67 Director; Peter Kielty, Minority General Counsel; Emily King,
68 Minority Member Services Director; Bijan Koohmaraie, Minority
69 Chief Counsel, O&I Chief Counsel; Clare Paoletta, Minority
70 Policy Analyst, Health; Kristin Seum, Minority Counsel,
71 Health; Kristen Shatynski, Minority Professional Staff
72 Member, Health; and Olivia Shields, Minority Communications
73 Director.

74

75 *Ms. Eshoo. The Subcommittee on Health will now come to
76 order.

77 And due to COVID-19, today's hearing is being held
78 remotely. All members and witnesses will be participating
79 via video conferencing.

80 As part of our hearing, microphones will be set on mute
81 to eliminate background noise and, members and witnesses, you
82 will need to unmute your microphone each time you wish to
83 speak. So please try to remember that.

84 Documents for the record should be sent to Meghan Mullon
85 at the email address we have provided to your staff. All
86 documents will be entered into the record at the conclusion
87 of the hearing.

88 The chair now recognizes herself for five minutes for an
89 opening statement.

90 Good morning, colleagues, and good morning, witnesses.
91 Vaccines are a powerful testament to scientific genius. As
92 President Biden said about the COVID-19 vaccine, "Every shot
93 is giving a dose of hope."

94 We have seen the power of the safe, effective, and free
95 COVID-19 vaccines. As they become widely available, fewer
96 COVID-19 hospitalizations and deaths are being reported each
97 day than at any point since the pandemic began. COVID-19
98 vaccines aren't unique in their lifesaving ability.
99 According to the CDC, routine childhood vaccinations have

100 prevented more than 21 million hospitalizations, and over
101 700,000 deaths among children born in the last 20 years.

102 But a vaccine that remains in its vial is zero percent
103 effective. That is why the Vaccines for Children program is
104 one of the most important public health achievements in our
105 nation's history. The Vaccines for Children program provides
106 free and easy access to vaccines to children in low-income
107 families. And thanks to the program, most children are no
108 longer vulnerable to measles or whooping cough.

109 But this continued success is not guaranteed. The
110 shelter-at-home orders caused childhood vaccinations to
111 plunge last year. According to the CDC, clinicians ordered
112 11-and-a-half million fewer vaccine doses for children,
113 compared to the previous year. Gaps in vaccine rates could
114 lead to deadly outbreaks among our nation's children.

115 Fortunately, Dr. Schrier, our subcommittee's resident
116 pediatrician, has introduced the bipartisan Strengthening
117 Vaccines for Children Act. The bill expands the Vaccines for
118 Children program to cover more children and clinicians at
119 more locations, and reduce the financial and administrative
120 barriers to boost vaccine rates. The bill provides vaccine
121 counseling for parents, which is important to address
122 misinformation, as well as making clear to parents that
123 vaccines are free for children, even if they are uninsured or
124 on Medicaid.

125 Representative Sewell's Maternal Vaccination Act helps
126 make sure that newborns and pregnant mothers are protected
127 from the flu and whooping cough. By receiving the Idap (sic)
128 and flu vaccines while pregnant, mothers avoid serious --
129 potentially serious hospitalizations, while also providing
130 the mother's gift of antibodies to their newborns.

131 While the benefits of maternal vaccinations are clear,
132 our health care system does a poor job of helping pregnant
133 women receive important vaccines. A CDC pre-pandemic survey
134 found that only 35 percent of mothers receive both the Tdap
135 and flu vaccine during pregnancy.

136 Vaccines are important as people age. Seniors should
137 receive vaccines to prevent the flu, pneumonia, shingles,
138 tetanus, and whooping cough. Representative Kuster's
139 bipartisan Protecting Seniors Through Immunization Act
140 ensures that all Medicare Part D-covered vaccines are free to
141 beneficiaries.

142 Our hearing today will cover 12 bills, most of them
143 bipartisan. The aim is to ensure that every American, no
144 matter their age, race, or income are empowered to receive
145 the dose of hope from vaccine protection. Our communities
146 can be completely free of vaccine-preventable diseases,
147 including COVID-19, so I look forward to hearing from our
148 superb witnesses today how the critical bills before us will
149 help achieve this important goal.

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

151

152 *****COMMITTEE INSERT*****

153

154 *Ms. Eshoo. The chair now recognizes with pleasure Mr.
155 Guthrie, the ranking member of our Subcommittee on Health,
156 for five minutes for his opening statement.

157 *Mr. Guthrie. Thank you. Thank you, Madam Chair, Chair
158 Eshoo, for holding this important hearing on vaccines.

159 Vaccines are the exact reason we can and should be in
160 person today in the hearing room. We are asking Americans to
161 come back to work. Members of Congress should also be back
162 at work in the hearing room. I am forward to -- looking
163 forward to the committee meeting together in person very
164 soon.

165 Without Operation Warp Speed, we would not have three
166 safe and effective vaccines that are currently being
167 administered to Americans. Congress and President Trump came
168 together to help unleash private-sector innovation to make
169 this possible. Without medical innovation, we would be
170 nowhere close to where we are currently with COVID-19
171 vaccination numbers. Roughly 52 percent of Americans have
172 received at least 1 dose, and about 43 percent of Americans
173 are fully vaccinated.

174 We have advanced and improved our COVID-19 vaccine
175 distribution strategies, and continue to do so. Congress has
176 appropriated nearly \$4 trillion in response to the COVID-19
177 pandemic. Most recently, Congress provided 1.9 trillion
178 through the American Rescue Plan, with only 9 percent of the

179 funding going directly to fighting COVID-19. Of the 9
180 percent of COVID-19 relief, 7-and-a-half billion was
181 appropriated for vaccine planning, distribution, monitoring,
182 and tracking; 1 billion for vaccine confidence activities;
183 and 6.05 billion for COVID vaccine supply chain; and 7.6
184 billion for community health centers for activities,
185 including COVID-19 vaccine distribution and administration,
186 testing, and community outreach.

187 This bill became law four months ago. Have these funds
188 been distributed? How are these funds currently being used?

189 As a former Republican leader of Oversight Investigation
190 Subcommittee, I believe that oversight is a very important
191 aspect of our response. I have supported much-needed relief
192 for American families, workers, and small businesses, but we
193 must ensure it is being used effectively and wisely.
194 Specifically, I am concerned that a number of these bills are
195 duplicative of current efforts already underway to address
196 the COVID-19 pandemic.

197 Let me be clear. I support efforts to give every
198 American the opportunity to be vaccinated, and any other
199 vaccine-preventable disease where a vaccination is
200 recommended. But at this point we need to fully evaluate the
201 current situation: Why are Americans not getting vaccinated?

202 We need to tailor meaningful solutions to these
203 problems. Cost may be part of the problem, but there are

204 likely other issues that negatively affect vaccination rates.

205 For example, we are considering today H.R. 979, the
206 Vaccine Fairness Act, which would require weekly reporting of
207 vaccines -- vaccine distribution. I agree with my colleagues
208 that this information is helpful, but this is currently
209 already being done by HHS, and each member of the committee
210 receives its Vaccine Information Weekly.

211 Additionally, today, we are examining H.R. 3013, the
212 COVID Vaccine Transportation Access Act. This bill would
213 provide grants for transporting -- transportation to receive
214 vaccines. I certainly agree that transportation should not
215 be a limiting factor for an individual, but currently there
216 are already several resources available for these services,
217 including Uber and Lyft, who stepped up to provide
218 transportation. Congress also authorized non-emergency
219 transportation for Medicaid individuals in the December
220 bipartisan COVID-19 relief package. Lastly, many areas offer
221 a phone number that an individual can text and make a
222 vaccination appointment, and they can also help you
223 coordinate a ride.

224 We do currently have gaps in our vaccine system, and I
225 look forward to discussing H.R. 3742, the Vaccine Information
226 for Nursing Facility Operators Act, or Vaccine INFO Act,
227 which would require nursing homes to provide educational
228 information on the value of getting all of the appropriate

229 ACIP-recommended vaccines for health care workers to their
230 staff in a similar manner to how they provide educational
231 information on certain vaccines for their residents.

232 I also look forward to discussing H.R. 1452. This bill
233 would require HHS to publish the formula used to distribute
234 that allocation of COVID-19 vaccines. This bill would allow
235 states, local governments, and certain entities to better
236 prepare for vaccine distribution.

237 And lastly, I encourage all to get vaccinated. Vaccines
238 save lives and help protect many diseases. The Democrat
239 bill, H.R. 3, would disincentivize further development of
240 vaccines, and hinder development of lifesaving drugs. During
241 a global pandemic they want to advance policies that would
242 lead to fewer cures and treatment. This is very backwards to
243 me, and I hope my colleagues fully evaluate how damaging a
244 slow vaccine development could have been for COVID-19.

245 Many around the world, particularly the European Union,
246 did exactly what H.R. 3 was trying to get us to do in the
247 United States. These behaviors have resulted in the EU being
248 way behind the U.S. in distributing COVID-19 vaccines to
249 their citizens. We must continue to be a leader of medical
250 innovation, and encourage the development of new treatments
251 and cures in our great country.

252 And I yield back.

253

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

255

256 *****COMMITTEE INSERT*****

257

258 *Ms. Eshoo. Thank you, Mr. Guthrie.

259 The gentleman yields back. The chair now is pleased to
260 recognize the chairman of the full committee for five minutes
261 for his opening statement.

262 Mr. Pallone.

263 *The Chairman. Thank you, Chairwoman Eshoo, for having
264 this very important hearing.

265 The COVID-19 pandemic has drawn the world's attention to
266 the value of vaccines, and the rapid development of COVID-19
267 vaccines was a direct result of decades of progress in the
268 immunization landscape, and laser focus on science and
269 safety, and historic investment by the Federal Government and
270 the courage of clinical trial participants.

271 While the development of these remarkable vaccines mark
272 a huge step forward, this terrible pandemic has also made
273 clear that we must do more to reduce incidents of all
274 vaccine-preventable disease. And this includes taking action
275 to raise awareness of the value of vaccines, improving
276 vaccine-related public health infrastructure, and reduced
277 barriers to access for these lifesaving preventative tools.
278 And this is, obviously, your focus today, Madam Chair.

279 One of the areas where we can most improve is on adult
280 vaccination rates. As our witnesses will mentioned in their
281 testimony today, while the vaccination rates for childhood
282 vaccines is generally considered high, vaccination rates for

283 adults are lower across the board. These low vaccine rates
284 increase the burden of vaccine-preventable disease in the
285 United States. Each year there are over 3,000 cases of
286 hepatitis B; 40,000 cases of pneumococcal disease; and about
287 one million cases of shingles. Vaccination rates in the
288 recommended adult population for each of these diseases are
289 all below 30 percent. Moreover, only 48 percent of adults in
290 the U.S. received a flu shot during the 2019-2020 flu season.

291 So clearly, we need to explore ways to increase these
292 rates, and one place to look is the approach we are taking
293 with children. After all, over 90 percent of American
294 kindergartners receive the majority of their recommended
295 vaccines for hepatitis, chickenpox, polio, tetanus, and
296 measles, among others. And those are strong results, but we
297 must remain vigilant.

298 Last week the Centers for Disease Control and Prevention
299 reported a decline in childhood vaccination rates during the
300 early days of the COVID-19 pandemic, which could pose a
301 serious public health threat.

302 And we also know that there are significant disparities
303 in vaccination rates by age, gender, race, ethnicity, and
304 economic status. Black and Hispanic adults have lower
305 vaccination rates than White adults for every recommended
306 vaccine from the Advisory Committee on Immunization, and only
307 40 percent of pregnant women received the 2 vaccines

308 recommended during pregnancy to protect the mother and unborn
309 child. Moreover, only 23 percent of Black pregnant women and
310 25 percent of Hispanic pregnant women received the
311 recommended shots.

312 So coverage of vaccines by private and public health
313 insurance plays a significant role in vaccine access. And
314 lack of health coverage correlates with significantly lower
315 vaccination rates.

316 The comprehensive collection of bills we are considering
317 today would make significant enhancements to vaccine coverage
318 for adults and children in Medicare, Medicaid, and the CHIP
319 program. This includes H.R. 1978, the Protecting Seniors
320 Through Immunization Act, which was introduced by
321 Representatives Kuster and Bucshon. This legislation would
322 ensure that Medicare beneficiaries are not charged out-of-
323 pocket costs when receiving a vaccine through Part D.

324 And H.R. 2170, the Helping Adults Protect Immunity Act,
325 introduced by Representative Soto, would require all state
326 Medicaid programs to cover ACIP-recommended vaccines for
327 adults, and prohibit cost sharing.

328 And then there is H.R. 2347, the Strengthening the
329 Vaccines for Children Act, introduced by Representatives
330 Schrier, Joyce, Butterfield, and McKinley, and that would
331 enhance vaccines for children. This program provides
332 vaccines to low-income children by extending eligibility and

333 boosting incentives for providers to participate in the
334 program.

335 H.R. 951, another bill, the Maternal Vaccination Act,
336 introduced by Representative Sewell, would create a public
337 awareness campaign for maternal vaccinations, with a focus on
338 communities with historically low vaccination rates. This
339 bill is an important continuation of our work to address the
340 maternal mortality and morbidity crisis in America.

341 And finally, I wanted to mention, Madam Chair, H.R. 550,
342 the Immunization Infrastructure Modernization Act, also
343 introduced by Representatives Kuster and Bucshon. This bill
344 would provide funding for significant improvements to
345 immunization information systems. These systems are critical
346 tools for providers in public health systems, but must be
347 brought into the 21st century information age.

348 Increasing immunizations in the U.S. will promote
349 longer, healthier lives, while saving billions of dollars in
350 health care costs. And as we climb out of the pandemic, our
351 focus cannot be returned to the status quo. Our mandate is
352 to build a stronger and more equitable public health system,
353 and today's hearing, Madam Chair, and these bills is an
354 important step.

355 So again, I thank you, and I yield back. Thank you.

356

357

358 [The prepared statement of the Chairman follows:]

359

360 *****COMMITTEE INSERT*****

361

362 *Ms. Eshoo. Thank you, Mr. Pallone.

363 The gentleman yields back. The chair is now pleased to
364 recognize Representative Cathy McMorris Rodgers, the ranking
365 member of our full committee, for five minutes for her
366 opening statement.

367 *Mrs. Rodgers. Thank you, Madam Chair and Republican
368 Leader Guthrie.

369 Vaccines are a bright spot in the fight to enable
370 Americans to live long, healthy lives. COVID-19 is the
371 latest chapter in that story. It is also a bright spot to be
372 in the committee room today with my colleagues.

373 We know that vaccines save lives. Thanks to vaccines,
374 four preventable diseases have been completely eliminated
375 from the Americas today. Between 2011 and 2020, immunization
376 programs in low-income countries are estimated to have saved
377 more than 23 million lives.

378 And now, thanks to the Trump Administration and
379 Operation Warp Speed, we have three authorized vaccines in
380 record time to crush COVID-19. It is because of the private
381 sector leveraging investment and regulatory flexibility
382 provided by Congress and the Trump Administration to unleash
383 innovation.

384 Think about it. Today, just over a year since the
385 pandemic began, we are holding a hearing about getting a
386 vaccine to every person who wants one. At the start of the

387 pandemic, experts were estimated at -- estimating it would
388 take much longer. This record speed is a remarkable story of
389 American innovation.

390 Since December, when the first COVID-19 vaccine was
391 authorized, COVID-19 deaths have plummeted, countless lives
392 have been saved, and, as more adults are getting vaccinated,
393 cases are decreasing all across the country. Operation Warp
394 Speed has brought us back from the brink, back to work, back
395 to school, attending weddings, visiting grandparents,
396 planning vacations without fear of an unknown virus.

397 Congress took unprecedented additional steps to make
398 sure every American could get a vaccine for COVID-19 for
399 free. But as we have seen, there is additional barriers to
400 vaccination. I am pleased that we are examining existing
401 programs that aim to improve access to all vaccines, to make
402 sure that those who want vaccines can get them and, in the
403 case of childhood vaccines, parents have the best information
404 to make decisions for their family.

405 The state and Federal Governments worked together to
406 implement two programs to make sure those who cannot afford
407 recommended vaccines have access. The Section 317 vaccine
408 program has been around for more than 50 years, and
409 authorizes the Federal purchase of vaccines for children,
410 adolescents, and adults.

411 Additionally, the Vaccines for Children, VFC program,

412 was established in 1993. The VFC provides vaccines at no
413 cost to children who are Medicaid-eligible, uninsured, under-
414 insured, and American Indian or Alaska Natives. With the
415 creation of the Vaccines for Children program, the Section
416 317 vaccine program focuses on uninsured adults and under-
417 insured children not eligible for VFC. These programs allow
418 the CDC to purchase vaccines directly from the manufacturer,
419 and then provide the vaccines to states.

420 As we have learned from the pandemic, state and local
421 public health agencies are best situated to tailor programs
422 for their communities. I am glad that we are looking at
423 these programs today, and I hope that any COVID-19 vaccines
424 approved by the FDA will soon be distributed through these
425 channels.

426 To win the future, America must lead in the development
427 and the discovery of safe and effective vaccines. I want to
428 make sure that, as we debate access to vaccines, we are not
429 disincentivizing the investment and the risk necessary to
430 study and bring vaccines to market. Unlike drugs for when
431 you are sick, vaccines are given to healthy children and
432 adults. Large studies are necessary to ensure safety and
433 build trust, given the breadth of the population often taking
434 the vaccine. The risk benefit profile is different than,
435 say, a cancer drug, where side effects may be more
436 acceptable, given the risk of the disease.

437 More vaccines are desperately needed for diseases we
438 know about, like HIV and flu. Just this month, promising
439 reports released about a universal flu vaccine and potential
440 novel ways to vaccinate against HIV.

441 We also need to be ready for the next unknown virus, as
442 COVID-19 was unknown to us in 2018. The Federal Government
443 needs to continue investing in research, and prioritizing
444 vaccine development, while also making sure that incentives
445 exist for private industry to do the same.

446 Making sure that patients have access to vaccines, once
447 they are developed and approved, is one important way to
448 promote and unleash innovation, and I look forward to hearing
449 what more we can do. I yield back, Madam Chair.

450 [The prepared statement of Mrs. McMorris Rodgers
451 follows:]

452

453 *****COMMITTEE INSERT*****

454

455 *Ms. Eshoo. The gentlewoman yields back. I thank her
456 for her statement.

457 Pursuant to committee rules, all members' written
458 opening statements will be made part of the record.

459 I now would like to introduce our four witnesses that
460 are with us today.

461 We are very grateful to each one of you. It is an honor
462 to have you as a witness at our subcommittee.

463 First, Dr. Lijen "LJ" Tan. He is the chief strategy
464 officer of the Immunization Action Coalition.

465 So good morning to you, Dr. Tan, and welcome.

466 Next, Dr. Yvonne Maldonado. She is a professor of
467 pediatrics and epidemiology and public health at Stanford
468 University's Center for Academic Medicine, Pediatric
469 Infectious Diseases. Dr. Maldonado is my constituent, and I
470 am very proud of that. And I am so pleased that our
471 subcommittee is going to benefit from her expertise today.

472 Importantly, colleagues, Dr. Maldonado is leading the
473 trial of the Pfizer drug for children under the age of 12 at
474 Lucile Packard Children's Hospital.

475 So welcome to you, Dr. Maldonado. We are thrilled you
476 are with us.

477 Rebecca Coyle, she is the executive director of the
478 American Immunization Registry Association.

479 We are so pleased and honored to have you with us.

480 And Phyllis Arthur, she is the vice president,
481 infectious diseases and diagnostic policy, at the
482 Biotechnology Innovation Organization.

483 Welcome to you, Ms. Arthur. We are pleased to have you
484 with us.

485 So, Dr. Tan, we will start with you. You have five
486 minutes for your testimony, and be sure to unmute.

487

488 STATEMENT OF LIJEN "LJ" TAN, CHIEF STRATEGY OFFICER,
489 IMMUNIZATION ACTION COALITION; YVONNE MALDONADO, CHAIR,
490 COMMITTEE ON INFECTIOUS DISEASES, AMERICAN ACADEMY OF
491 PEDIATRICS, PROFESSOR OF PEDIATRICS AND OF EPIDEMIOLOGY AND
492 PUBLIC HEALTH, STANFORD UNIVERSITY, STANFORD UNITED CENTER
493 FOR ACADEMIC MEDICINE, PEDIATRIC INFECTIOUS DISEASES; REBECCA
494 COYLE, EXECUTIVE DIRECTOR, AMERICAN IMMUNIZATION REGISTRY
495 ASSOCIATION; AND PHYLLIS ARTHUR, VICE PRESIDENT, INFECTIOUS
496 DISEASES AND DIAGNOSTIC POLICY, BIOTECHNOLOGY INNOVATION
497 ORGANIZATION

498

499 STATEMENT OF LIJEN "LJ" TAN

500

501 *Dr. Tan. Thank you very much, Chairman Eshoo, Ranking
502 Member Guthrie, members of the committee for allowing me to
503 testify today. I am LJ Tan. I am the chief strategy officer
504 for the Immunization Action Coalition. And I also co-chair
505 and co-founded the National Adult and Influenza Immunization
506 Summit. I also serve on the board and steering committee of
507 the Adult Vaccine Access Coalition.

508 As you have heard, the enormous benefits that we have
509 received as a result of our successful pediatric immunization
510 program, in terms of deaths and diseases averted and health
511 care costs saved, is clear. Policies that facilitate access
512 to immunizations play an important part in that success. For

513 example, the Federal Vaccines for Children program covers
514 uninsured and under-insured children, so that income status
515 is not a barrier to receiving that lifesaving vaccine.
516 However, our adult immunization coverage rates remain
517 dramatically low.

518 Before the onset of this pandemic, adult rates across
519 all vaccines recommended by the A-C-I-P, or ACIP, would be
520 low, federally-set targets. These low coverage rates result
521 in significant mortality, morbidity, and cost to the U.S.
522 health care system. It is estimated that more than 50,000
523 adults die annually from a vaccine-preventable disease.
524 Hundreds of thousands suffer consequences from these
525 diseases, including hospitalizations, time lost from work and
526 family, and reduction in their personal quality of life.

527 Adults aged 50 and over are particularly susceptible to
528 many vaccine-preventable diseases, and account for a
529 disproportionate number of the deaths and illnesses
530 associated with them. And if that is not enough, data
531 indicates that, for adults over 50 years of age, 4 major
532 vaccine-preventable diseases accounted for about \$26.5
533 billion in annual health care costs.

534 And as we all deal with the COVID-19 pandemic, adult
535 immunization coverage rates have gotten even worse. You
536 heard about the decline in pediatric rates. Adult rates have
537 also declined drastically. And while pediatric coverage

538 rates are now improving, adult rates have not been recovering
539 at the same pace.

540 So, despite all this evidence to the benefits of
541 immunizing adults, particularly older adults, why are
542 immunization coverage rates so low?

543 Access to vaccines and vaccination is the biggest
544 barrier to improving adult immunization coverage rates.
545 Adult care tends to be acute-based. So you go in to see a
546 physician when you are not feeling well, and well care visits
547 are challenging to adhere to in that busy adult life. As
548 such, patients are often not aware of the vaccines that they
549 need as adults. When you combine this lack of awareness and
550 education with the access challenges facing adult patients,
551 physical and logistical, many adults end up forgoing their
552 recommended vaccines.

553 Many older adults live on fixed incomes, and studies
554 indicate that additional cost to get vaccinated will delay or
555 even prevent them from getting vaccinated.

556 We must improve our public health infrastructure, and
557 particularly our immunization infrastructure, to be able to
558 ensure that any adult in the United States is able to receive
559 a vaccine that is recommended for them.

560 As we emerge from this pandemic, we need to maintain the
561 investments made as a result of COVID-19, and recognize that
562 the time to invest in our capacity to vaccinate all our

563 adults is now. The ability to deliver vaccines into this
564 population will predict our ability to respond effectively
565 when the next pandemic rears its ugly head. Annual readiness
566 translates into pandemic preparedness.

567 What can we do to develop the immunization
568 infrastructure that will support not only better health, but,
569 as I suggest, also prepare us for the next pandemic to come?

570 We must ensure that our most vulnerable adults, our
571 older adults and adults with chronic health conditions, can
572 be vaccinated without barriers. In doing so, we are not only
573 preparing the infrastructure, we are also making immunization
574 of adults a societal norm, a preventive health intervention
575 that we value.

576 The Protecting Seniors Through Immunization Act ensures
577 all vaccines under Medicare are available to beneficiaries
578 with no cost sharing or deductibles as part of your budget
579 proposal to Congress. This bill brings parity to out-of-
580 pocket costs between Medicare Part B and Medicare Part D
581 plans. The bill also strengthens vaccine confidence by
582 providing education on and increasing equitable access to
583 recommended vaccines for Medicare beneficiaries.

584 We cannot ignore those who are more vulnerable to
585 vaccine-preventable diseases as a result of their
586 socioeconomic status. For low-income individuals, any
587 financial barrier may impede people showing up to get

588 vaccinated. We must fix current disparities in coverage and
589 payment in the Medicaid program by providing a baseline of
590 consistent and reliable Medicaid coverage for patients across
591 the country.

592 The Helping Adults Protect Immunity Act seeks to ensure
593 that all Medicaid enrollees have access to this important
594 preventive health service, and do not face financial burdens
595 to become vaccinated with recommended vaccines.

596 A fully vaccinated public is an investment in our
597 future, well-being, and economic success of our nation. We
598 can make a difference in terms of morbidity, mortality, and
599 quality of life for our population, and in terms of cost to
600 our health care system. Our annual readiness will translate
601 into pandemic preparedness.

602 Thank you for your time and your commitment to vaccines.
603 I am happy to answer any questions.

604 [The prepared statement of Dr. Tan follows:]

605

606 *****COMMITTEE INSERT*****

607

608 *Ms. Eshoo. Thank you, Dr. Tan, for your excellent
609 testimony.

610 Next, Dr. Maldonado, welcome again, and thank you, and
611 you have five minutes to deliver your remarks to our
612 committee.

613 [Pause.]

614 *Ms. Eshoo. You need to unmute.

615 *Dr. Maldonado. Yes, I think I should. I should have
616 known that already, sorry. Okay, here we go.

617 *Ms. Eshoo. Here you are. Welcome.

618 *Dr. Maldonado. Thank you so much.

619

620 STATEMENT OF YVONNE MALDONADO

621

622 *Dr. Maldonado. Chairman Eshoo, Ranking Member Guthrie,
623 and members of the committee, thank you for the opportunity
624 to testify today before you. It is an honor to talk about
625 the importance of vaccines for children. My name is Dr.
626 Yvonne Maldonado, and I am testifying today on behalf of the
627 American Academy of Pediatrics, AAP, a nonprofit professional
628 membership organization of 67,000 pediatricians dedicated to
629 the health and well-being of children.

630 I am an infectious disease pediatrician, and serve as
631 the chair of the AAP's Committee on Infectious Disease. I am
632 also a professor of pediatrics, epidemiology, and population
633 health, chief of the division of pediatric infectious
634 diseases at Stanford University School of Medicine, where I
635 also practice at the Lucile Packard Children's Hospital. I
636 currently lead several COVID-19 treatment and prevention
637 programs.

638 The past year and a half has been extremely challenging
639 for adults and children alike, as we have lived through the
640 COVID-19 pandemic. While the vast majority of deaths and
641 severe illness from COVID-19 have occurred in adults,
642 children have experienced severe harmful impacts of the
643 pandemic. Nearly 4 million children have been infected with
644 the virus, over 16,000 have been hospitalized, and more than

645 315 have died, with more than two-thirds of those being Black
646 and Latinx children.

647 The pandemic has also led to make limited social
648 interactions with peers and relatives, and curtailed access
649 to other activities that help children develop social,
650 emotional well-being, and maintain good mental health. This
651 is why we are so grateful that we finally have a COVID-19
652 vaccine for adolescents aged 12 and up. We strongly
653 encourage parents to get the vaccine for themselves and for
654 their eligible children. Vaccinating children and families
655 against COVID-19 will save lives, and help them return to a
656 more normal life.

657 Pediatricians believe in strengthening child
658 immunization rates as a major path to advancing child health.
659 That is why we must vigorously support the Vaccines for
660 Children program, the backbone of the childhood vaccine
661 delivery system in the United States, which provides
662 immunizations at no cost to children who are enrolled in
663 Medicaid, are uninsured, or under-insured, or who are Native
664 American or Native Alaskan. Since its inception in 1993, the
665 VFC program, which provides half of all vaccines to American
666 children, has increased vaccination rates and reduced the
667 risk of preventable infections across all races, ethnicities,
668 and income groups, and reduced racial and ethnic disparities.

669 Unfortunately, over the last 15 months, we have seen a

670 staggering decrease in routine childhood immunizations.
671 Recent CDC data shows that overall VFC provider orders for
672 non-flu vaccines are down by more than 11.5 million doses,
673 compared to the previous year. When children miss
674 recommended vaccinations, they leave themselves, other
675 children, and adults in their communities more vulnerable to
676 outbreaks of preventable diseases like measles and whooping
677 cough, particularly in school settings.

678 While the VFC program has been a tremendous success,
679 current financial and administrative barriers make it
680 difficult for clinicians to participate. The COVID-19
681 pandemic has only exacerbated these challenges, as dramatic
682 decreases in revenue from fewer patient visits, compounded
683 with higher overhead costs, has financially stressed many
684 practices.

685 As such, the American Academy of Pediatrics strongly
686 supports the strengthening of the Vaccines for Children
687 Program Act of 2021, and we thank Representative Schrier, a
688 fellow pediatrician, and Representatives Joyce, Butterfield,
689 and McKinley for introducing this strong, bipartisan piece of
690 legislation. This bill provides incentive payments for
691 participating providers to stay in the program, and entices
692 new providers to join. It also addresses providers'
693 financial burden by increasing Medicaid payment for vaccine
694 administration to match Medicare payment rates for two years.

695 The legislation also extends VFC eligibility to children
696 enrolled in the Children's Health Insurance Program, and
697 enables under-insured children to receive VFC vaccines in
698 their medical home, as opposed to having to go to another
699 clinic to receive care.

700 Additionally, the legislation would finally allow VFC
701 payments for administration of multiple component vaccines,
702 vaccines that protect against more than one disease. In
703 short, the Vaccines for Children program is the heart of the
704 childhood vaccine delivery system, and we need to do all we
705 can to support it.

706 In addition, it is imperative that we bolster
707 immunization information systems, IIS. The Immunization
708 Infrastructure Modernization Act would provide critical
709 resources for IIS modernization, and has the ability to
710 capture and share immunization data, thus improving our
711 ability to keep children up to date on their vaccines.

712 Thank you so much for the opportunity to testify today.
713 We appreciate the subcommittee calling attention to the
714 importance of vaccines this morning, and we look forward to
715 working with you to ensure that all Americans have access to
716 routine vaccinations, including the COVID-19 vaccines.

717

718

719

720 [The prepared statement of Dr. Maldonado follows:]

721

722 *****COMMITTEE INSERT*****

723

724 *Ms. Eshoo. Thank you, Dr. Maldonado. And you
725 delivered your testimony not using all of your time, which is
726 always noted by members, so thank you very much.

727 Next, Ms. Doyle (sic), you are recognized for five
728 minutes. And again, all of our thanks for being willing to
729 be a witness before our subcommittee today. You have five
730 minutes, so make sure you unmute. We want to hear every
731 word.

732 [Pause.]

733 *Ms. Eshoo. We can't hear you.

734 [Pause.]

735 *Ms. Eshoo. We can't hear you.

736 *Ms. Coyle. Yes.

737 *Ms. Eshoo. There you are.

738 *Ms. Coyle. Great.

739 *Ms. Eshoo. I hope you heard me welcome you. And thank
740 you again for being a witness today. You have five minutes
741 for your testimony.

742

743 STATEMENT OF REBECCA COYLE

744

745 *Ms. Coyle. Thank you, Chairwoman Eshoo, Ranking Member
746 Guthrie, and members of the committee. I appreciate the
747 opportunity to be part of the hearing today to talk about
748 immunization information systems, also known as immunization
749 registries.

750 My name is Rebecca Coyle. I serve as the executive
751 director of the American Immunization Registry Association,
752 known as AIRA. AIRA members include IIS and immunization
753 program staff working in state and local health departments,
754 and organizations such as IIS implementers, nonprofits, and
755 others interested in IIS.

756 IIS are confidential, population-based computerized
757 databases that record all immunization doses administered by
758 participating vaccination providers to persons residing
759 within a state or jurisdiction. IIS exists in all states,
760 territories, and several large cities and counties.
761 Nationally, 96 percent of children, 82 percent of
762 adolescents, and 60 percent of adults have immunization
763 records and an IIS as of 2019. IIS are primarily funded
764 through Federal investments using cooperative agreement funds
765 from CDC's immunization program using section 317 funds. IIS
766 support the administration of the Vaccines for Children
767 program, with a majority of VFC vaccines being ordered by

768 providers using an IIS.

769 However, there is no overarching Federal policy that
770 requires VFC providers to record these doses in an IIS. And
771 there is no equivalent vaccination program for adults. Many
772 jurisdictions have implemented reporting requirements, but
773 policies vary by jurisdiction. States have similar but
774 different laws and policies for a variety of functions,
775 including data exchange, vaccine reporting, access, and
776 sharing data with another IIS. And it is these variations
777 that are most often criticized, because not all states
778 function the same.

779 IIS are part of the immunization program infrastructure,
780 and are powerful tools for managing immunization records and
781 supporting healthier communities. IIS are used to
782 consolidate vaccination data from multiple providers into one
783 record. They are used for vaccine ordering and managing
784 inventory, which minimizes waste and saves money.

785 IIS has been used in nearly all vaccine-preventable
786 disease outbreaks in the past decade: the 2009 H1N1 pandemic
787 and the current COVID-19 pandemic.

788 Of the utmost concern is the privacy and security of all
789 system data. Standards set by CDC state that all IIS must
790 have a written policy that clearly defines expectations, such
791 as the type of information contained, and how the data will
792 be used, and who has access to that information. IIS are

793 expected to mirror industry standards for system security.

794 COVID-19 vaccine efforts have highlighted multiple areas
795 where investments in IIS are critical. Without an
796 investment, IIS will continue to face failing and capacity
797 issues. The ability to process and manage the volume of data
798 that has been generated from COVID-19 vaccination events
799 highlights the need for systems to move to cloud-based
800 hosting, with scaling and surge capacity capabilities.

801 To put it simply, most jurisdictions were operating the
802 highway, but with the pandemic traffic there was a need to
803 expand to an eight-lane freeway.

804 Additional efforts are also needed to identify and
805 expand bidirectional data exchange. Bidirectional means
806 sending information to an IIS, and also receiving a vaccine
807 history and forecast in return. There is a need to onboard
808 small providers that are often located in rural areas, as
809 well as the many unique and varied entities administering
810 vaccinations to adults. It is critical to have a workforce
811 that can support and perform system management functions and
812 leverage new technologies to increase efficiencies. Many of
813 our current workforce are leaving for better-paying jobs.

814 The present pandemic is the first time near real-time
815 vaccination data has been shared with CDC to provide a
816 comprehensive surveillance at the Federal level. These data
817 are primarily coming from IIS. Special policies were

818 instituted to allow for this sharing of data. However, these
819 policies do not extend to other vaccines, and this limits our
820 nation's public health agencies' ability to monitor outbreaks
821 and routine vaccine administration from a national
822 perspective. A national policy framework is needed to align
823 reporting and consent requirements, authorized use, and data
824 access.

825 Congress has an opportunity to improve, enhance, and
826 expand the ability of IIS to securely exchange real-time
827 immunization data, while safely protecting personal
828 information. The Immunization Infrastructure Modernization
829 Act, H.R. 550, introduced by Representatives Kuster and
830 Bucshon, will help provide the needed national framework for
831 IIS operations. Providing resources and supporting policies
832 to modernize IIS will allow better management of routine
833 immunization efforts and enhance public health's ability to
834 respond to pandemics and outbreaks of other vaccine-
835 preventable diseases.

836 Thank you for this opportunity to share the information
837 with you today, and I look forward to your questions.

838 [The prepared statement of Ms. Coyle follows:]

839

840 *****COMMITTEE INSERT*****

841

842 *Ms. Eshoo. Thank you, Ms. Coyle, for your testimony.

843 The chair is pleased to recognize Phyllis Arthur.

844 Welcome to the subcommittee. Please unmute. We are

845 happy to have you with us, and you have five minutes.

846 *Ms. Arthur. Thank you.

847

848 STATEMENT OF PHYLLIS ARTHUR

849

850 *Ms. Arthur. Good morning, Chairwoman Eshoo, Ranking
851 Member Guthrie, and members of the committee. I am Phyllis
852 Arthur, vice president of infectious diseases and diagnostics
853 policy at the Biotechnology Innovation Organization. Thank
854 you for the opportunity to speak on the vaccine legislation
855 being considered today.

856 Our association includes companies that are committed to
857 bringing vaccines to people of all ages. Vaccine
858 manufacturers conduct research to the highest regulatory
859 standards to ensure safety, efficacy, and manufacturing
860 quality. And they are a vital -- they are vital to national
861 and global public health.

862 Vaccines are the cornerstone of public health, reducing
863 or eliminating many infectious diseases. The CDC projects
864 that pediatric vaccines given between 1994 and 2018 will
865 actually prevent over 400 million illnesses, 27 million
866 hospitalizations, and over 936,000 deaths, while saving over
867 \$1.9 trillion in societal costs, including 406 billion in
868 direct health care costs.

869 The pandemic taught us several lessons.

870 First, public health infrastructure is vital in
871 peacetime and during a pandemic. We saw a dangerous drop in
872 pediatric, adolescent, and adult routine immunizations this

873 past year. Reinvigorating public health through catch-up
874 vaccination is crucial to avoid future outbreaks from
875 vaccine-preventable diseases. The Immunization
876 Infrastructure Modernization Act seeks to modernize our
877 immunization registries, helping states manage public data on
878 routine immunizations, while enhancing our response to
879 outbreaks and future pandemics.

880 Second, BIO, like others, partnered with many
881 organizations to educate the public on the COVID-19 vaccines.
882 Education must expand to other vaccines, and outreach to at-
883 risk populations using trusted messengers can increase
884 immunization rates. Congress should pass H.R. 951, H.R.
885 1550, and H.R. 3742 for these goals.

886 Lastly, we realize the different barriers to access,
887 especially for people of color, seniors, and those in rural
888 areas. Many faced financial and logistical impediments.
889 Congress acted early to ensure COVID-19 vaccines were covered
890 and accessible. Please do the same for the full complement
891 of CDC-recommended vaccines for adults by passing the
892 Protecting Seniors Through Immunization Act and the HAPI Act.
893 These bills will reduce financial barriers by addressing cost
894 sharing in Medicare and Medicaid.

895 Cost sharing for vaccines is senseless, because of their
896 immense benefits. Vaccines not only prevent a person from
897 getting sick, they prevent others, as well, and thus, they

898 generate a high societal benefit.

899 Infectious diseases exacerbate underlying conditions,
900 leading to long-term negative outcomes. COVID-19 made this
901 clear. Under Medicare Part D, seniors pay significant
902 copayments on vaccine. Not all Medicaid programs fully cover
903 ACIP-recommended vaccines, and many have copayments that
904 discourage uptake. The Protecting Seniors and the HAPI Act
905 will encourage parity by covering vaccines at no cost
906 sharing, just as they are in Medicare Part B and private
907 insurance. Removing this barrier provides direct financial
908 and health benefits, improving access and equity for those
909 adults who will benefit the most from vaccination.

910 Patient safety is also critical. Vaccines are one of
911 the safest medical interventions, and serious injuries are
912 exceptionally rare. The U.S. has one of the most
913 comprehensive compensation programs, the National Vaccine
914 Injury Compensation Program, or VICP. This no-fault
915 compensation makes compensation quicker, cheaper, and easier
916 for those injured by vaccines. The Vaccine Injury
917 Compensation Modernization Act would update and strengthen
918 the program by providing more adequate compensation, while
919 extending protection to adult vaccinees.

920 BIO is excited to see bipartisan legislation focused on
921 vaccines, and we should continue the tremendous collaboration
922 that carried us through this pandemic. These policies are --

923 can dramatically impact the uptake and access to vaccines,
924 leading to a healthier population, a robust economy, and new
925 innovation in vaccines and preventive monoclonal antibodies
926 that tackle unmet medical needs.

927 Increased investment by vaccine developers of all sizes
928 could lead to new immunization options, and health care
929 savings in the United States and around the world.

930 Thank you for the opportunity to testify today.

931 [The prepared statement of Ms. Arthur follows:]

932

933 *****COMMITTEE INSERT*****

934

935 *Ms. Eshoo. Thank you very much. We will now move to
936 members' questions, and I -- the chair recognizes herself for
937 five minutes first to Dr. Maldonado, and then a question to
938 Dr. Tan, and a question to Phyllis Arthur.

939 To Dr. Maldonado, vaccine hesitancy and misinformation,
940 I think, have become a new culture war, with news media and
941 with some politicians who are hyper-focused on highlighting
942 the latest rumors. It is just so damaging, in my view. In
943 looking at CDC data, it -- I think it becomes clear that
944 insurance status and income play a major role in keeping
945 people, especially children, from getting vaccines.

946 So tell us what you think the barriers are that your
947 pediatric patients face in getting their vaccinations, and
948 what should be done to -- for children, to make it easier for
949 children to get vaccinations.

950 And then I am just going to state my questions off the
951 top, so each one allow time for the other.

952 To Dr. Tan, what do you think the barriers are that
953 Congress should address to help more adults get their
954 vaccines?

955 And to Ms. Arthur, prior to COVID-19, vaccine research
956 was really underfunded, because vaccines are less profitable
957 than other innovative treatments. So can you tell us if you
958 think COVID-19 and the success of mRNA vaccines have changed
959 this?

960 And what is needed to make sure the United States of
961 America has the strongest pipeline for new and effective
962 vaccines?

963 So, Dr. Maldonado, back to you.

964 *Dr. Maldonado. Thank you for this important question.
965 And so I think there are two major components to our failure
966 to vaccinate all of our children.

967 This is a remarkable opportunity for us to save lives,
968 to make lives healthier.

969 I have been in practice for over 30 years, myself, and I
970 have seen diseases completely disappear from my practice
971 across the street here, at this children's hospital, where I
972 saw, on a weekly basis, children die from diseases that I no
973 longer see. And that is because -- entirely because of
974 vaccination.

975 And so what we are seeing are two different things. One
976 is the rise of vaccine hesitancy. I won't say it is new. It
977 has been around since Benjamin Franklin's days and before.
978 What is new is social media, and the -- a rapid spread of
979 misinformation.

980 I think we need to do a better job of making sure that
981 people hear proper messaging from trusted leaders, that they
982 can feel -- hearing the proper news, the right information
983 about vaccines, and making sure that they know that vaccines
984 are safe and effective, and that here in the United States we

985 have the safest vaccine development delivery systems in the
986 world.

987 The second issue that I think is important for children
988 is health and income disparities that really reduce the
989 access for children to get vaccinated. They have to travel
990 frequently to different locations where they can get access
991 to vaccines, for example, through VFC sites that are allowed
992 to give them vaccines.

993 We are hearing, for example, even before the pandemic,
994 about practices that don't -- can't afford to give vaccines
995 because of the poor reimbursement rates for the cost that it
996 takes them in small practices to give vaccines. They are
997 writing prescriptions to children to go to publicly-funded
998 clinics, where they can get the vaccines, losing their
999 medical home, and losing that trusted source of other routine
1000 childhood care.

1001 So those are the two major areas. One is really getting
1002 good, safe, proper information out to all venues, public and
1003 private venues; as well as to making it easier for our
1004 providers, public and private providers, to give vaccines to
1005 all children, regardless of their income status.

1006 *Ms. Eshoo. Thank you very much.

1007 Dr. Tan?

1008 *Dr. Tan. Oh, thank you, Chairwoman Eshoo. I am going
1009 to be brief. I think, with adults, it is about convenience

1010 and access again.

1011 You know, adults have to get access to vaccines through
1012 multiple venues. You know, I am not -- you know, with
1013 pediatrics you have got a pediatrician, a family physician.
1014 With adults you are talking all over, right? Employers,
1015 grocery stores, you know, outpatient settings, and so on and
1016 so forth.

1017 So I think, you know, firstly, we need to make sure that
1018 access is available. And then that means incentivizing
1019 providers to make themselves providers for adult vaccines.

1020 And then secondly, when we then bring our patients in,
1021 the patients have to go in and recognize that they are going
1022 to be paid -- that they don't have something that is going to
1023 get in their way, like financial barriers. When someone goes
1024 in and says, "I am ready to get my vaccine," and then they
1025 find out, oh, you have got a \$160 copay, they are going to
1026 back away from that, for adults, especially.

1027 So I think those are the two big things I can think
1028 about right now.

1029 *Ms. Eshoo. Thank you.

1030 Ms. Arthur, I don't have time for you to answer, but I
1031 will submit my question to you in writing. Thank you.

1032

1033

1034

1035 [The information follows:]

1036

1037 *****COMMITTEE INSERT*****

1038

1039 *Ms. Eshoo. The chair is now pleased to recognize the
1040 chairman of the full committee, Mr. Pallone, for his five
1041 minutes of questions.

1042 *The Chairman. Thank you, Madam Chair. I just wanted
1043 to thank all the witnesses for their testimony. And as I
1044 mentioned in my opening statement, we are taking a
1045 comprehensive look at how to improve vaccine infrastructure
1046 awareness and access in our country. But I wanted to start
1047 out with Ms. Coyle.

1048 In your testimony you mentioned that 96 percent of
1049 children and 82 percent of adolescents have records in
1050 Immunization Information Systems in the U.S., but only 60
1051 percent of adults have immunization records in these same
1052 systems. So could you explain why there is such a
1053 significant drop-off among adults, and how can we improve
1054 these systems so health care providers have ready access to
1055 immunization data for the adult patients?

1056 [Pause.]

1057 *The Chairman. Were you guys able to hear me?

1058 *Ms. Eshoo. We can hear you, Mr. Chairman, but we can't
1059 hear the witness.

1060 You need to unmute.

1061 *The Chairman. Ms. Coyle?

1062 *Ms. Eshoo. I don't know what happened to her. Why
1063 don't you move to your next question, Frank. We will see

1064 what we can do --

1065 *The Chairman. Okay, well, let me just -- Dr.
1066 Maldonado, I wanted to ask you, as -- you know, as a
1067 physician, can you explain how increasing vaccinations among
1068 pregnant women can also protect their infants?

1069 *Dr. Maldonado. Yes. Maternal immunization is a
1070 critical new area that has really long been overlooked. And
1071 we are really proud and happy to see that more and more
1072 maternal immunizations are being administered, for example,
1073 for influenza, for -- and for whooping cough, and now for
1074 COVID-19.

1075 We know that, when mothers get vaccinated, especially
1076 during pregnancy, it does increase the safety of the infant
1077 through passively-acquired maternal antibodies that are
1078 transferred to their infant. For example, for pertussis,
1079 that has been absolutely shown to be the case.

1080 And we also know that it keeps the mother safe from
1081 infectious diseases herself during a vulnerable period, and
1082 also helps to cocoon the child, protecting the child from
1083 infections because she -- this young infant will be very
1084 close to their mother.

1085 So we do applaud these efforts to encourage maternal
1086 immunization.

1087 *The Chairman. And then, Doctor, it is also critical
1088 that we ensure all children get their recommended

1089 vaccinations. Are you aware of any data which shows how
1090 improving vaccination rates among pregnant women will affect
1091 the likelihood that the child receives recommended vaccines
1092 on time?

1093 *Dr. Maldonado. Yes, there are some data that have been
1094 published over the years showing that women and families who
1095 get vaccinated sooner are more likely to engage in
1096 vaccinating their children at a young age. It is important
1097 to engage them early on, because children need their first
1098 well child visits at two weeks of age, sometimes sooner. And
1099 that first vaccinations are given at two months. So engaging
1100 families before the birth of the baby has been shown to
1101 increase well child visits and immunizations of their
1102 subsequent family -- children and family members.

1103 *The Chairman. Well, thank you, Doctor.

1104 And finally, I wanted to mention the importance of
1105 having vaccines covered without cost sharing, because, under
1106 the Affordable Care Act, individuals in commercial health
1107 insurance plans cannot be charge out-of-pocket costs for
1108 vaccines they received in network. However, in Medicare Part
1109 D and Medicaid, some beneficiaries may be required to pay a
1110 copay to receive a recommended vaccine.

1111 So, Dr. Tan, can you explain how having a copay,
1112 including at a level that some might consider a low dollar
1113 amount, can negatively affect vaccination rates in the

1114 Medicare and Medicaid programs, if you will?

1115 *Dr. Tan. Well, thank you for that question.

1116 Absolutely.

1117 I think one of the things that we found out, especially
1118 people from lower socioeconomic status and older adults who
1119 are on fixed income, is that when you tackle all the
1120 logistical barriers and get them to a point of vaccination,
1121 when they show up and they find out all of a sudden that they
1122 have to pay a copay, there is a -- there is already data that
1123 shows that they do what we call abandoning the prescription.
1124 They basically turn around and walk away without getting that
1125 lifesaving vaccine.

1126 And it is a surprise to them, if you are going in
1127 thinking the vaccine is free because you are hearing from
1128 your child, for example, right, that -- who is under a
1129 commercial private plan, that, "Hey, I got my flu vaccine for
1130 free, Mom. You need to go get in and get vaccinated," and
1131 they go in and, you know -- or for shingles, for example, and
1132 then they find out, you know, I can't get vaccinated without
1133 a copay, they are going to be very surprised and walk away.
1134 And that is a major challenge.

1135 I think it is important also to recognize that providers
1136 are important reason why adults get vaccinated. And a lot of
1137 providers have uncertainty with the Part D copays, especially
1138 as to what is going to be there for their patients. And as a

1139 result, they hesitate to recommend vaccines as strongly,
1140 because they don't want to succumb their patients to a copay.

1141 Thank you very much.

1142 *The Chairman. Thank you.

1143 Thank you, Madam Chairwoman.

1144 *Ms. Eshoo. The gentleman yields back, and now anyone
1145 that understands Latin, mea culpa, mea culpa, mea maxima
1146 culpa. I made a mistake. Mr. Guthrie, our ranking member,
1147 was to be next, and I blew it.

1148 So all of my apologies to you, Mr. Guthrie. You have
1149 five minutes for your questions.

1150 *Mr. Guthrie. Thanks, Madam Chair. I knew it was an
1151 oversight. And if we were sitting next to each other, we
1152 could have elbowed each other and said, "Hey, it is time to"
1153 -- so, hopefully, we will be back together soon.

1154 So, thanks to Operation Warp Speed and the successful
1155 development and deployment of 3 safe and effective COVID-19
1156 vaccines, millions of American adults, adolescents, and
1157 recently children age 12 years old and older, are being
1158 vaccinated every day. These vaccinations are key to
1159 combating the COVID-19 pandemic.

1160 Yet we still have many not getting vaccinated. CMS
1161 released data last week breaking down vaccination rates among
1162 staff in nursing homes by state. States range from 78
1163 percent vaccinated to 39.9 percent vaccinated. I was alarmed

1164 to see Kentucky only had 44 percent of staff vaccinated.

1165 And we talked about logistics in getting people all the
1166 various vaccines. When you consider vaccines are free, and
1167 retail pharmacies went to nursing homes and offered staff and
1168 residents vaccination through their partnership with the
1169 Federal Government, the challenge for Americans to obtain a
1170 COVID-19 vaccine isn't about affordability or an individual's
1171 health insurance coverage. Instead of tossing more money of
1172 the billions of dollars we have already allocated for vaccine
1173 distribution, testing, and pandemic mitigation programs,
1174 among others -- need to evaluate how we get more individuals
1175 vaccinated.

1176 So, Ms. Coyle, the nationwide average for vaccinated
1177 nursing home staff is only 60 percent. I would hope these
1178 individuals can see the value of vaccines, considering they
1179 work with the most vulnerable population. How can Congress
1180 better leverage Immunization Information Systems to address
1181 vaccination gaps and reach more people?

1182 [Pause.]

1183 *Mr. Guthrie. Ms. Coyle?

1184 *Ms. Eshoo. I think IT is working with her, Mr.
1185 Guthrie.

1186 *Mr. Guthrie. Okay, well, let me switch to my next
1187 question, then --

1188 *Ms. Eshoo. But we have lost her, and that is

1189 unfortunate. But why don't you go on with your --

1190 *Mr. Guthrie. Okay --

1191 *Ms. Eshoo. -- questions, and perhaps we will get her
1192 back.

1193 *Mr. Guthrie. Okay, good.

1194 So Ms. Arthur, maybe you might want to speak to that,
1195 but my real question that I had for you was can you please
1196 speak to vaccine innovation that is on the horizon?

1197 And I know there are many interested in the flu COVID
1198 vaccine shot. Do you see this possible in coming years,
1199 where there will be universal flu, along with the COVID shot?

1200 And then how would any policy, such as maybe H.R. 3,
1201 affect that innovation?

1202 *Ms. Arthur. Thank you very much, Congressman, for the
1203 question. So definitely, we are excited by the pipeline of
1204 vaccines that could be coming in the future. You have
1205 mentioned companies that are working on combining COVID with
1206 influenza, given the potential seasonality, companies that
1207 are working on universal flu vaccines so we may not have to
1208 get a vaccine for flu every single year. And of course, the
1209 technologies used for the COVID vaccines could be used for
1210 multiple unmet medical needs in the future.

1211 I think -- I am an expert in vaccines, and not so much
1212 in reimbursement. But I do think it is extremely important
1213 to note that we always worry about policies that

1214 disincentivize private and public-sector investment in new
1215 technologies and new medicines. And so there are some
1216 concerns that some policies put forward could actually make
1217 companies think of investing not so much in infectious
1218 diseases. It is extremely important for us to have
1219 incentives for industry to continue to invest in solving
1220 these unmet medical need problems.

1221 H.R. 3 could actually have companies decide that they
1222 don't want to invest in things that are as complicated and,
1223 as I think Chairwoman Eshoo said, not as much a return on
1224 investment as vaccines. And this could mean that we don't
1225 have some of the novel vaccines that are in the pipeline, or
1226 actually leverage this technology for new unmet medical needs
1227 in the future.

1228 Thank you for the question.

1229 *Mr. Guthrie. Okay, thank you. And my remaining
1230 question is for Ms. Coyle, so I will submit those for the
1231 record.

1232 [The information follows:]

1233

1234 *****COMMITTEE INSERT*****

1235

1236 *Mr. Guthrie. So thank you, and I will yield back.

1237 *Ms. Eshoo. The gentleman yields back.

1238 And again, my apologies to you.

1239 The chair is pleased to recognize the ranking members of
1240 the full committee, Mrs. McMorris Rodgers.

1241 *Mrs. Rodgers. Thank you, Madam Chair, and thank you to
1242 all our witnesses for joining us today.

1243 I wanted to start with a question for Ms. Arthur, and
1244 ask what we, as Members of Congress, can do to make sure that
1245 America remains the leader when it comes to vaccine
1246 innovation, and if there is any ways that we can improve the
1247 regulatory process.

1248 *Ms. Arthur. So thank you so much for the question. In
1249 actuality, a lot of the great things that happened during
1250 COVID were -- happened because of the collaboration of
1251 sponsors, Operation Warp Speed, and the regulatory agencies.
1252 They really worked very hard to work with sponsors of drugs
1253 to shorten the timelines for doing some of the key things we
1254 needed to do for research for the vaccines, the treatments,
1255 and the diagnostics, while still maintaining that high
1256 caliber standard of efficacy, safety, and manufacturing
1257 quality.

1258 And so many of those things actually could remain. And
1259 I think, as we work through the next steps of pandemic
1260 preparedness, we should be thinking about incorporating some

1261 of those regulatory advantages: de-centralized clinical
1262 trials, use of telehealth in our trials, master protocols for
1263 therapeutics. These kinds of activities could help us go
1264 faster the next time, but also could help us shorten
1265 development.

1266 A second part of your question that is very important is
1267 actually that we need to continue to support these great
1268 platforms we developed in the United States, and make sure
1269 the incentives are there to really get the full maximum
1270 benefit out of the investment we made. There is quite a bit
1271 of great technology we have developed, in partnership with
1272 the U.S. Government and with industry, and we need to make
1273 sure we maintain that in the United States, and actually
1274 offer it from the U.S. to the world. It is an American
1275 strength, to say the least.

1276 *Mrs. Rodgers. Thank you. As a follow-up, would you
1277 speak to the challenges that manufacturers face when they are
1278 researching and developing innovative vaccines to treat
1279 either existing or emerging infectious diseases?

1280 *Ms. Arthur. Absolutely. Companies actually approach
1281 their vaccine programs from a global perspective. And so
1282 they want to make sure that they have thought about how they
1283 are going to manufacture for the world, what is their
1284 strategy for where they place their manufacturing sites, how
1285 are they going to make sure they have the broadest clinical

1286 trials, how are they going to make sure that they have all
1287 the data needed for regulators, both in the United States, in
1288 Europe, and around the world?

1289 We work a great deal with those countries, those
1290 companies and organizations that serve low and middle-income
1291 countries. So how do we make sure we are working with big --
1292 WHO and others? It is a global strategy that companies need
1293 to undertake, and they make sure that they are investing in
1294 the safety worldwide, the manufacturing scale-up worldwide,
1295 and that they are able to bring that product to as many
1296 people as possible through their partnerships with other
1297 organizations, other manufacturers, and non-governmental
1298 organizations.

1299 It is quite a complicated process, because you are
1300 vaccinating healthy people everywhere that you go.

1301 *Mrs. Rodgers. Right. Are there any innovative
1302 technologies in the pipeline that you are especially excited
1303 about?

1304 And would you just take a minute to describe the
1305 potential that they have to transform health care in the
1306 United States, as well as around the world?

1307 *Ms. Arthur. Absolutely. So very excited about what we
1308 might accomplish with the platforms being used for COVID. I
1309 think we are going to see these platforms become the
1310 springboard for a lot more innovation, in terms of conquering

1311 some diseases we had not been able to conquer scientifically
1312 in the past. So you are going to go for cytomegalovirus
1313 virus, better flu vaccines, malaria, and other diseases that
1314 are travel or endemic in -- here and in other places.

1315 And then I think you are going to see innovations around
1316 new platforms that might oral. You are going to see
1317 innovations in using monoclonal antibodies as preventions for
1318 diseases. This is another opportunity to actually leverage
1319 new technology we developed during the pandemic, and use it
1320 to actually more quickly get immunity and protection for more
1321 people, and could be a very good strategy, coupled with
1322 regular vaccination. So there is quite a bit of exciting
1323 vaccine and immunization technology on the horizon.

1324 *Mrs. Rodgers. That is great. Well, thanks for being
1325 with us today. I really appreciate hearing your insights.

1326 I will yield back, Madam Chair.

1327 *Ms. Eshoo. The gentlewoman yields back.

1328 I just want to add something, and that is that vaccines
1329 are not profitable, for the most part. It was the Federal
1330 Government that put the billions and billions of dollars into
1331 this, and we have seen the success. And now that -- those
1332 successes, I believe -- and I think everyone on the
1333 subcommittee would like to see built upon. So -- but it was
1334 the Federal Government's investment that guaranteed that to
1335 the companies, guaranteed a market.

1336 So where do we go? All right.

1337 Now the next on deck is the bridegroom, the gentleman
1338 from North Carolina, with all of our congratulations to you,
1339 Mr. Butterfield. We are thrilled. And it was a beautiful
1340 wedding. I couldn't wait to tune in, and we are all thrilled
1341 for you. So you have five minutes for your questions.

1342 *Mr. Butterfield. Thank you. Thank you very much,
1343 Madam Chair. Thank you for your friendship, and thank you
1344 for joining Sylvia and I on our very special day. The day
1345 was May 31st, and it was one of the best days of my life.
1346 Thank you so very much, and thank you for convening this very
1347 important hearing.

1348 And thank you to the witnesses for your testimony today.
1349 All of you are experts, by any definition.

1350 Let me just, before I get started, let me join my
1351 Republican friends in hoping that we can very soon resume in-
1352 person hearings. There is no substitute for an in-person
1353 hearing when it is possible. My Election Subcommittee that I
1354 chair will be experimenting with in-person hearings very
1355 soon. But, you know, it would be very, very helpful if all
1356 members would publicly disclose whether they have been
1357 vaccinated. That is the fly in the ointment, if you will.
1358 We need to know who has and has not been vaccinated.

1359 I saw on television this morning that eight states --
1360 eight states -- are reporting that infections are actually

1361 rising.

1362 But having said that -- first question to our witnesses
1363 -- witness, Dr. Maldonado -- I cannot pronounce it properly,
1364 please excuse me.

1365 But, Doctor, routine childhood immunizations are
1366 important tools to keep children safe and healthy. We heard
1367 during today's testimony that the pediatric vaccines given
1368 through the Vaccines for Children program will prevent over
1369 400 million illnesses, over 900,000 deaths. The benefit is
1370 absolutely clear. That is why I am proud to co-lead H.R.
1371 2347, the Strengthening the Vaccines for Children Act of
1372 2021, along with my colleagues, Dr. Schrier, Dr. Joyce, and
1373 Mr. McKinley. This bill will make improvements to the
1374 program to ensure that physicians can afford to participate
1375 in the program, and children can continue to have access to
1376 lifesaving vaccinations.

1377 And so, Doctor, in your testimony you said that the
1378 program, the VFC program, has increased vaccination rates
1379 across all ethnicities, and has reduced racial health
1380 disparities among children -- are down by more than 11.5
1381 million doses, compared to last year.

1382 What can we expect to see regarding vaccination rates
1383 among different racial groups? Help us with this.

1384 *Dr. Maldonado. Yes, it is a major concern. What we
1385 have seen since the pandemic began is a reduction, overall,

1386 of 27 percent of -- among visits to pediatricians for well
1387 child care. And a lot of that was, understandably, due to
1388 fear of going out. Part of it was lock-down. Part of it was
1389 practices that couldn't handle dealing with multiple sick
1390 visits plus well child visits.

1391 So what we have been doing at the American Academy of
1392 Pediatrics is providing resources. I serve on a number of
1393 guidance committees for masking, for distancing, for return
1394 to school. We were one of the first to advocate for
1395 returning to school last June, in a safe manner, providing
1396 guidance to pediatricians to make sure that they understood
1397 how to bring children back, not only to school, but to their
1398 practices. And we are pushing that information out to all of
1399 our 67,000 members, as well as to federally-qualified health
1400 centers and others around the country, so that they can
1401 actually encourage children to come back.

1402 We are trying to get children to be visited in whatever
1403 their medical home is, and we believe in the value of their
1404 medical home. It is what gets the children through their
1405 formative years. So --

1406 *Mr. Butterfield. Our children -- you work with
1407 children every day, and, you know, children are precious.
1408 Can you explain why it is so important that we catch children
1409 up on the vaccines that they have missed during the pandemic,
1410 and how contagious are diseases like measles and mumps,

1411 compared to COVID?

1412 *Dr. Maldonado. Measles is almost 10 times more
1413 infectious than COVID-19. It has a very different mechanism
1414 of transmission. Very few diseases are as infectious as
1415 measles, chickenpox, and tuberculosis. And we, fortunately,
1416 have suppressed most of those infections. But we run the
1417 risk, if we don't get our children back up to par on
1418 vaccinations for those diseases, to having measles outbreaks
1419 again in the U.S., mumps outbreaks, which can lead to -- that
1420 can lead to sterility, for sure, and other --

1421 *Mr. Butterfield. My last question, I am going to ask
1422 you to give it to me in writing, if you will. Insufficient
1423 payment rates for vaccine administration have contributed to
1424 a decrease in participation in the VFC program. This
1425 decrease has coincided with an increase in Medicaid
1426 enrollment.

1427 How will the incentives in H.R. 2347 work to ensure that
1428 physicians continue to participate in the program, and
1429 children are able to access the vaccines that they need?

1430 I would ask that you give me that response in writing.

1431 [The information follows:]

1432

1433 *****COMMITTEE INSERT*****

1434

1435 *Mr. Butterfield. Thank you, Madam Chair. I yield
1436 back.

1437 *Ms. Eshoo. The gentleman yields back.

1438 Actually, Mr. Upton is next, but he is not immediately
1439 available.

1440 So we will go to Dr. Burgess of Texas for your five
1441 minutes of questions.

1442 *Mr. Burgess. I thank the chair, and I thank the
1443 witnesses for being here this morning. This is an important
1444 topic.

1445 Madam Chair, I do have an opening statement that I will
1446 submit, ask that it be made part of the record.

1447 Dr. Maldonado, you have a difficult task, with the
1448 advent of the -- now vaccinating the pediatric population for
1449 the coronavirus, and I think you have written some about
1450 this. There are some concerns about perhaps some side
1451 effects that have emerged, and let me just hasten to say I
1452 wasn't entirely convinced that the pause on the J&J vaccine
1453 was the correct response.

1454 I understood how it was important that the FDA and the
1455 CDC show that they were serious about evaluating any
1456 potential complications, but we have seen just the data since
1457 the J&J pause, the actual vaccine rate, nationally, seems to
1458 have declined. And whether that is just because we reached
1459 that point, where so many people had already been vaccinated,

1460 that now it is just getting harder -- the last mile of the
1461 vaccination line is the hardest one to reach.

1462 But now also, in the pediatric literature, there is
1463 surfacing the question about some potential for some side
1464 effects. And let me just stipulate this is a difficult
1465 problem. With a therapeutic, someone who is sick, and they
1466 need help, and you administer a therapeutic, and you accept a
1467 certain risk of side effects. With a vaccine, though, it is
1468 entirely different. You are giving it to a person who is not
1469 ill. And then, of course, any side effects or any untoward
1470 effects will be magnified.

1471 But could you speak a little bit to that? I know the
1472 CDC convened an emergency meeting. Can you give us any
1473 update as to where things are with the vaccine for the
1474 younger-age population?

1475 *Dr. Maldonado. Yes. So, very briefly, there are
1476 vaccines that were -- we are vaccinating today and the rest
1477 of this week with some of the vaccine trials in the children
1478 in 5 to 11, and we will proceed with children under 5, as
1479 well, soon.

1480 So the -- as I mentioned in my initial opening
1481 statements -- and thank you for the question -- we know that
1482 COVID-19 is critically important to prevent in children. We
1483 know that it is not as serious as it appears to be in adults.
1484 But currently it is still the 10th highest cause of death in

1485 children in the United States. And that is because children
1486 are not supposed to die. So when you see 300 to 600 children
1487 die, with 16,000 hospitalizations, it is a serious disease in
1488 children. It is two-and-a-half to three times more likely to
1489 kill children than the flu.

1490 And so we do recognize that vaccines need to have the
1491 highest standards for safety. And at this point, the CDC
1492 will give us more data this Friday at an ACIP meeting. And
1493 the FDA convened a seven-hour meeting last week around the
1494 safety of the vaccines in children.

1495 So in summary, there is a concern that there might be a
1496 link to cardiac inflammation. But so far, that link, if it
1497 exists, is extremely rare. And the children that have been
1498 followed so far have recovered from that illness. So we will
1499 find out more on Friday. And we have been clear at the
1500 American Academy to make those data as transparent as
1501 possible to all pediatricians and all families, to make sure
1502 they can calculate the risks and the benefits that they think
1503 are involved in getting their children vaccinated against
1504 COVID-19. Thank you for that --

1505 *Mr. Burgess. Yes, well, to be sure, it is something
1506 that is -- I mean, it is hard to get everything right, but
1507 this is one that just simply doesn't allow any margin for
1508 error.

1509 Ms. Arthur -- Dr. Arthur, if I may ask you just a brief

1510 question on some of the issues surrounding the pause in the
1511 patents that the Administration has proposed, how do you see
1512 that as impacting investment in new and innovative vaccines?

1513 *Ms. Arthur. Thank you very much, Dr. Burgess, for the
1514 question.

1515 In actuality, we, as BIO, are very concerned about this
1516 particular policy around intellectual property. We think
1517 that -- we definitely share the same goal as the
1518 Administration, in the sense of getting more vaccines to more
1519 people, worldwide. This is everyone's mission, everyone's
1520 mission. And companies are extremely committed to this.
1521 They are ramping up production right now, worldwide. And we
1522 are on track to, through the 250 partnerships that companies
1523 have engaged in worldwide, deliver about 11 billion doses --
1524 that is with a B, billion doses -- this year, and many of
1525 those going through COVAX, and also to the African Union and
1526 PAHO.

1527 So we think that, in essence, this particular policy is
1528 not the answer to the question. Intellectual property is not
1529 what is blocking us from getting more doses to more people
1530 worldwide. We are very concerned this could disincentivize
1531 pandemic response in the future.

1532 *Mr. Burgess. Right, and the public-private
1533 partnerships have been so critical. And it is not three
1534 vaccines. We always forget about AstraZeneca, and now

1535 Novavax has come on the scene, not to mention the Soviets and
1536 the Chinese. I mean, the Russian and Chinese vaccines that
1537 were also produced. So it really is phenomenal, with a
1538 year's time, to see this many agents.

1539 But I thank you for your testimony today. I have other
1540 questions. I will follow up with questions for the record.

1541 [The information follows:]

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1543 *****COMMITTEE INSERT*****

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1545 *Mr. Burgess. And thank you, and I yield back.

1546 *Ms. Eshoo. The gentleman yields back. It is a
1547 pleasure to recognize the gentlewoman from California, Ms.
1548 Matsui.

1549 You have five minutes for your questions, it is great to
1550 see you.

1551 *Ms. Matsui. It is great to see you, too, and thank you
1552 very much, Madam Chair, for having this very, very important
1553 hearing. And I want to thank the witnesses for being here
1554 today. You know, this question is for Dr. Tan.

1555 Our healthcare workers have been true heroes during the
1556 pandemic. However, I have been troubled by the fact that a
1557 large number of nursing home staff have not been vaccinated
1558 against COVID-19, despite the devastating impact the virus
1559 has had on seniors living in nursing homes and long-term care
1560 facilities. And a lot of these healthcare workers have seen
1561 the consequences if -- when the vaccine was not available.

1562 In March the Centers for Disease Control and Prevention
1563 reported that over 80 percent of nursing home residents had
1564 received at least one dose of the vaccine, but only half of
1565 the facility had even been partially vaccinated. And Dr.
1566 Tan, just briefly discuss the reasons behind this trend,
1567 because I have other questions for you.

1568 *Dr. Tan. Thank you for the opportunity. Absolutely.
1569 I think, you know, we have done some work in nursing homes,

1570 and a lot of it has to do with outreach and education of the
1571 nursing homes -- nursing aides. The predominant number of
1572 unvaccinated folks resides in that nursing aide population.
1573 And we need to help them understand why is it that, not just
1574 do we want to vaccinate the patient, we also need to
1575 vaccinate them to cocoon the patient, so that they don't
1576 spread infection to that one patient that might not have
1577 taken the vaccine well.

1578 I think sometimes they feel, oh, my patient is
1579 vaccinated. Therefore, I can decline. And part of that
1580 declination comes from a hesitancy that results from
1581 misinformation that they might have heard from friends,
1582 family about the potential or alleged side effects of a
1583 vaccine.

1584 *Ms. Matsui. Well, this immunization of the healthcare
1585 workforce is important. Do we see similar trends in other
1586 vaccine-preventable diseases, such as flu and pneumonia?

1587 *Dr. Tan. Yes, absolutely. So we have done a study,
1588 actually, in nursing homes, and a lot of the challenges of
1589 influenza vaccination of nursing aides is actually turnover.
1590 And that also partly turns -- is -- plays into this idea of
1591 education and outreach, as well. Nursing homes turn -- aides
1592 turn over very rapidly.

1593 And so, with influenza, for example, having to make sure
1594 that they get vaccinated when they first start the flu

1595 season, by the time the season is in full swing, many of
1596 those nursing aides have already turned over and moved on to
1597 other facilities. And so -- basically, make -- tracking is
1598 really, really difficult. So there are logistic problems
1599 with that.

1600 *Ms. Matsui. Okay, certainly the legislation we are
1601 discussing today, the Vaccine Information for Nursing
1602 Facility Operators would really require healthcare workers
1603 are educated on the benefits of ACIP-recommended vaccines.

1604 *Dr. Tan. Yes, absolutely --

1605 *Ms. Matsui. Thank you, Dr. Tan. And I have a question
1606 -- is Dr. Coyle here?

1607 I can see you now, I can see you on the screen now,
1608 great. I wanted to ask you, following up on your testimony,
1609 that you mentioned that 96 percent of children and 82 percent
1610 of adolescents had records in Immunization Information
1611 Systems. But only 60 percent of adults have an immunization
1612 records in these systems.

1613 Can you explain why there is such a significant drop-off
1614 among adults? And how can we improve these systems, so
1615 healthcare providers can have ready access to these
1616 immunization records for their adult patients?

1617 *Ms. Coyle. That is a very great question, and thank
1618 you for that.

1619 I think it is important to note that the history of IIS

1620 really started with the pediatric population. And so these
1621 systems are really designed to get kids in, because they were
1622 the ones receiving the bulk of the immunizations. As the
1623 platforms have been built out for an adolescent vaccine
1624 platform, and now more vaccines are administered to adults,
1625 we are just slowly seeing that growth within those
1626 populations.

1627 I should also note that those statistics that I gave
1628 you, that is all pre-COVID. So we don't actually know what
1629 it is going to look like, you know, post-COVID. But my
1630 assumption is those adult capture are going to be
1631 significantly higher.

1632 *Ms. Matsui. Okay, well, I really believe it is
1633 something we have to do, because I know when you are growing
1634 up, and you are -- you know, you get a vaccine all the time,
1635 and your parents keep track of that so closely. But once it
1636 is an adult, we just kind of get our shots whenever we feel
1637 we need them.

1638 I also want -- so thank you for touching on the
1639 importance of interoperability in your testimony. Can you
1640 expand on how -- use financial incentives to play a role in
1641 helping to establish provider interfaces with IIS?

1642 *Ms. Coyle. Certainly. Thank you for the question. So
1643 back when interoperability was first being established
1644 between electronic health records systems, which are the

1645 systems that are employed by a lot of physicians and health
1646 care systems, the idea of connecting to a registry was sort
1647 of that Holy Grail. Like, this is a great idea, let's do
1648 this. But it was really difficult to try and get providers
1649 to invest the time and energy and resources to make that
1650 connection.

1651 Meaningful use did a lot to really enhance those
1652 connections, and we saw a tremendous number of systems being
1653 able to connect. So pre-COVID we had about 117,000 live
1654 connections with systems and IIS. So it is a very broad
1655 network that has really been leveraged during this pandemic.

1656 *Ms. Matsui. Well, thank you very much. And we
1657 certainly have a responsibility here to help our public
1658 health surveillance systems modernize. And I appreciate the
1659 committee prioritizing this work.

1660 Thank you, and I yield back.

1661 *Ms. Eshoo. The gentlewoman yields back. It is a
1662 pleasure to recognize the gentleman from Michigan, the former
1663 chairman of the full Committee of Energy and Commerce.

1664 Mr. Upton, you have five minutes for your questions.

1665 *Mr. Upton. Well, thank you, Madam Chair. Sorry, I am
1666 in and out. We have got a lot of different activities, but
1667 obviously, this is a very important hearing, and I am very
1668 pleased, actually, to see legislation that I am leading with
1669 Representative Doggett on the list. The Vaccine Injury

1670 Compensation Modernization Act is on the list of bills that
1671 we are discussing today.

1672 This bill provides updates for the Vaccine Injury
1673 Compensation Program, which, frankly, hasn't been
1674 substantially updated since its creation in the 1980s. It
1675 provides much-needed modernization to address case backlogs,
1676 inappropriately low damages involving vaccine market.
1677 Obviously, it is time -- we experienced this last year. I
1678 look forward to the committee moving the bill to the House
1679 floor soon.

1680 I guess my first question for -- is for Ms. Arthur. The
1681 21st Century Cures Act, which every one of us voted for, was
1682 introduced by DeGette and myself. We really wanted to solve
1683 healthcare problems, and expedite the approval of drugs and
1684 licensing -- we do, in fact, have a better understanding of
1685 reforms that still need to be embraced -- patients need.

1686 We understand better today than what we did back in 2019
1687 the importance of vaccines to prevent illnesses from
1688 diseases. And we know that some segments of our patient
1689 population is -- difficult, the majority of patients do not.
1690 That is why Representative DeGette and myself will be putting
1691 out our latest discussion draft in the next few days. It is
1692 going to help support vaccine access, and coverage -- improve
1693 coverage for new cures, modernize our healthcare programs,
1694 and improve development and better medicine.

1695 As we have witnessed recently, vaccines are preventative
1696 measures and also medical responses. Global health --

1697 [Audio malfunction.]

1698 *Mr. Upton. So as we consider reform to our healthcare
1699 system, I am interested in the ways to improve vaccine
1700 access. Part of that puzzle is how do we encourage
1701 manufacturers to develop the drugs and vaccines needed to
1702 prevent the next global pandemic?

1703 What recommendations might you suggest as we tackle the
1704 issue of improving vaccine access and use in the future?

1705 *Ms. Arthur. Thank you so much, Mr. Upton. And,
1706 actually, thank you so much for the work that you and
1707 Congresswoman DeGette did on Cures. Many of the provisions
1708 there helped to stimulate vaccine investment. And so it is
1709 extremely important, and we look forward to working with
1710 everyone on Cures 2.0 when that happens.

1711 So I think that access is extremely important to all of
1712 us in the vaccine community. The best success of vaccines is
1713 when everyone gets them. It is a very unique medical
1714 intervention, in the sense that my getting vaccinated
1715 protects you and me, and that is what makes them such a
1716 special part of the medical and public health infrastructure.

1717 So I think that what we would like to do is, therefore,
1718 support the legislation, any of the legislation that are
1719 being discussed today, because they are meant to remove some

1720 of those barriers like financial barriers, access barriers
1721 that keep people from getting the vaccines when they are
1722 standing there in front of a learned intermediary, a
1723 healthcare professional who is telling them about the value.

1724 I think, in addition, we need to do education, and
1725 springboard from what we have learned from COVID, all the
1726 education we have done in the last year about vaccines, using
1727 the trusted messengers that have been out there, talking
1728 about COVID in our communities, and have them explain to
1729 people why they need to get the other vaccines that are
1730 already recommended for their health.

1731 Doing these things actually makes the vaccine space an
1732 extremely important area of investment for vaccine companies.
1733 These things go hand in glove. So we support access, because
1734 we want everyone to be able to get the vaccines that are
1735 recommended for them by the process. And that brings more
1736 vaccines to people, as they understand the value.

1737 *Mr. Upton. Ms. Coyle -- and I will be quick in my
1738 question -- so Michigan, we rank 23rd out of 50, in terms of
1739 the percentage of the eligible population getting vaccinated.
1740 I represent 6 counties, and there are a number of counties in
1741 my district that are under 40 percent vaccinated. These
1742 numbers are surprising from a state that -- you know, the
1743 several of the devastating waves of deaths and
1744 hospitalizations, we were number one for a number of weeks.

1745 Vaccine hesitancy remains a huge part of the problem.

1746 Can you talk about how this vaccine injury compensation
1747 program can be used as a tool to help us to get to a better
1748 percentage?

1749 *Ms. Coyle. So I think the question was directed at me.
1750 However, I am not going to be your best witness to talk about
1751 the Vaccine Injury Compensation Act.

1752 *Ms. Arthur. But I can just say to your point,
1753 Congressman, that I think having a vaccine injury
1754 compensation program that is robust, that is clear to
1755 patients, that actually quickly takes them through the injury
1756 compensation process is extremely important to reinforcing
1757 our very strong safety system in the United States. And it
1758 is a part of how we help people understand that, although
1759 injuries are rare from vaccines, there is a system in place
1760 to make sure they are compensated, should something arise.

1761 *Mr. Upton. Thank you. I yield back. Thank you, Madam
1762 Chair.

1763 *Ms. Eshoo. Yes, the gentleman's time has expired.
1764 It is a pleasure to recognize the gentlewoman from
1765 Florida, Ms. Castor, for your five minutes of questions.

1766 *Ms. Castor. Well, thank you, Madam Chair, and thank
1767 you to our expert panel for being with us today. I am so
1768 appreciative that you have included my bipartisan bill with
1769 Congresswoman Schrier, the Prevent HPV Cancers Act.

1770 Colleagues, if the NIH's Dr. Francis Collins called a
1771 press conference today to announce that a cure for cancer had
1772 been found after the years of funding research, it would be
1773 cause for celebration. Well, you know, since 2006, there has
1774 been a safe and effective vaccine that prevents cancer. It
1775 is pretty remarkable. It has saved lives. The human
1776 papillomavirus causes six types of cancer, including cervical
1777 cancer, and head and neck cancer.

1778 And by the way, the rates of head and neck cancer in men
1779 over the past two decades have increased fivefold. So we
1780 have special work to do there. And unlike cervical cancer,
1781 there is no test for head and neck cancer.

1782 The -- what has been very concerning is, with all of
1783 these vaccinations, is during COVID we have had a very
1784 dramatic drop-off. And before the pandemic the HPV
1785 vaccination rates were lower than most other childhood
1786 vaccines, especially for adolescents in rural areas, and in
1787 boys.

1788 But now, with the COVID effect, the childhood
1789 vaccination rates, especially for HPV, are way down. HPV
1790 doses fell by almost 64 percent for kids ages 9 to 12, and 71
1791 percent for young people 13 to 17, compared to the last 2
1792 years. So last year alone, more than one million doses were
1793 missed.

1794 Our bill takes four necessary steps to raise awareness

1795 about HPV cancers and the vaccine that can help prevent them.
1796 It creates a national public awareness campaign at CDC, it
1797 increases help to the NCI to expand and coordinate research,
1798 it gives states additional resources, and an additional focus
1799 on early detection. This is about saving lives.

1800 So for Dr. Maldonado and Dr. Tan -- first, maybe, for
1801 Dr. Maldonado -- AAP has been doing great work over the years
1802 on your efforts to increase HPV vaccination rates. How do
1803 you think the -- a targeted new effort would benefit families
1804 across the country?

1805 *Dr. Maldonado. Well, I can tell you the first thing
1806 that we have been pushing very strongly to do at the AAP is
1807 to reinforce to families that the vaccine can be given at
1808 nine years of age. The current ACIP recommendation is 11 to
1809 12, with as young as 9.

1810 We think -- and there are data now that support -- that
1811 giving vaccines at nine years of age, before children enter
1812 adolescence, actually -- it strengthens the immunization
1813 rates, because the children are easier to access at that age.
1814 So that is a simple thing that can be done. It is already
1815 approved at that age group. And if we could just reinforce
1816 getting them vaccinated younger, it is easier for them to
1817 come back for their second dose.

1818 And the AAP has been putting -- it supports the bill,
1819 overall. There are some issues around the NIH provisions.

1820 We tend to favor more broad, non-restricted research
1821 opportunities for NIH to distribute the funds how they see
1822 fit.

1823 But in addition, we actually have put together
1824 resources, HPV tool kits for families and for providers. And
1825 I do think that the biggest challenge is getting those
1826 adolescents back. So moving the vaccination back to the age
1827 where it is already approved at nine years would improve,
1828 right off the bat, immunization rates.

1829 *Ms. Castor. Dr. Tan?

1830 *Dr. Tan. Yes, I think I am just going to follow up and
1831 say that we shouldn't forget also the older adolescents that
1832 have, obviously, had a huge decline in immunization coverage
1833 rates for HPV vaccine, and they aren't recovering as fast as
1834 the pediatric population. So we want to make sure that, as
1835 part of this education, we help bring them back in, as well,
1836 for their catch-up, so that they can complete the HPV
1837 vaccination series.

1838 And then also to remind us, speaking for the adult
1839 population, again, you know, there is a shared clinical
1840 decision-making recommendation from ACIP regarding HPV
1841 vaccination for women -- sorry, for adults 19 through the age
1842 of 45. So 26 through the age of 45. My apologies. So I
1843 just don't want to leave them out, as well.

1844 *Ms. Castor. And -- but thank you very much.

1845 Ms. Coyle, I am sorry I don't have time for your input,
1846 but thank you so much. You have been very helpful, as we did
1847 broad outreach in building the provisions in this bill. So I
1848 will ask you to respond for the record.

1849 [The information follows:]

1850

1851 *****COMMITTEE INSERT*****

1852

1853 *Ms. Castor. Thank you so much. I yield back.

1854 *Ms. Eshoo. The gentlewoman yields back.

1855 I hope the witnesses will tell us -- feel very
1856 comfortable in telling us what you think we are missing.

1857 I mean, we have 12 bills. Half of them are bipartisan.
1858 And I am listening very hard to each one of you, and trying
1859 to figure out if -- what you are pointing out, if we have
1860 actually covered the bases. If we haven't, please say so,
1861 because we need your expertise.

1862 Now to the gentleman -- and he is a gentleman -- from
1863 Virginia, Mr. Griffith, for your five minutes of questions.

1864 *Mr. Griffith. Thank you very much. You are very kind,
1865 Madam Chair.

1866 Ms. Arthur, it is my understanding that vaccine
1867 developers have received emergency use authorization, but
1868 when they receive that they are not free to communicate
1869 information about their vaccine, because the vaccine doesn't
1870 have an FDA-approved label. Is that true?

1871 *Ms. Arthur. So, yes. Under an EUA, companies that
1872 have that authorization cannot directly talk to healthcare
1873 providers.

1874 *Mr. Griffith. And so what -- you mentioned healthcare
1875 providers. What entities are prohibited from receiving
1876 information about vaccines that do not have the FDA-approved
1877 labeling, in addition to healthcare providers that you just

1878 mentioned?

1879 *Ms. Arthur. So, by and large, companies focus their
1880 direct energies on information to health care providers:
1881 pharmacists, nurses, doctors. So that is the primary
1882 audience they would probably want -- they would mostly share
1883 information with, and those providers would share information
1884 with the general public.

1885 *Mr. Griffith. And so --

1886 *Ms. Arthur. Companies also do talk to insurance
1887 companies and state health departments, as well.

1888 *Mr. Griffith. I know it has gotten a lot of attention,
1889 but how might these entities use that information about
1890 vaccines?

1891 And if we see a problem developing in the future that
1892 maybe -- not shuts the whole country down, do you think it
1893 would be helpful if companies were able to share that
1894 information with --

1895 *Ms. Arthur. I do.

1896 *Mr. Griffith. -- healthcare providers?

1897 *Ms. Arthur. I think that it is extremely important,
1898 because companies should have a way to, with the approval of
1899 the FDA, and with the shared messaging, following the
1900 guidelines of their authorization, to be able to actually
1901 speak to healthcare providers so that healthcare providers
1902 have the latest possible data.

1903 Healthcare providers are extremely busy, and they can't
1904 necessarily keep up with all the information that is
1905 happening every day. We are all trying to do that. So
1906 certainly, as we go into this next phase of the pandemic,
1907 where we are going to have updates on -- by age, we are going
1908 to have updates on the performance of the vaccine for
1909 variants, healthcare providers probably have quite a number
1910 of questions they are getting from their patients and from
1911 mothers and fathers. And this would certainly help them more
1912 quickly answer those questions, if they could have a
1913 systematic interaction with the companies on the approved
1914 information.

1915 *Mr. Griffith. Well, and as a parent of children who
1916 are in that 13 to 16 age bracket, I might want to know, okay,
1917 ask my healthcare providers, "Which vaccine do you think is
1918 better for my child, with his background" -- they are both
1919 boys -- "with his background?"

1920 And so, in answer to the question that the chairwoman
1921 asked, what are we missing, I have recently introduced a
1922 bill, H.R. 3705, that would allow vaccine sponsors who have
1923 received an EUA to communicate information about the vaccine
1924 to certain entities without fear of violating the law. And
1925 based on what you have said, I think you would think that
1926 something along those lines would be helpful for the -- both
1927 the producers of the vaccines, the developers, but also for

1928 the healthcare providers, and then those of us who rely on
1929 our healthcare providers to give us the information. Am I
1930 reading that correctly?

1931 *Ms. Arthur. Yes, sir. You are.

1932 *Mr. Griffith. All right. I appreciate that. I am
1933 going to switch over. Thank you so much for your testimony.
1934 I am going to switch over to Dr. Maldonado, briefly.

1935 And I am changing gears on you just a little bit, but in
1936 talking with Mr. Butterfield, you mentioned tuberculosis. I
1937 have been looking at phage therapy, and I don't know --
1938 because that is a bacterial infection, I don't know, do we
1939 have a vaccine, or is there a vaccine in the works for
1940 tuberculosis?

1941 *Dr. Maldonado. Oh, we have been working on vaccines
1942 for tuberculosis for 30-plus years. There are some recent
1943 updates. There has been a vaccine in the last five years
1944 that seems to do a reasonable job. That is, it is about 30
1945 percent effective. But we really haven't advanced as well.

1946 Tuberculosis is a very complicated disease. It is a
1947 bacterial infection, and we don't really understand very well
1948 how it grows. And so I -- we are urging additional resources
1949 to understand, first of all, how the bacteria itself causes
1950 latent or silent infection, because that is the key. It
1951 somehow manages to slow down, and then pop up at unexpected
1952 times. And that has been very difficult for vaccination.

1953 But there are a number of breakthroughs that we hope
1954 will be coming through with innovative new technologies at
1955 this point. But certainly one in three people in the world
1956 is infected, and clearly a very important target for
1957 research. Thank you for bringing that up.

1958 *Mr. Griffith. Yes, absolutely. And as we deal with
1959 it, it is something I have been interested in, because I read
1960 a marvelous book on -- I think it was -- but on phage
1961 therapy, which deals with bacterial infections, not TB
1962 particularly, but bacterial infections that are now resistant
1963 or immune to our current antibodies, and I think that is
1964 something this committee and the O&I Committee should look
1965 at.

1966 I yield back, Madam Chair, thank you.

1967 *Ms. Eshoo. The gentleman yields back. The chair is
1968 pleased to recognize the gentleman from Maryland, Mr.
1969 Sarbanes, a name that is revered in the State of Maryland.
1970 You are recognized for five minutes for your questions.

1971 *Mr. Sarbanes. No more so than the name Eshoo is
1972 revered in the State of California, Madam Chair.

1973 In any event, thank you for holding a hearing today. It
1974 is very, very important.

1975 During this pandemic, we have all witnessed the power of
1976 timely, effective health care, and particularly the power of
1977 vaccinations. As we continue to come out of the pandemic, we

1978 must make sure that we are building on the lessons that we
1979 learn, and investing in reforms from healthcare workforce
1980 reforms to increased investment and preparedness that can
1981 help bolster the healthcare infrastructure, and make sure
1982 that health care is available and accessible to everybody in
1983 our communities.

1984 On access to health care, particularly preventive health
1985 care, it is especially important for our children. That is
1986 why I am a very strong supporter of school-based health
1987 centers. SBHCs provide high-quality, comprehensive
1988 healthcare services to primarily low-income children and
1989 adolescents across the nation.

1990 During the COVID-19 pandemic, many SBHCs have been using
1991 telehealth to provide key healthcare services to their
1992 student populations. As children return to school, these
1993 school-based health centers will play a critical role, along
1994 with many other providers, in making sure that children can
1995 access the important health and mental health services that
1996 they need.

1997 One of those key services, of course, is vaccinations.
1998 Last fall, data from the Centers for Medicare and Medicaid
1999 Services showed that rates of vaccinations, primary and
2000 preventive health care, had declined for children in Medicaid
2001 and CHIP during the pandemic. In other words, across the
2002 board. Today's hearing is so important so we can examine the

2003 ways that Congress can act to make vaccinations and other key
2004 services even more affordable and accessible.

2005 Dr. Maldonado, I would like to ask you a few questions
2006 on this. Your expertise as a pediatrician is critical to our
2007 discussion. Pediatricians, obviously, are a very trusted
2008 voice for parents, when explaining the importance, safety,
2009 and effectiveness of vaccines, and play a central role in
2010 getting children vaccinated.

2011 The Vaccines for Children program, which you have talked
2012 about, is perhaps the most critical tool we can use to bring
2013 childhood vaccinations back on track, especially for very
2014 vulnerable communities. In your testimony you discussed some
2015 of the financial and administrative barriers to improving the
2016 vaccine delivery system for children. I would like to
2017 elaborate on this, and discuss how the legislation we are
2018 considering will enhance the pediatric workforce and vaccine
2019 landscape.

2020 Compared to other physician specialties, what challenges
2021 do pediatricians face in recruiting a sustainable workforce
2022 to meet the needs of children in communities throughout the
2023 country?

2024 *Dr. Maldonado. Well, thank you very much for that
2025 question.

2026 Pediatricians, if you look at the compensation scale --
2027 and I know we all think that physicians are highly-paid

2028 individuals -- but pediatric providers are at the very low
2029 end of compensation among physicians. They frequently serve
2030 under-insured and uninsured populations, and frequently the
2031 vaccine components of their practice, which is a major
2032 component in addition to other well-care services, is highly
2033 under-compensated, and has been for a long time. And that is
2034 why we were really excited to see that the VFC bill proposal
2035 would actually help to provide some parity.

2036 So what happens with pediatricians is they have to give
2037 multiple component vaccines, and that is good for children,
2038 because they can get multiple vaccinations in one shot. But
2039 they spend a lot of time explaining, rightly so, vaccines to
2040 children and to their families. And they are not compensated
2041 for that time that they spend in the office. So this bill
2042 would actually help provide some parity to pediatricians, who
2043 are spending that amount of time building that trusted
2044 relationship so that they could get some compensation for the
2045 time that they are spending.

2046 They would also be able to provide resources to provide
2047 separate refrigerators, which are required for different
2048 types of vaccines versus public and private-funded vaccines,
2049 and also to incentivize some providers to accept VFC
2050 patients, which some don't do because of the reductions in
2051 their ability to be compensated for their time.

2052 So, again, while we don't like to think about

2053 compensation as a primary driver, it does -- and especially
2054 in these times -- keep our practitioners afloat, especially
2055 in areas that are rural, and lower-income areas where
2056 patients don't have the wherewithal to provide have
2057 insurance.

2058 *Mr. Sarbanes. Excellent. Thank you very much for that
2059 testimony. I want to thank Congresswoman Schrier and others
2060 who have helped put forward important legislation in this
2061 space.

2062 With that, I yield back, Madam Chair,

2063 *Ms. Eshoo. The gentleman yields back. We thank him
2064 for his questions.

2065 It is a pleasure to recognize the other Greek from --
2066 this time from Florida. Mr. Sarbanes from Maryland, Mr.
2067 Bilirakis.

2068 You have five minutes for your questions. Great to see
2069 you.

2070 *Mr. Bilirakis. Good seeing you, too.

2071 *Ms. Eshoo. What are you doing, growing a goatee? My
2072 goodness.

2073 *Mr. Bilirakis. Yes, yes, yes.

2074 *Ms. Eshoo. We will call you "Professor" pretty soon.

2075 *Mr. Bilirakis. I am experimenting with this. We will
2076 see what happens.

2077 But anyway, some people seem to like it. My wife seems

2078 to like it, which is more important --

2079 *Ms. Eshoo. Well, that is what counts the most.

2080 *Mr. Bilirakis. Yes, exactly, exactly.

2081 Okay, here we go. Dr. Tan, how easily can infections
2082 spread in nursing home facilities?

2083 And are vaccines effective at lowering transmission
2084 rates in these settings?

2085 I know that you could -- if you could answer that
2086 question quickly, and I have got some follow-ups here.

2087 *Dr. Tan. Oh, absolutely. It is like a spark into dry
2088 hay. It goes really, really fast. You have got people who
2089 are vulnerable because of some compromised immune responses,
2090 and then you have got family members coming in and out. So
2091 absolutely, it can spread very, very quickly.

2092 *Mr. Bilirakis. Okay. Why has there been COVID vaccine
2093 hesitation among healthcare workers? It seems ironic, no?

2094 *Dr. Tan. Yes, I think it has --

2095 *Mr. Bilirakis. I know you mentioned this, but if you
2096 could elaborate a little bit, please.

2097 *Dr. Tan. Yes, absolutely. I think you have to kind of
2098 figure out the healthcare worker, and who the healthcare
2099 worker is getting information from. I think you will find
2100 that surveys have recently said that there are -- physicians,
2101 pharmacies have actually been showing an increased acceptance
2102 and, actually, vaccination rate.

2103 I think we still have challenges with healthcare
2104 workers, such as nursing aides, who work predominantly in
2105 nursing homes because of education. And I think -- and also
2106 because of the fact that these healthcare workers are
2107 extremely high stressed, and they are also looking to
2108 continue to move on in their careers. There is a lot of
2109 turnover.

2110 And so I think, as a result of that, I think we need to
2111 continue to emphasize the education and outreach to
2112 healthcare workers in nursing homes -- nurses, nursing aides
2113 -- because they don't always have access to the most
2114 important information. And sometimes the anti-vaccine
2115 messages may predominate in some of their social circles. So
2116 I think we need to be very, very aware of what they are
2117 hearing, what they are listening to. And providing education
2118 is, indeed, one of the most important ways we can move them
2119 along, with regards to, obviously, accepting a COVID-19
2120 vaccine, and getting those rates up among the nursing aides
2121 and nurses.

2122 *Mr. Bilirakis. Thank you very much. The nursing home
2123 facilities with higher reported rates of vaccination in
2124 residents, staff have lower rates -- in other words, if they
2125 are vaccinated, and I know that not everyone has access to a
2126 vaccine -- are there lower rates of infection?

2127 *Dr. Tan. Yes, absolutely. So not only just --

2128 *Mr. Bilirakis. We have stats?

2129 *Dr. Tan. Yes, we do have data on that, not just in
2130 terms of what we see with COVID-19, where the effect of
2131 vaccination of both the patients and the staff has been
2132 tremendous in reducing mortality, we also have data with
2133 regards to the more traditional adult vaccines, like
2134 influenza, and how vaccinating staff, as well as the
2135 patients, have reduced infections in those facilities, as
2136 well.

2137 *Mr. Bilirakis. Now, what about other -- in other
2138 words, other diseases, as far as educating staff, what have
2139 you, with regard to other vaccines?

2140 I mean, one silver lining is that we have learned so
2141 much during the pandemic. But shouldn't we go further with
2142 other vaccines?

2143 *Dr. Tan. That is a great point, sir. I think
2144 absolutely. I think what COVID-19 vaccination education has
2145 shown us is that we have got a public that is hungry for
2146 information about vaccines. And the great news is that now,
2147 when I speak to the public, I don't have to go into those
2148 details about why vaccines are important anymore.

2149 And so I think this is a rising tide that can lift all
2150 boats. We can make sure parents, patients, adults, younger
2151 adults, adults with chronic conditions all understand the
2152 importance of vaccination and getting a vaccine. And I think

2153 this is so critical. This is what COVID-19 has shown us.
2154 And I think we need to build upon that, and make sure that
2155 now, when these adults and these other patients show up to
2156 get vaccinated, they don't get turned away because of a
2157 financial or logistical barrier.

2158 So thank you very much for that question.

2159 *Mr. Bilirakis. Well, my pleasure. And I would like to
2160 recommend -- I have said this before to the committee, Madam
2161 Chair -- I had a telephone town hall meeting, and plan to do
2162 some in-person meetings, as well, with my constituents. And
2163 we invited experts to come in and answer questions with
2164 regard to the vaccine. I think it is so very important to
2165 get the word out there.

2166 Thank you very much, Madam Chairman, and I will yield
2167 back the 45 seconds. Thank you.

2168 *Ms. Eshoo. I thank the gentleman. And I do telephone
2169 town hall meetings every week into the communities in my
2170 district, and Dr. Maldonado is the trusted voice to my
2171 constituents.

2172 And so I join the gentleman in making that
2173 recommendation to all of our colleagues. It really makes a
2174 difference to our constituents, to have doctors come home
2175 with us. And boy, am I grateful, deeply grateful, and get
2176 terrific feedback from them.

2177 Okay. Now to the gentleman from Vermont, Mr. Welch.

2178 *Mr. Welch. Thank you very much.

2179 *Ms. Eshoo. There you are.

2180 *Mr. Welch. Thank you very much. I want to thank the
2181 witnesses.

2182 You know, we are really excited in Vermont. As you may
2183 know, we hit the 80 percent vaccine rate yesterday. And
2184 Governor Scott, our Republican governor who has done an
2185 incredibly good job, incredible job, was able to announce the
2186 reopening. So there is a view in Vermont that vaccines work,
2187 and a lot of excitement. And we are a rural state.

2188 And one of the areas I wanted to ask is how do we
2189 address this difference in vaccination uptake in rural versus
2190 urban areas?

2191 The CDC found in rural counties about 39 percent versus
2192 46 percent. And Dr. Tan, knowing of the rural access
2193 differences, are there things we can do better to reach rural
2194 communities?

2195 *Dr. Tan. Yes, absolutely, and I think, with rural
2196 communities, I think there are some lessons that we are
2197 learning from COVID-19.

2198 I think, certainly, we need to be finding individuals in
2199 those communities that can be -- that can serve as
2200 representatives for vaccination, in general, you know, folks
2201 that are trusted leaders in that -- in those communities that
2202 the rural community listens to. They can be church leaders,

2203 they can even be farmers. I mean, there is initiatives going
2204 on right now with rural outreach to the farming community,
2205 using farmers that have sought out and got COVID-19 vaccines,
2206 to communicate why they did so.

2207 *Mr. Welch. Okay, one other question. You know, this
2208 vaccine, the COVID vaccine, was free. And by all accounts,
2209 it made a huge difference. It eliminated the barrier all
2210 together. Does it make sense, from a public health
2211 standpoint, to have vaccines be free?

2212 *Dr. Tan. In my personal opinion, absolutely. I think
2213 we need to make sure that access to all these lifesaving
2214 vaccines across the lifespan happens with no cost to the
2215 patient.

2216 *Mr. Welch. Thank you.

2217 And Dr. Maldonado, I am a big supporter of the work of
2218 my colleagues, Congresswoman Schrier, Butterfield, McKinley,
2219 and Joyce on their Strengthening Vaccines for Children Act.
2220 That is one of the bills before us. It would increase
2221 provider payments for beneficiary counseling and education.

2222 Can you just comment on the role of hesitancy, and how
2223 that comes into play, and how my colleagues' bill may be
2224 helpful in addressing that, and increasing vaccination rates?

2225 *Dr. Maldonado. Yes, so I have been involved with the
2226 National Vaccine Advisory Committee for two different
2227 appointments. And over that period of time, we have spent

2228 some time with the National Vaccine Plan, and assessing how
2229 well we are doing as -- at a national level in vaccine
2230 hesitancy and vaccine confidence. And I do think that
2231 messaging to individuals is important.

2232 The vast majority of people are not anti-vaxxers, they
2233 are vaccine questioners. They want information. In this day
2234 and age, with social media and access to the Internet, people
2235 have a lot of information that they cannot always digest
2236 properly on their own. And I do think that the role of the
2237 trusted provider, the trusted local leader, whatever that
2238 person might be, or whatever their profession is, is going to
2239 be critical to providing information to people, helping them
2240 answer their questions, because most people, as I mentioned,
2241 are just questioning.

2242 We also know that there is a now-new group that we have
2243 called vaccine apathy. So these are people who don't see the
2244 value, because they don't see the disease in front of them.
2245 We, as providers, see the diseases, but most people don't
2246 generally see that on a daily basis. And getting that
2247 apathetic viewpoint away, and making it clear that this can
2248 affect them and their family members, is another critical way
2249 to communicate.

2250 So a lot of this comes down to communication, getting
2251 those VFC providers back on track, so that they can actually
2252 provide the important information that our academic societies

2253 provide to them is going to be important. And making sure
2254 that that happens across the board is important.

2255 Let me give you an example. In the 1980s we had a big
2256 measles outbreak in the United States. And at the end of the
2257 day, when people thought it was due to a failure of the
2258 vaccine, it was actually because of a failure to vaccinate.
2259 And the failure to vaccinate occurred in urban inner-city
2260 populations that had just been overlooked, because they
2261 didn't have access. With the strengthening of that process,
2262 access to -- in their urban inner-city areas, we have
2263 essentially eliminated measles in this country, so far.

2264 But we need to keep vigilant, because these diseases are
2265 not gone yet, and they can come back at a moment's notice.
2266 So really, keeping our providers access to vaccine and
2267 messaging out is really important. Thank you so much for
2268 that question.

2269 *Mr. Welch. Thank you very much, and I yield back.

2270 *Ms. Eshoo. The gentleman yields back. It is a
2271 pleasure to recognize the gentleman from Missouri, Mr. Long.
2272 And I would add that, if there were to be an auction of
2273 vaccines, there would be one person in this country that
2274 would make sure it was the most successful auction.

2275 So we now recognize you from your five minutes of
2276 questions.

2277 *Mr. Long. Thank you, Madam Chair.

2278 And Dr. Tan, I would like to start out by talking about
2279 the situation that happened to a Member of Congress and his
2280 wife during the COVID epidemic. And I don't know how many
2281 cases like this went on, but when our medical system was
2282 completely upended, routine things were delayed, or whatever.
2283 But unfortunately, Representative Andy Barr's wife, Carol,
2284 who was 39 years old at the time, went to her doctor. And on
2285 her chart the doctor wrote, "Echo when virus subsides."'
2286 That is echocardiogram. Unfortunately, she subsided before
2287 the virus did, leaving Andy with two beautiful young
2288 daughters to raise. So there was a lot of things like that
2289 that went on during this epidemic that are not reported, I
2290 don't think counted in the totals.

2291 But, as I mentioned, COVID-19 upended a lot of routine
2292 care with lockdowns, and with the strain it placed on our
2293 overall healthcare system. What have we seen in terms of
2294 utilization of recommended vaccines for adults over the
2295 course of the last year? And how did that compare to the
2296 year 2019?

2297 *Dr. Tan. Thank you, sir, for that question, and my
2298 condolences to the representative. I am so sorry to hear
2299 that. And indeed, that is -- those are stories that we are
2300 hearing, and they do count to that toll.

2301 I have to say the last year has seen similar dramatic
2302 impact, as we have heard, not just on pediatric, but also on

2303 adolescent and adult vaccination coverage rates. We have got
2304 numbers like 85 percent reduction in coverage rates for one
2305 particular adult vaccine. We have had a tremendous
2306 reduction, in terms of vaccines that have been going out to
2307 adults. And a lot of it has to do with the fact that, you
2308 know, a lot of the preventive care visits that a lot of our
2309 older adults used to go to declined dramatically, as well,
2310 during this past year, as you have mentioned.

2311 So yes, we are, unfortunately, really in the pit here,
2312 with adult immunization coverage rates. We are trying to dig
2313 back out of it. We are not doing as well as the pediatric
2314 population right now. And that is because of wonderful
2315 people like Dr. Maldonado working really hard to get them
2316 vaccinated.

2317 The adult population is more challenging. It is
2318 broader, it is more diverse. And we need to, therefore, make
2319 sure that, when you can get them out of the pit, they don't
2320 find reasons to not get vaccinated. So thank you for that
2321 question, sir.

2322 *Mr. Long. Excuse me. We are getting back to routine
2323 healthcare services, but there are still issues with older
2324 Americans getting vaccines recommended by the CDC, whether it
2325 is for measles, or for shingles, or whatever the case may be.
2326 What is the biggest impediment for vaccine utilization for
2327 older adults?

2328 Is it cost, or lack of adequate information about
2329 recommended vaccine, and how does H.R. 1978, the Protecting
2330 Seniors Through Immunization Act, address both of those
2331 concerns?

2332 *Dr. Tan. Thanks for the question. All of the above.
2333 I took the easy way out on that one.

2334 But specifically, with the Protecting Seniors Act, I
2335 think one of the things that -- you know, if you think about
2336 how adults over 65 get -- pay for their vaccines, they go
2337 either through the Medicare Part B or the Medicare Part D
2338 plans. And some of those vaccines, you know, flu,
2339 pneumococcal, and hepatitis B are in Part B, and there is no
2340 cost sharing.

2341 In the Part D plans, unfortunately, that is where some
2342 of the more recent vaccines for adults have gone, and we do
2343 have a lot of research and development that you have heard
2344 about that will introduce better and newer adult vaccines
2345 into the market. They will all, at this time, currently,
2346 will go into Medicare Part D, where, unfortunately, there is
2347 a copay for those Medicare Part D beneficiaries.

2348 When those beneficiaries go in, they are not aware as to
2349 what that level of copay may be, and that number may actually
2350 give them sticker shock. You know, they are looking at
2351 others getting vaccines for free, like if their kids are on
2352 private plans, and they go into their pharmacy to get, let's

2353 say, their shingles. And they find out that there is a \$150
2354 copay, for example. It gives them sticker shock. They turn
2355 away, and say, "You know, I can't afford that right now,
2356 because I am on fixed income.'"

2357 So absolutely, sir, I think we need to think about how
2358 this Act will actually even that playing field between
2359 copays, between B, which has none, and D, which has a varying
2360 and confusing array of copays, and make them all the same,
2361 which is no copay to the patient.

2362 *Mr. Long. Okay, let's talk about the longer-term
2363 financial cost. Vaccines, of course, have an up-front cost,
2364 as you mentioned, but what are the longer-term financial
2365 costs that vaccine-preventable conditions have on the system,
2366 particularly for older adults?

2367 *Dr. Tan. So, as you know, I think, to talk about
2368 costs, we are talking about the cost of caring for an adult
2369 who perhaps develops shingles, and perhaps postherpetic
2370 neuralgia. All those costs are extremely expensive to the
2371 healthcare systems, not to mention just the cost of
2372 hospitalizations for flu and pneumococcal disease.

2373 The other cost I think we need to remember is there is a
2374 quality of life cost to the older adults. Now, when I talk
2375 to older adults, most of the time they are not talking to me
2376 about fear of death, or hospitalizations -- a fear of death,
2377 sorry. They are talking to me about whether their quality of

2378 life will suffer. So I think we need to just also remind
2379 ourselves that it is not just actual dollars, which are
2380 immense, but also this cost of quality of life.

2381 *Mr. Long. Okay, I have run over my time and, Madam
2382 Chair, thank you again, and I do yield back.

2383 *Dr. Tan. Thank you, sir.

2384 *Ms. Eshoo. The gentleman yields back. It is a
2385 pleasure to recognize the gentleman from Oregon, Mr.
2386 Schrader, for five minutes of questions.

2387 *Mr. Schrader. Oh, thank you very much, Madam Chair,
2388 great hearing, great panel today.

2389 As a veterinarian, I have relied on vaccinations my
2390 entire career to prevent a lot of the serious diseases that
2391 incapacitate or kill some of my clients' patients. And
2392 frankly, it is a much lower-cost way to prevent the higher-
2393 cost, more invasive chemical, you know, treatments and stuff
2394 that go on. So it is hard for me to believe people will not
2395 vaccinate either themselves and, certainly, their children.

2396 And to that point, I guess, Dr. Maldonado, I -- we have
2397 talked a lot about this. I may have missed a specific point,
2398 but what is the actual cost for, you know, some of these
2399 childhood vaccinations? I know it all varies. The seniors'
2400 ones are a little more expensive, potentially. But what is
2401 the actual cost to the pediatrician?

2402 And then what is the commercial -- if there is such a

2403 thing as the average commercial reimbursement, and what is
2404 the reimbursement for Medicaid, and what is the reimbursement
2405 for Medicare?

2406 *Dr. Maldonado. You know, those are great questions.
2407 And as you said, it is a complicated formula. The cost will
2408 vary, depending on the product, and depending on whether you
2409 are a public or private recipient, and I won't be able to
2410 provide you the specific numbers, unfortunately, but we can
2411 certainly get those numbers to you, and provide them for the
2412 record. Yes.

2413 *Mr. Schrader. Yes, and I would appreciate if anyone on
2414 the panel has some examples. I just wanted everyone to hear.
2415 I mean, the cost of vaccines in -- for most of them, or for
2416 many of them, are actually not that high. And the problem
2417 that the physician has is, as you have alluded to, and Dr.
2418 Tan, and others, that, you know, it is just the cost of
2419 administration. I mean, you have got to store the stuff.
2420 That is a cost. You have got to have the refrigeration, in
2421 some cases. That is a cost. You have got to train your
2422 staff. The staff person gets paid --

2423 *Dr. Maldonado. Yes.

2424 *Mr. Schrader. -- they spend the time. So the cost of
2425 administration is really what we should be trying to
2426 reimburse our physicians and physician assistants and nurses
2427 for at the end of the day. I think that often times gets

2428 lost. But I would really love to get some examples in front
2429 of the committee, so they can see the great disparity that is
2430 out there.

2431 Could you talk a little bit about the difference between
2432 Medicaid and Medicare reimbursement?

2433 *Dr. Maldonado. Yes, absolutely. So the Medicaid
2434 reimbursement will vary from state to state. As you know,
2435 each state provides its own limits.

2436 And as you had mentioned before, while I can't give you
2437 the specific numbers, they actually pale in comparison, say,
2438 to the cost of major invasive procedures that insurance
2439 frequently will cover, or other -- Medicare or other
2440 providers will cover. Immunizations are not expensive on the
2441 grand scale, but pediatricians and, in particular, family
2442 practitioners, who may only provide vaccines to a portion of
2443 their population, may find them prohibitive because, while
2444 they aren't quite as highly cost-driven, there are -- they
2445 are, many times, un-reimbursable, and they may wind up taking
2446 a big hit, overall, because the volume, especially for
2447 pediatricians, of immunizations is such a large component of
2448 their practice.

2449 And so, when you are taking a -- actually, a loss, which
2450 many of them do on these amounts over time, it really does
2451 affect their bottom line and their ability to take new
2452 patient and -- and patients.

2453 And so, yes, so the Medicaid is really all over the map,
2454 truly, literally and figuratively. Every state has its own
2455 reimbursements, and --

2456 *Mr. Schrader. Dramatically below Medicare --

2457 *Dr. Maldonado. And it is absolutely below Medicare.
2458 So in many cases, actually bringing providers' reimbursement
2459 up to the Medicare rate, even for a short period of time,
2460 would bring them back up to parity, especially during this
2461 time when, again, we have seen the visits really plummet for
2462 most of our providers. And they are really, really on the
2463 precipice, especially in those rural and smaller population
2464 areas, just having a hard time keeping their doors open, as
2465 well.

2466 *Mr. Schrader. Very well said, very well said, I
2467 totally agree.

2468 Dr. Tan, you talked a little bit also about the problem
2469 of getting seniors vaccinated. It would seem like a no-
2470 brainer, again, to me, because that age, you know, some of us
2471 don't respond as well to a lot of the more invasive
2472 procedures, or newer drugs that have other side effects. It
2473 seems like a no-brainer to get your vaccination.

2474 What are some of the things we could do to encourage the
2475 seniors -- you have talked a little, others have talked a
2476 little about this -- but encourage seniors to get the
2477 vaccinations?

2478 And what is the best way, easiest access way, for
2479 seniors to get the vaccinations, in your opinion?

2480 *Dr. Tan. So I think we have to deal with, firstly, the
2481 logistical challenges some seniors face. There are mobility
2482 issues, for example. And I think transport issues remain a
2483 challenge for a lot of seniors getting to vaccines. So I
2484 think, by increasing more access points, bringing pharmacies,
2485 bringing in community centers where seniors can actually get
2486 to easily, is a great way to start. And then, taking away
2487 that financial barrier when they get there, so they don't get
2488 sticker shock.

2489 But then thirdly, I think very quickly, I think we need
2490 to be reminding the seniors that vaccines do more than just
2491 prevent infection. They protect them from getting
2492 hospitalized and, in many cases, quality of life. I
2493 sometimes say to seniors that I talk to, you know, "If you
2494 don't get the flu vaccinations, you may walk into a hospital
2495 with influenza, but chances are you might actually walk out
2496 with a walker four weeks later, because of influenza."

2497 *Mr. Schrader. Very good, very good. Thank you all
2498 very much for your testimony.

2499 And I yield back, Madam Chair.

2500 *Ms. Eshoo. I thank the gentleman, and he yields back.
2501 It is a pleasure to recognize one of the terrific doctors
2502 that we are so fortunate to have on our subcommittee, the

2503 gentleman from Indiana.

2504 Dr. Bucshon, you have five minutes for your questions.

2505 *Mr. Bucshon. Thank you, Madam Chairwoman. I very much
2506 appreciate that.

2507 I would like to thank Chair Pallone, Ranking Member
2508 McMorris Rodgers for holding this important hearing, and
2509 including two bipartisan bills, H.R. 1978 and H.R. 550, that
2510 I authored with Representative Kuster. These bills aim to
2511 prioritize preventive health care through vaccines, and
2512 modernize our nation's vaccine infrastructure, respectively.

2513 It is a great frustration of mine that Congress often
2514 times doesn't properly incentivize and want to pay for
2515 preventive care, simply because of its budget impact over a
2516 10-year budget window, completely neglecting the fact that
2517 keeping patients healthy by preventing disease and sickness
2518 actually saves the system much more in avoided
2519 hospitalizations, doctor visits, et cetera. It leads to a
2520 better quality of life outcome over time, and keeps people
2521 active in society and contributory, which is why I believe
2522 that H.R. 1978 is such an important bill.

2523 Dr. Tan, we have been over some of this territory, but I
2524 want to talk about this bill a little bit. Do commercial
2525 insurance plans cover vaccines under their medical benefit,
2526 their pharmacy benefit, or both?

2527 *Dr. Tan. Yes, so thank you for that question, sir.

2528 Commercial, private plans cover vaccines under both pharmacy
2529 benefits, as well as under medical benefits. And in fact,
2530 that is the reason why, you know, someone who is under a
2531 commercial private plan can go in and get a vaccine and,
2532 essentially, there is no copay to that person.

2533 *Mr. Bucshon. Right. And I think you have already went
2534 over this, but it is different than Medicare under Part B and
2535 D, and you -- can you summarize that again, just -- because I
2536 think this is a really important point.

2537 *Dr. Tan. Yes, absolutely. So, for Medicare Part B,
2538 there are three vaccines: flu, pneumococcal, and hepatitis B
2539 vaccines that are covered with no copay for the patient.

2540 Unfortunately, because of the Medicare Modernization
2541 Act, a lot of new adult vaccines now go under the Medicare
2542 Part D plan. And in the Medicare Part D plan, those plans
2543 are subject to copay to the patients. And as you know, that
2544 copay will vary, depending on individual patients and on the
2545 carrier plans, of which there are thousands in the United
2546 States, which adds a lot of confusion, a lot of variability
2547 to the patient.

2548 *Mr. Bucshon. And that is why our H.R. 1978 extends
2549 Medicare Part B cost sharing policy to Medicare Part D plan
2550 coverage of vaccines which are recommended for adults by the
2551 Advisory Committee on Immunization Practices. The bill
2552 removes the application of the beneficiaries deductible

2553 coinsurance initial coverage limit and annual out-of-pocket
2554 threshold for ACIP-recommended vaccines. And it also
2555 requires the Medicare new handbook to include relevant
2556 vaccine coverage and cost sharing information. I do believe
2557 this bill will increase the utilization of vaccines in the
2558 adult population.

2559 Ms. Coyle, another subject, the COVID-19 pandemic has
2560 revealed some important deficiencies that Representative
2561 Kuster and I have introduced legislation to help address.
2562 Immunization Information Systems serve as a vital link
2563 between public health officials, community providers, and
2564 individuals, not only in cases of disease outbreaks or
2565 emergencies, but also during routine vaccination efforts.

2566 Can you talk a little bit about how these systems have
2567 been traditionally used by healthcare providers, how the
2568 provider use of these systems changed during the pandemic,
2569 and what lessons we should take away from this experience to
2570 improve immunization data exchange efforts?

2571 *Ms. Coyle. Thank you for your question, and thank you
2572 for your leadership in this area. We really appreciate that
2573 attention.

2574 So, in terms of how providers have typically accessed
2575 this system, particularly within our pediatric and family
2576 practice and larger medical systems, they are connected to
2577 Immunization Information Systems using electronic data

2578 exchange. That has been the traditional way. We have
2579 certainly seen a lot of different settings, where vaccines
2580 have been administered, such as baseball stadiums, parking
2581 lots, you name it. And so those types of settings may or may
2582 not yield a system with which to connect. And so there is
2583 often some data entry that has to happen on the back end of
2584 that.

2585 Reporting is critical. There is certainly a required
2586 timeframe for reporting, and that has been very different
2587 this time around. While we always want fast information, it
2588 is important to make sure that we also have accurate
2589 information.

2590 So, where this -- what we have also seen is just that
2591 volume, with -- the number of vaccines that are flowing on
2592 any given day, you know, are significantly more than what we
2593 have ever seen before. And what that has really called to
2594 light is a need to really modernize and beef up a lot of our
2595 systems. Without that, the ability to actually query an
2596 immunization registry for a provider history -- or sorry,
2597 patient history is limited. And in some cases that has had
2598 to be turned off, just so that the IIS could receive
2599 vaccines, let alone not -- they just don't have the bandwidth
2600 to push that information back out.

2601 So we have seen some real gaps over the last several
2602 months.

2603 *Mr. Bucshon. Thank you very much for that input, and
2604 that is why I think H.R. 550 is so important.

2605 With that, Madam Chairwoman, I yield back. Thank you
2606 very much.

2607 *Ms. Eshoo. The gentleman yields back, and we all thank
2608 you for your good work.

2609 And I would just add to that that I believe that it was
2610 our former colleague, Donna Shalala, and former Secretary of
2611 HHS, that was the original sponsor of the bill. And now you
2612 have taken it up with Ms. Kuster, and we are grateful to you
2613 for it. It is important work.

2614 The chair now recognizes the gentleman from California,
2615 Mr. Cardenas, for his five minutes of questions.

2616 *Mr. Cardenas. Thank you, Madam Chairwoman and Ranking
2617 Member, for having this very important committee hearing to
2618 discuss these very excellent bills that -- we hope to have
2619 all of them move forward as soon as possible, addressing
2620 issues of vaccination of seniors, children, and everybody in
2621 between.

2622 But equally important, I think, it is wonderful to see
2623 so many experts coming before us, Members of Congress, to
2624 educate us and also the American people who are watching this
2625 public hearing, as it should be. Deliberating and discussing
2626 the policies that affect everyday life of Americans and
2627 beyond is important for us to continue to do that in full

2628 view of the public. Thank God for modern technology.

2629 We are getting through this COVID-19 pandemic. Things
2630 are improving, but we are not out of the woods yet. And what
2631 this pandemic has proven is that there are wide inequities
2632 that persist. They persisted before this pandemic, and this
2633 pandemic exacerbated the truth of these inequities.

2634 For example, Hispanic populations continue to contract
2635 this COVID-19 virus at the highest rates of any other race,
2636 while having some of the lowest rates of vaccine uptake.
2637 According to recent polling conducted by the Kaiser Family
2638 Foundation, Hispanic adults are about twice as likely as
2639 White adults to say that they want to get the COVID-19
2640 vaccine, yet have expressed facing more barriers to accessing
2641 the vaccine than their White counterparts.

2642 Barriers to access include, but are not limited to,
2643 concern regarding missing work, trust in their provider, and
2644 travel to vaccination sites. That is why Representative
2645 Barragan's bill, H.R. 3013, the COVID-19 Transportation
2646 Access Act -- I am pleased to see that she has introduced it,
2647 and I am glad to cosponsor that bill, as well, along with
2648 many of my colleagues.

2649 With that said, our efforts cannot stop there. We need
2650 to make sure that people are aware of the resources that we
2651 are working to provide for them.

2652 Research has also shown that, despite the vaccine being

2653 available free of cost, thanks to the leadership of our
2654 committee and others, 59 percent of Hispanic adults have
2655 reported concerns about having to pay out-of-pocket costs to
2656 get the vaccine.

2657 Similarly, despite all U.S. adults being eligible for
2658 the vaccine, no matter their citizenship status, 42 percent
2659 of Hispanic adults are not sure whether they are currently
2660 eligible to get a vaccine where they live. So awareness is a
2661 big, big issue to make sure that what -- the good work that
2662 we do, the good things that we fund actually -- that people
2663 can actually have the confidence and ability to realize that
2664 we are there for them, and that we are providing these
2665 resources for them.

2666 And discussing vaccine efforts more broadly, and as we
2667 continue to work to better our public health systems, let us
2668 learn from the successes and failures of the COVID-19
2669 vaccination efforts to ensure that every person has equitable
2670 access to information, resources, and vaccinations.

2671 Further, equity should be intertwined in every
2672 conversation we have, and we should commit to finally
2673 understanding and meeting the needs of the populations we
2674 have historically failed to consider and serve, as well as
2675 some others.

2676 From the perspective of our witnesses, what are some --
2677 and you are teaching us some of the largest lessons learned

2678 throughout the COVID-19 pandemic, and how we can use those
2679 lessons to build better, more equitable legislation to guide
2680 future vaccination programs.

2681 So my question to you, Ms. Maldonado, is there anything
2682 you would like to share with us that we can express from the
2683 -- what we have learned from this COVID-19 pandemic, when it
2684 comes to disparities?

2685 *Dr. Maldonado. Yes, thank you for that important
2686 statement. I actually set up one of the first outpatient
2687 outdoor tent treatment centers in the country, here at
2688 Stanford. We did it, actually, in the football field parking
2689 lot of the university, when everything was shut down last
2690 March. And I helped run that site, and continue to help run
2691 the site.

2692 And what we saw were Latino families coming in in large
2693 numbers, carloads of families who were infected, people who
2694 were afraid to come in, because they knew that, if they were
2695 sick, they would have to stop going to work. People who had
2696 no resources for food, we were trying to help provide them
2697 with resources to get delivered food and -- through food --
2698 to food banks and other places.

2699 The disparities here in California, as you probably
2700 know, were just incredible. We were completely unprepared
2701 for the disparities that we saw in these communities. And I
2702 actually witnessed a couple that came in with their two

2703 children. They were -- the children were not sick, the
2704 parents were sick. They were both urged to be hospitalized,
2705 but there was nobody to take care of their -- the children.
2706 So they had to decide which one was sicker to be hospitalized
2707 here, at our hospital. The other one went home to take care
2708 of the kids.

2709 This is just one story, but it is absolutely
2710 representative of what is happening across our entire
2711 country, with all of our racial, ethnic, and lower
2712 socioeconomic populations facing the biggest brunt of this
2713 disease now. Initially, obviously, it was the older
2714 population, but now, with that high vaccination rate in the
2715 old people --

2716 [Audio malfunction.]

2717 *Dr. Maldonado. -- in our racial, ethnic, and lower
2718 socioeconomic minorities. Thank you for those questions.

2719 *Mr. Cardenas. Thank you. It is unfortunate to hear
2720 stories like that happening in America. Let's do what we can
2721 to make sure that we end that.

2722 So thank you, Madam Chair. I am sorry I went over my
2723 time. I yield back.

2724 *Ms. Eshoo. The gentleman yields back. The chair now
2725 recognizes the gentleman from Oklahoma, Mr. Mullin.

2726 And we hope that your son is feeling just better and
2727 better and better.

2728 *Mr. Mullin. Thank you, Madam Chair. I -- Bakersfield
2729 right now, and I -- he is doing much better. So --

2730 *Ms. Eshoo. Great.

2731 *Mr. Mullin. Thank you for asking.

2732 *Ms. Eshoo. Thank you.

2733 *Mr. Mullin. This month he has been testing, and
2734 everything is looking good. So I appreciate your concern.

2735 Sorry about the bad connection. I have very bad
2736 reception, even though I am in Bakersfield. We need a rural
2737 development out here, too, I guess, not just in my district.

2738 But I got a couple of questions, and I -- Madam Chair, I
2739 appreciate so much you holding this meeting and this hearing,
2740 because it is important to all of us. Unfortunately,
2741 sometimes it does become political, and my questions may not
2742 seem to be much different, but we want to make sure that we
2743 are being transparent with the American people.

2744 Ms. Phyllis Arthur, Russia and China both have pre-
2745 approved -- vaccines utilize mRNA technology?

2746 *Ms. Arthur. The vaccines that have been authorized in
2747 China do not use the mRNA technology at this time, although
2748 they do, it appears, have an mRNA vaccine in development in
2749 China. Not sure where the technology comes from.

2750 *Mr. Mullin. What about Russia? Are we familiar with
2751 that?

2752 *Ms. Arthur. Russia does not have an mRNA vaccine in

2753 development in their labs and companies.

2754 *Mr. Mullin. Well, the reason I ask is these countries
2755 are both a significant threat to our democracy. I mean,
2756 obviously -- an advisory over the years. And do you think
2757 that it is wise for the Biden Administration to hand over a
2758 novel vaccine technology to these adversaries?

2759 *Ms. Arthur. I think it is extremely important to
2760 maintain the great biotechnology industry innovations that we
2761 have developed over decades within the private sector, and in
2762 partnership with the U.S. Government, regardless of the
2763 Administration.

2764 And so, knowing that we have actually had decades of
2765 research and development in all of the different platforms
2766 that led to the COVID vaccines, I think it is very important
2767 that we put forward policies that allow us to maximize that
2768 in the United States, and also partner, as we should, with
2769 countries that guarantee that the great work that we have
2770 done in U.S. companies, in partnership with others, is
2771 protected and allowed to bring other innovations forward.

2772 *Mr. Mullin. Right. Under the Trump Administration --
2773 Operation Warp Speed produced three COVID vaccines in under a
2774 year, which was unheard of. In any issue we have ran into
2775 throughout the country, we have never seen the development of
2776 -- the partnership between -- the private-public partnership
2777 come together like we did during Operation Warp Speed. What

2778 can we learn from the success of Operation Warp Speed?

2779 *Ms. Arthur. So thank you very much for that question.

2780 Operation Warp Speed was definitely a success, in terms of
2781 the public-private partnership it represented. It leveraged
2782 the skills and management of the U.S. Government, and the
2783 expertise and skills and decades of experience of industry in
2784 developing safe and effective vaccines.

2785 One of the hardest parts about going so quickly was
2786 figuring out what things could be done in collapsed time, and
2787 what things had to be done in the regular amount of time we
2788 use for development, because we wanted to make sure the
2789 American people -- actually, people all over the world --
2790 could feel like they were getting vaccines that were
2791 researched in a safe way, that they could see themselves in
2792 the data, and that we were manufacturing to proper quality.

2793 And it is -- I think Operation Warp Speed is an example
2794 of the kind of public-private partnership that brings forward
2795 success, especially during an emergency. It is extremely
2796 important to learn how we thought about the collapsing of
2797 timelines. How we approach the manufacturing scale-up was
2798 another success. I think, more importantly, Operation Warp
2799 Speed really leveraged all the investments government and
2800 industry had been making all this time in platforms, which
2801 allowed us to go quickly.

2802 So galvanizing the FDA, NIH, and other agencies and

2803 industry really allowed for that success. And it was that
2804 coordination and that reliance on expertise that allowed that
2805 to happen.

2806 *Mr. Mullin. Thank you. Thank you so much. I hope
2807 that the Biden Administration rethinks this before they start
2808 handing over the intellectual property, because, you know,
2809 American people, we invested a lot in this. And we are not
2810 just talking about the investment of the tax dollars, but it
2811 is also part of our national security. So we need to make
2812 sure we put those first, before we start handing out this
2813 intellectual property, especially to our adversaries.

2814 And with that, I will yield back. Thank you so much.

2815 *Ms. Eshoo. The gentleman yields back. It is a
2816 pleasure to recognize the gentlewoman from Michigan, Mrs.
2817 Dingell. And we are so glad that you are feeling much
2818 better, Debbie.

2819 *Mrs. Dingell. Thank you, Madam Chair. It is good to
2820 be feeling better. I really want to thank you --

2821 *Ms. Eshoo. Some person needs to unmute -- to mute in
2822 their offices, because there is a background conversation,
2823 and the gentlewoman from Michigan is recognized for her five
2824 minutes. Thank you.

2825 *Mrs. Dingell. Thank you, Madam Chair -- thanks, Madam
2826 Chair and Ranking Member Guthrie, for convening this very
2827 important bipartisan hearing to discuss improving public

2828 health through vaccination.

2829 You know, it is -- but I think we need to, you know,
2830 continue to look at the broader picture. As we have seen in
2831 the current pandemic, vaccines, if properly deployed, are one
2832 of the most single effective public health interventions we
2833 had to address COVID-19. But as well is influenza and other
2834 vaccine-preventable diseases like measles, chickenpox, et
2835 cetera.

2836 However, too often the cost in our fragmented health
2837 care infrastructure serves as a barrier to immunization. We
2838 have got to ensure people get vaccines when recommended
2839 throughout their lifetime, not just when they are kids, but
2840 also throughout adolescence. But most vaccines are given to
2841 protect our very young. In our older populations, the fact
2842 of the matter is that we have got to ensure -- fall through
2843 the gaps in the in-between, and there are a lot of
2844 vaccinations we need to be keeping up with throughout our
2845 lifetime.

2846 So I have a question for each of you, and I will go one
2847 by one.

2848 Dr. Maldonado, can you talk more about the importance of
2849 immunizations as part of healthy aging?

2850 As a pediatrician, how can we set kids and adolescents
2851 up to get recommended vaccines as they move throughout
2852 their --

2853 *Dr. Maldonado. Yes, I think this issue -- thank you so
2854 much, Representative Dingell, for this question.

2855 We do think something called life course is a really
2856 important issue. And that is, as a pediatrician, as
2857 pediatricians, we focus on prevention. It is -- fundamental
2858 to how we work with children is how do we prevent diseases
2859 that will affect people 20 or 30 or 40 years or more in their
2860 life course. And we are doing more and more research in this
2861 area.

2862 What is it that we do for the pregnant woman, for the
2863 young infant, and the child, and the adolescent that will
2864 affect their lives, and even their children's lives? And so
2865 this is an area that we are starting to study in more detail,
2866 as we have more access to genomics and precision health and
2867 precision medicine.

2868 But from the immediate perspective, well child care,
2869 preventive care, anticipatory guidance, that is all really
2870 fundamental to every single pediatric provider. That is why
2871 the Vaccines for Children and other bills are important to
2872 really bring families in. This is what really brings the
2873 families in, knowing that they need these vaccines.

2874 But what comes along with that is the ability to provide
2875 all the other platform information that families need around
2876 -- all the guidance that families would need to raise their
2877 children properly, give them proper food, proper nutrition,

2878 and track all of the milestones that they need to develop as
2879 young children.

2880 And as adolescents, the same thing is important. We
2881 need to start talking to them about issues that children may
2882 -- that age group may not talk to their parents about, and
2883 they will trust their provider to discuss. And these are
2884 things that I personally have seen over the years, as well.
2885 So these are things that will help us move our -- into the
2886 adult age group.

2887 And as you have heard from my colleagues, adult
2888 immunizations are important, as well, making people aware
2889 that it is not just the vaccine, but everything that comes
2890 along with it.

2891 *Mrs. Dingell. Thank you, Doctor. I am going to -- I
2892 had a couple, and I am probably not going to have time, so
2893 Dr. Tan, do you have recommendations on how to help spread
2894 this important message in order to help more older adults,
2895 especially those with chronic conditions, understand the role
2896 of immunization in healthy aging?

2897 *Dr. Tan. Well, thank you for the question,
2898 Representative Dingell, and I want to point out that the
2899 Seniors Act is going to also talk about education for the
2900 adults, and I think that is extremely important.

2901 I think we need to think about helping them understand
2902 what the access to -- what vaccines they are -- they need to

2903 have, and then also finding ways to get them access and
2904 removing those potential financial barriers to that vaccine.

2905 I want to pick up also a little bit on something you
2906 said about the chronic diseases that might sometimes impact
2907 adults that are perhaps between the ages of 50 to 64 years of
2908 age. We sometimes forget that they are also vulnerable. So
2909 they are outside the Medicare population, but they are also
2910 vulnerable to severe consequences from vaccine-preventable
2911 diseases. So I think helping to reach out to them, as well,
2912 is probably as important, to make sure that, if you have got
2913 a chronic illness, you are recommended for immunizations, and
2914 you should be seeking those out.

2915 *Mrs. Dingell. And I am really not going to have enough
2916 time to ask another question, Madam Chair, but I would also
2917 -- and we were talking a little about it, the other question,
2918 getting accurate -- I was -- accurate information to people
2919 is really important. I had Guillain-Barre from a swine flu
2920 shot, but I still know -- I am not an anti-vaxxer -- how
2921 important we need to educate ourselves, and get information.
2922 I was scared to death of the COVID vaccine. But here I am,
2923 alive and well, and in a normal life. So working with people
2924 really -- okay, maybe -- Anna, but I survived the COVID
2925 vaccine, and I yield back my time.

2926 *Ms. Eshoo. The gentlewoman yields back. And as I said
2927 at the top of the meeting, we want to get -- hear the rest of

2928 the bounce in your voice returned. So please take good care
2929 of yourself.

2930 The chair is so pleased to recognize our colleague from
2931 North Carolina, Mr. Hudson, for your five minutes of
2932 questions.

2933 *Mr. Hudson. Thank you, Chairwoman Eshoo and Ranking
2934 Member Guthrie, for holding this hearing. And thank you to
2935 our witnesses for your time and testimony today.

2936 As a proud cosponsor of H.R. 1978, the Protecting Senior
2937 Through Immunization Act, and the lead on H.R. 3743
2938 supporting the Foundation for NIH and the Reagan-Udall
2939 Foundation for the FDA, I am particularly happy to be here
2940 discussing these important issues.

2941 I would also like to thank Chairwoman Eshoo for her
2942 leadership and her partnership in introducing H.R. 3743
2943 together. This bill builds on our work together in the last
2944 Congress, and I am pleased to say the bill has already passed
2945 the Senate Health Committee last month under the leadership
2946 of our old friend, Senator Lujan, as well as Senator Collins.

2947 This bill seeks to build upon the immense success we
2948 have had over the past year with public-private partnerships
2949 for medical breakthroughs.

2950 Both the NIH and FDA have nonprofit, independent
2951 organizations established by Congress to help carry out each
2952 agency's mission. These organizations create and manage

2953 relationships between public and private institutions,
2954 administering research programs, supporting education and
2955 training, and providing support to patients. Together, the
2956 Foundation for NIH and the Reagan-Udall Foundation have been
2957 incredibly successful over the years, and are strong stewards
2958 of promoting innovation.

2959 In fact, the FNIH was a crucial supporter of creating
2960 ACTIV, the partnership in April 2020 in response to the
2961 COVID-19 pandemic. ACTIV brought together agencies,
2962 academia, philanthropic organizations, and --

2963 [Audio malfunction.]

2964 *Mr. Hudson. -- promising COVID-19 vaccines and
2965 treatments. As a result, six COVID-19 treatments are now
2966 well underway.

2967 We also saw the success of Operation Warp Speed, another
2968 public-private partnership that, in my opinion, and because
2969 it really -- not receive the credit it deserves. Putting
2970 politics aside, though, Operation Warp Speed, through that
2971 program, we were able to develop, manufacture, and distribute
2972 vaccines in record time.

2973 One critical way we can build on this success is to
2974 continue to support our public institutions, and encourage
2975 them to further partner with private entities. I am honored
2976 to work with Chairwoman Eshoo on this bill that would
2977 increase the level of funding that NIH and FDA transfer to

2978 their foundations to do just that. This bill will continue
2979 to build on the success of ACTIV, and Operation Warp Speed,
2980 and other public-private partnerships to develop novel
2981 vaccines, diagnostics, and therapeutics at even faster rates
2982 in the future.

2983 Turning to Ms. Arthur thank you for your testimony so
2984 far today. I have two questions I will ask, and then I will
2985 let you use the rest of the time to answer.

2986 The first question is I mentioned ACTIV, with the
2987 support of FNIH, has been extremely successful. Can you
2988 explain how my bill, H.R. 3743, might further enhance these
2989 partnerships, and bring more innovative vaccines to the
2990 American people?

2991 And then my second question, in response to the COVID-19
2992 pandemic, key sectors of the pharmaceutical industry acted as
2993 partners with the U.S. Government to mobilize and unleash
2994 innovation. However, recent news about the Biden
2995 Administration's support for waiving IP patents for COVID-19
2996 vaccines is extremely alarming to me. I believe doing so
2997 would jeopardize industry incentives for innovation, undercut
2998 America's leadership in the life sciences, and endanger over
2999 four million pharmaceutical jobs. Could you speak about
3000 industry might respond if the U.S. Government suddenly
3001 undercut the decades of research and billions of dollars
3002 invested in R&D innovation, and how this might impact our

3003 future response to pandemics or public health emergencies?

3004 And I will mute and let you answer, thank you.

3005 *Ms. Arthur. Thank you.

3006 First, I just want to add something to the great
3007 discussion on what we can do to have more people get
3008 vaccinated. Dr. Tan mentioned that we want to make this a
3009 social norm. And so I think it is important to continue to
3010 build on the great investments we made in trusted messengers
3011 for very -- for many communities. A lot of African American,
3012 Latinx, Native American organizations rose up and educated on
3013 COVID. We can't lose all the investment in what they built,
3014 in talking to their constituents, and I hope we make sure
3015 that we think of that as a gap, and we do something about
3016 that, moving forward.

3017 For ACTIV, Congressman, I think ACTIV was an excellent
3018 way to spearhead research across many different therapeutics
3019 and vaccines. And it actually could be a model, moving
3020 forward, for pandemic preparedness response, so that we have
3021 a more organized way to approach the R&D we need to do in a
3022 pandemic, when we have millions of patients, and many
3023 products coming forward. And I think that it was an example
3024 of what could be done across many stakeholders, including
3025 industry.

3026 Lastly, I think we have talked about the waiver.
3027 Industry is definitely concerned that, if the waiver moves

3028 forward, not only would it jeopardize the way we are managing
3029 a very constrained supply chain, globally, because we would
3030 have to have all these different manufacturers around the
3031 world who might want to start manufacturing the product, but
3032 aren't necessarily ready to do so, it could actually, more
3033 importantly, jeopardize the way industry thinks about their
3034 investments in both the commercial sector, and then, as
3035 congresswoman Eshoo mentioned, in the way they think about
3036 pandemic response.

3037 Companies brought 950 products to bear on COVID-19
3038 across the world. They brought every technology they had,
3039 and they stopped working on what they were working on before
3040 to turn their attentions to COVID, regardless of whether they
3041 were going to get funded by the U.S. Government. We want to
3042 make sure that we guarantee companies continue to do that
3043 every time we need to respond to an unknown pathogen or known
3044 pathogen. And one of the cornerstones for industry in doing
3045 that is knowing that there is intellectual property
3046 protections.

3047 *Mr. Hudson. Thank you, and I yield back, Madam Chair.

3048 *Ms. Eshoo. The gentleman yields back. It is a
3049 pleasure to recognize the gentlewoman from New Hampshire, Ms.
3050 Kuster, for your five minutes of questions.

3051 *Ms. Kuster. Thank you so much, Chairwoman Eshoo, and
3052 thank you for holding this important hearing to discuss

3053 efforts to improve public health through specific and
3054 targeted vaccine initiatives. And I particularly appreciate
3055 the inclusion of two bipartisan pieces of legislation that I
3056 have authored this Congress.

3057 Before I dive into questions, I want to take a moment
3058 and encourage all Americans to consult with your doctor and
3059 get vaccinated against COVID-19. We have recently passed the
3060 grim milestone of 600,000 Americans who have died from this
3061 terrible pandemic. And while we have over 43 percent of our
3062 adult population fully vaccinated, Americans are still ending
3063 up in the ICU, and succumbing to this disease because they
3064 have not yet been vaccinated.

3065 We have come too far to allow this virus to move us
3066 backwards. So please roll up your sleeves and do your part
3067 to crush this awful virus.

3068 As we continue to make progress toward ending the
3069 pandemic, it is critical that we not lose sight of the
3070 lessons we have learned. And one lesson we have learned is
3071 that our system for adult immunization needs serious
3072 improvement, and we need to expand access.

3073 While the COVID-19 vaccine is free of cost, regardless
3074 of your insurance status, for other routinely-recommended
3075 vaccines Medicare beneficiaries may still be required to pay
3076 a copay or coinsurance out of pocket. And that is why I have
3077 partnered with my colleague and friend, Representative -- Dr.

3078 Larry Bucshon, on introducing the Protecting Seniors Through
3079 Immunization Act, which provides Medicare beneficiaries with
3080 Part D coverage the same access to vaccines that individuals
3081 under the age of 65 currently enjoy. Medicare beneficiaries
3082 should not be forced to choose between getting a provider-
3083 recommended vaccine or other medicines to manage chronic or
3084 acute medical issues.

3085 So I have a question for Dr. Tan.

3086 Could you speak to the importance of initiatives that
3087 prioritize high-value care for seniors and expand access to
3088 routine vaccination for seniors?

3089 And in your opinion, would the Protecting Seniors
3090 Through Immunization Act help improve access to recommended
3091 vaccines under Medicare?

3092 *Dr. Tan. Oh, yes, thank you very much, and thank you
3093 to you, and also to Representative Bucshon, for introducing
3094 this bill. Thank you.

3095 Yes, absolutely. I think part of the bill also talks
3096 about the fact that there is an education component and an
3097 outreach component. And I think that is really, really vital
3098 to not just help seniors understand that they can get access
3099 to these vital vaccines, hopefully, at no copay, but also to
3100 help providers understand that, as well.

3101 Sometimes provider hesitation to recommend vaccines is
3102 because they don't want to put a burden of a payment on their

3103 patients, especially those who are on fixed incomes. And so,
3104 by taking that concern away, we can also strengthen that
3105 provider recommendation, "I recommend you get the vaccine
3106 because it doesn't cost you anything," and they can say that
3107 with confidence. So I think that is extremely important.

3108 And --

3109 [Audio malfunction.]

3110 *Dr. Tan. -- playing field, right, as you have said.
3111 We need to make sure that my grandparents -- well, actually,
3112 my parents -- can get a vaccine the same way I can get one
3113 through commercial health plans. So that is an important,
3114 important part of the bill, as well. So thank you very much
3115 for that question.

3116 *Ms. Kuster. Thank you. I also want to highlight --
3117 excuse me -- I also want to highlight my bipartisan bill,
3118 also with Dr. Bucshon, that would provide critical funding to
3119 bolster our immunization infrastructure around the country,
3120 and bring it into the 21st century. The Immunization
3121 Infrastructure Modernization Act would boost funding to
3122 improve information technology, data collection, and
3123 interoperability between IIS systems.

3124 This is a question for Rebecca Coyle: Through your work
3125 and experience working with IIS systems, what has hindered
3126 states and local health departments from bringing their
3127 systems into the 21st century?

3128 *Ms. Coyle. Thank you for that question, and I really
3129 appreciate your leadership in this area. I think the
3130 question you ask is great. You know, what has hindered us
3131 from moving forward?

3132 And quite frankly, it boils down to prioritization.
3133 There are a number of different things that public health is
3134 faced with trying to navigate.

3135 And then the other piece is funding. There has not been
3136 any sort of dedicated resources for immunization information
3137 systems. They are part of the much larger immunization
3138 program funding, which then relies upon the state or
3139 jurisdiction to dictate where their priorities rest, and
3140 making those modernization efforts.

3141 I think, as a result of that, we have seen a variety of
3142 different systems across the U.S. Some are more highly
3143 functioning than others, and I think our goal here is to
3144 really try and improve that flow and the operation to the
3145 same level.

3146 *Ms. Kuster. Great. Perfect timing. My time is up
3147 and, with that, I yield back.

3148 *Ms. Eshoo. The gentlewoman yields back. It is a
3149 pleasure to recognize another one of our outstanding doctors
3150 on our subcommittee, and we are so fortunate to have them.

3151 Dr. Dunn of Florida, you are recognized for your five
3152 minutes of questions.

3153 *Mr. Dunn. Thank you very much, Madam Chair, for your
3154 kind words, and Ranking Member Guthrie, for hosting this
3155 hearing today.

3156 You know, the United States has a wonderful story to
3157 tell when it comes to the development of the vaccines. It is
3158 my hope that the success of this public-private partnership
3159 that brought us these vaccines can be leveraged to continue
3160 innovating, and move towards eradicating vaccine-preventable
3161 diseases in the U.S. and beyond.

3162 For any vaccination we know that immunity may fade over
3163 time. The most appropriate way to ensure that a vaccine has
3164 produced a strong immune response is to test for persistent
3165 immunity in both a qualitative and quantitative sense.
3166 Testing for immunity can be an important tool in determining
3167 when, after any vaccination, a booster shot may be needed, or
3168 to determine if someone was previously infected with a
3169 specific virus, and already has significant immunity.

3170 Some viruses principally evoke a B cell immune response,
3171 such as hepatitis B and A. This we measure with antibody
3172 titers. In other viral diseases, the principal immune
3173 response is mediated by T cells. We call this humoral
3174 immunity, and it is best measured by testing for activated T
3175 cells, not antibodies, which are fleeting after vaccination
3176 or infection with SARS-CoV-2.

3177 Coronavirus is such a virus. Testing for antibodies is

3178 of little use in detecting or quantifying immune status. T
3179 cells are available -- T cell tests are available, although
3180 not nearly as widely or cheaply yet. But our experience in
3181 Singapore, SARS-Cov-1 showed, essentially, 100 percent
3182 immunity to this disease in survivors fully 17 to 18 years
3183 later. This was measured by testing for activated T cells to
3184 SARS-CoV-1. Interestingly, these same patients demonstrated
3185 a similar level of immunity to SARS-CoV-2.

3186 This underscores the obvious conclusions that we need to
3187 have readily-available T cell immunity testing, so that we
3188 can definitively determine who has immunity and who does not.
3189 Someone may have had the vaccine, but failed to mount a
3190 significant immune response, as some five percent of vaccine
3191 recipients do. Or they may have unknowingly had a
3192 subclinical infection, and still demonstrate clinical
3193 immunity, significant clinical immunity, thereby not needing
3194 the vaccination.

3195 Indeed, there may be a small, but real risk that
3196 vaccination in these patients, especially the younger ones,
3197 may excite a cytokine storm response that renders them
3198 seriously ill.

3199 So on that subject, Dr. Maldonado, do you have anything
3200 to add regarding the importance of being able to test for
3201 humoral immunity, T cell immunity, compared to antibody
3202 testing when it comes to COVID-19?

3203 *Dr. Maldonado. Yes. Clearly -- thank you so much for
3204 that comment, Representative Dunn.

3205 So we have a Human Systems Immunology Center, here at
3206 Stanford, and there are centers all around the country and
3207 within, actually, the industry, as well, that are conducting,
3208 actively, very cutting-edge work around measurement of T and
3209 B cell immunity. So clearly, humoral and cell-mediated
3210 immune markers are critical for understanding not only how
3211 this virus is producing the effects that it does, but also
3212 the --

3213 *Mr. Dunn. But also the vaccines. I am going to
3214 reclaim my time, because we are running out, and I have other
3215 questions for you.

3216 Are other members of your specialty pediatricians
3217 routinely using T cell testing?

3218 *Dr. Maldonado. So we are --

3219 *Mr. Dunn. In this country.

3220 *Dr. Maldonado. So we are doing T cell testing here at
3221 Stanford, absolutely. We are working with NIH, and FDA, and
3222 others to do studies. I have a -

3223 *Mr. Dunn. But outside academic centers, I think it is
3224 not as widely available, am I correct?

3225 *Dr. Maldonado. There are some T cell assays, but we
3226 don't have a good understanding of how they are going to
3227 work. So, yes, absolutely, we need to understand them better

3228 so they could be potentially commercially used.

3229 And then the question will be, of course, whether we
3230 should use them -- use these to identify booster -

3231 *Mr. Dunn. Okay, I am going to move on, but I
3232 appreciate that. And I am -- by the way, I will be
3233 submitting questions in writing after this.

3234 As the industry seeks to -- this is to Ms. Arthur -- as
3235 the industry seeks to determine the specifics of when COVID-
3236 19 booster shots might be necessary, if -- or if they are
3237 necessary, do you know if vaccine manufacturers are
3238 evaluating T cell immunity data to drive decision-making?

3239 *Ms. Arthur. So I am not sure. I think that companies
3240 are working with the FDA to look at different markers, and so
3241 they are trying to look at --

3242 *Mr. Dunn. So I am going to -- again, I am going to
3243 interrupt, because we are -- but I would urge your companies
3244 to look at the Singapore data. They have a lot of experience
3245 with this and SAR-CoV-1. It was very good data. I look
3246 forward to learning more about this testing in the future,
3247 and how we are using it clinically, and in research. And I
3248 would submit the data on human immunity would be extremely
3249 valuable to doctors treating patients on a daily basis, and
3250 to our vaccine makers. And, as I say, I will be submitted
3251 questions.

3252

3253 [The information follows:]

3254

3255 *****COMMITTEE INSERT*****

3256

3257 *Mr. Dunn. And thank you very much, Madam Chair and
3258 Ranking Member Guthrie. I yield back.

3259 *Ms. Arthur. Dr. Dunn, I would love to have that
3260 question in writing so we can respond to you.

3261 *Mr. Dunn. You will. You will, I promise.

3262 *Ms. Arthur. Thank you.

3263 *Ms. Eshoo. The gentleman yields back. It is a
3264 pleasure to recognize the gentlewoman from Illinois, Ms.
3265 Kelly, for your five minutes of questions.

3266 *Ms. Kelly. Thank you, Chairwoman Eshoo and Ranking
3267 Member Guthrie, for your leadership, and for holding this
3268 hearing to discuss improving vaccination rates, especially in
3269 populations that are at higher risk for vaccine-preventable
3270 diseases.

3271 According to the CDC, pregnant people, and recently --
3272 pregnant people have a higher risk for severe illness from
3273 COVID-19, compared to non-pregnant people. A recent study
3274 published in JAMA found that people with COVID-19 diagnosis
3275 have an increased risk of maternal morbidity and mortality,
3276 and that newborns of people with a COVID-19 diagnosis had a
3277 higher risk of morbidity. We must, must ensure that COVID-19
3278 vaccinations make it to the arms of the people who need it
3279 most.

3280 Unfortunately, vaccination rates tend to be low on
3281 pregnant people, overall. In 2019, only 40 percent of

3282 pregnant women received recommended vaccines. The rates were
3283 even lower for Black and Latinx women, with 23 percent and
3284 25.4 percent, respectively, getting vaccinated, compared to
3285 46 percent of White women.

3286 This is personal to me. My daughter just had a baby, so
3287 I have a grandbaby, another one, as of two days ago, and she
3288 hasn't been vaccinated yet.

3289 So Dr. Tan, why aren't all pregnant women getting access
3290 to potentially lifesaving vaccines?

3291 And what actions are needed to ensure that maternal
3292 populations and providers who care for them are able to make
3293 preventive health measures such as that?

3294 *Dr. Tan. Thank you very much for that very important
3295 question.

3296 I think, when I was in the National Vaccine Advisory
3297 Committee, we actually issued a report on maternal
3298 immunization, looking at some of the barriers. And I think
3299 it is important to recognize that one of the major reasons
3300 why a pregnant person gets vaccinated is a healthcare
3301 provider recommendation. And so it is because of that
3302 recognition that a lot of work was done to bring on board
3303 OB/GYNs to become immunizers, to provide recommendations for
3304 immunizations, and give the vaccines. I think that has been
3305 a testimony to ACOG on their efforts on that.

3306 But I think, that being said, I think we have now hit a

3307 point where we went from 15 percent to about 50 percent, for
3308 example, for flu, and we are not getting much higher. And I
3309 think that reflects, actually, some traction with regards to
3310 what other providers can we engage to provide access to
3311 vaccines for pregnant women.

3312 And I think one of the challenges that we have is that
3313 it does cost providers a lot of money to start vaccinating.
3314 You know, the family physicians have been vaccinating for
3315 forever. Pediatricians have done this very well for a long
3316 time. But when we start expanding to providers of health
3317 care to pregnant women, internists, we need to figure out
3318 ways to incentivize them to absorb -- to take on these costs,
3319 to start up, to vaccinate people. And I think that is one of
3320 the most important things that we can do, with regards to the
3321 provider component.

3322 And the maternal immunization bill that is in front of
3323 us, actually, is really, really important, because it starts
3324 that conversation between the patient and the provider by
3325 providing education and outreach on why maternal
3326 immunizations are important.

3327 I am going to just wrap by saying, you know, there is a
3328 lot of new vaccines coming up for maternal immunizations, and
3329 it would be a shame if we did not move this forward to a
3330 point where we get to see the benefits of those new vaccines.
3331 Thank you so much.

3332 *Ms. Kelly. Well, I very much support H.R. 951, the
3333 Maternal Vaccinations Act. I think it is really important.

3334 Dr. Maldonado, some women are reluctant about these
3335 vaccines for safety concerns. As a physician, can you speak
3336 to the safety and importance of maternal vaccinations,
3337 specifically the inclusion of pregnant people in vaccine
3338 research?

3339 *Dr. Maldonado. Yes, absolutely. Thank you so much for
3340 this important question.

3341 As we know, these vaccines are recommended by the CDC
3342 now for use in pregnant women. The ACOG, American College of
3343 Obstetrics and Gynecology, also recommend the safety of these
3344 vaccines for pregnant women -- persons. The issue is that
3345 there has been some misinformation on social media that has
3346 been circulating much faster than others -- than people was -
3347 - were expected, that there is -- around the inability of --
3348 the ability of the vaccine to potentially cause infertility.
3349 That is absolutely baseless. It is based on non-science, and
3350 it has frightened a number of individuals into not getting
3351 vaccinated, for fear of fertility issues.

3352 But in addition, it has also frightened pregnant people
3353 into not considering getting the vaccine. So I do think
3354 that, again, coming back to this issue of providing more
3355 support, as LJ mentioned, we published this paper, white
3356 paper, many years ago on maternal immunization efforts. And

3357 there are some, still, very good recommendations there on how
3358 to educate our OB/GYN providers, our private practice
3359 providers, our communities around the safety of these
3360 vaccines, because we do have an extremely safe surveillance
3361 systems. The FDA, CDC, and others do track vaccines very
3362 carefully and cautiously. And we have the highest confidence
3363 in vaccination of pregnant people.

3364 *Ms. Kelly. And I know I am out of town -- time, but I
3365 just want to say passing the Helping Adults Protect Immunity
3366 Act is critical to ensuring access to vaccines.

3367 And I thank Representative Soto for his leadership here,
3368 in -- continue pushing my bill, the MOMMA's Act, which would
3369 mandate Medicaid programs to expand postpartum coverage from
3370 60 days to 1 (sic). Together, these changes will ensure that
3371 both pregnant people and new moms can receive the
3372 vaccinations they -- receive.

3373 Thank you, and I yield back.

3374 *Ms. Eshoo. I thank the gentlewoman for her terrific
3375 work.

3376 It is a pleasure to recognize Mr. Curtis from Utah for
3377 your five minutes of questions.

3378 *Mr. Curtis. Thank you.

3379 *Ms. Eshoo. And thank you for your patience.

3380 *Mr. Curtis. Thank you, Madam Chair. A special thanks
3381 to Representative Kelly. Congratulations on that new, little

3382 grandbaby. As a grandfather of 11, I can really relate to
3383 your joy.

3384 I can also relate to some of the concerns expressed. I
3385 have heard this from my own daughters, who are -- some
3386 expecting, and some -- I have six kids, by the way. And it
3387 has been real frustrating to me, as their father, somebody
3388 who is a strong advocate of getting a vaccination, to watch
3389 them struggle with this personal decision. And we just have
3390 to do a much better job of getting information out there, and
3391 I am struggling in my own family to do that.

3392 I have been a strong proponent for getting vaccinations.
3393 I had an early vaccination myself, and yet I represent a
3394 district --

3395 [Audio malfunction.]

3396 *Mr. Curtis. -- are reluctant to get a vaccination.
3397 And I feel compelled just to speak for them, just to some
3398 degree, to say that it is still a personal choice, and
3399 something that cannot be forced upon them. As a matter of
3400 fact, I think the more we talk about it in these terms, the
3401 more resistant they are to doing it. It reminds me a little
3402 bit of somebody who is diabetic, or susceptible to diabetes
3403 who wants to sit on the couch and watch TV, no matter how
3404 much we talk and tell them to go out and exercise. They
3405 don't.

3406 I am a little frustrated when I hear things like we

3407 can't hold our committee meetings until we know who
3408 vaccinated and who is not. Nobody has exactly explained that
3409 science to me, of why we need to know that. And I realize
3410 there is many cases that are quite personal, where we don't
3411 know that.

3412 I would like to switch gears just a little bit to
3413 vaccinations, in general, and ask Dr. Maldonado, how many
3414 annual immunizations are recommended for children, and at
3415 what ages are children recommended to receive these
3416 immunizations?

3417 And then, a follow-up to that is, is there an age
3418 bracket in which we see these drop, the immunization rates
3419 drop? And, if so, what can we do to close that gap?

3420 *Dr. Maldonado. Yes, thank you. There are over 27
3421 different types of diseases that are prevented by
3422 immunizations, not all of them recommended for every single
3423 child. So it really depends on whether children have
3424 underlying risk factors or not.

3425 But the vaccinations generally start by around two
3426 months of age in this country, and they can continue all the
3427 way through adulthood, as we know, for HPV, for example, and
3428 pneumococcal diseases. But the age groups are generally
3429 concentrated in the first five years of age. And then they
3430 tend to have an adolescent platform, where there are vaccines
3431 recommended in the 11 to 12-year-old age group and above, and

3432 then there are some vaccines that are recommended for young
3433 adults, and then, again, pregnant people, and then finally
3434 for seniors.

3435 So there is a whole, very nicely put-together schedule
3436 that the American Academy of Pediatrics harmonizes with ACIP.
3437 It is available on the CDC website, and it includes regular
3438 vaccinations, vaccinations for catch-up, and for different
3439 ages.

3440 *Mr. Curtis. Thank you.

3441 Ms. Arthur, there has been a lot of discussion at
3442 today's hearing about President Biden's Administration
3443 proposal to hand over the COVID-19 vaccine intellectual
3444 property. I think you have been pretty clear about how you
3445 feel about that. And I might say that I think those are
3446 legitimate fears.

3447 But let me kind of change that question just a little
3448 bit, and say we all agree that we want to get vaccinations
3449 out to the world. What can we be doing, without losing an
3450 intellectual property?

3451 In many ways, I think we have seen a great display with
3452 that, with President Biden's recent commitment to put a half
3453 a billion out there. But what would you advise us, as
3454 Members of Congress, that we can do, short of giving away
3455 that intellectual property to get vaccinations out to the
3456 world?

3457 *Ms. Arthur. Thank you so much for that question,
3458 Congressman. I think that is actually exactly where we would
3459 like to focus the policy energies around COVID for the world,
3460 is actually thinking about those very important things we can
3461 do right now to get more vaccines produced.

3462 We have put out our BIO Share program, and we have
3463 encouraged anything the government could do to help reduce
3464 export controls around the world that limit the free
3465 movement, particularly of the key raw materials we need to
3466 manufacture more vaccines, not just here, but in other
3467 countries that are also serving their nations and other
3468 nations.

3469 Secondly, the donations that are organized are really,
3470 really important.

3471 And third, we need to actually use, as the President
3472 said, our arsenal of power in the United States, and all the
3473 manufacturing capacity that we built over the last year, to
3474 actually export doses to countries, so that companies can
3475 honor the commitments they have made to COVAX and to other
3476 nations to bring more doses as quickly as possible to people.

3477 *Mr. Curtis. Thank you. It appears to me that that is
3478 actually a much quicker way to get vaccinations out to the
3479 world, rather than letting people redevelop so many things
3480 that you have already done.

3481 *Ms. Arthur. These are things that could happen today,

3482 and are happening right now.

3483 *Mr. Curtis. Thank you. I am out of time.

3484 Madam Chairman, I yield. Thank you.

3485 *Ms. Eshoo. The gentleman yields back. The gentlewoman
3486 from Delaware, a small state, but with big representation.

3487 Ms. Lisa Rochester, you are -- Blunt Rochester, you are
3488 recognized for five minutes.

3489 *Ms. Blunt Rochester. Thank you so much, Madam
3490 Chairwoman, for the recognition, also of the recognition of
3491 our small wondrous state, and for calling this important
3492 hearing today. I would also like to thank the witnesses for
3493 being here.

3494 President Biden declared June a month of action in order
3495 to help the country reach the target goal of 70 percent of
3496 adults immunized against COVID-19 by the Fourth of July
3497 holiday. While the United States has vaccinated more people
3498 than anywhere else in the world, we are still working on
3499 connecting vaccines to individuals at that last mile,
3500 especially among racial and ethnic minorities.

3501 Due to investments from the American Rescue Plan and
3502 leadership from the Biden Administration, we have seen
3503 healthcare providers, community-based organizations, civil
3504 rights and religious leaders come together around targeted
3505 COVID-19 vaccination campaigns.

3506 And in my state, Beebe Healthcare and local partners

3507 have re-purposed a bus normally used as a mobile library with
3508 vaccine workstations to, literally, meet people where they
3509 are. And while we have made progress, the data shows we
3510 still have much work to do. According to the Kaiser Family
3511 Foundation, Black and Hispanic individuals have received
3512 smaller shares of vaccinations compared to their shares of
3513 cases, and compared to their share of total population in
3514 most states.

3515 Dr. Tan, can you talk about how these outreach
3516 activities have helped reach these critical populations, and
3517 what more can be done?

3518 *Dr. Tan. Well, thank you so much for that question. I
3519 think it is -- I think COVID-19 woke us all up to the
3520 discrepancies that we see in our access to care. And I think
3521 these initiatives that came out of that have been very
3522 successful.

3523 I think one of the big pictures it has shown us is that
3524 with rural, with low socioeconomic, with ethnic and disparate
3525 populations, we need to figure ways to bring the vaccine to
3526 the community. And that starts, also, with bringing people
3527 in the community to the vaccine, in the sense that -- you
3528 know, bringing leadership that can speak to the benefits of
3529 getting vaccinated.

3530 In the African American population there has been
3531 previous work that has demonstrated success where, when you

3532 engage a respected pastor to talk about vaccination,
3533 vaccination being offered in his or her church, that
3534 increases immunization coverage rates. And I think these
3535 programs that you talked about that started with COVID-19 are
3536 achieving that success.

3537 What I would urge is that we continue to use these
3538 techniques, that -- these interventions that we have learned
3539 to do this with all the adult vaccines, going forward, and to
3540 build on that, so we don't lose that momentum.

3541 *Ms. Blunt Rochester. Well --

3542 *Dr. Tan. Thank you so much for that question.

3543 *Ms. Blunt Rochester. Well, you actually read my mind,
3544 because my next question was, how can this increased
3545 coordination be utilized to help with catch-up activities for
3546 routine immunizations, as well?

3547 *Dr. Tan. So that is a great follow-up. Thank you for
3548 that. I would like to speak a little bit longer to that,
3549 absolutely. And I think this is the other thing that we are
3550 also beginning to figure out with COVID-19, is that -- this
3551 exquisite collaboration between state public health, county
3552 public health, and the communities that they serve, are
3553 really required in order to bring these programs to fruition.

3554 And on that note, I think it is important to recognize
3555 that a lot of the work that we are doing, you know, needs to
3556 be sustained with improvements in our public health

3557 infrastructure. And I think that is the big picture that we
3558 also want to not forget, that, in order to continue and
3559 sustain these improvements, we need to fund public health
3560 infrastructure the way it has not been funded before. Thank
3561 you again.

3562 *Ms. Blunt Rochester. Yes. You testified that coverage
3563 is key for getting people vaccinated. What does the data
3564 tell us about how health coverage affects vaccination rates
3565 among racial and ethnic minorities?

3566 *Dr. Tan. Yes, a one-word answer. The more someone has
3567 to pay out of pocket for a vaccine, the more likely they are
3568 going to refuse or not even show up for that vaccine. So we
3569 need to make sure that patients have no copay, so that they
3570 will get the vaccines that will potentially save their lives.

3571 *Ms. Blunt Rochester. I really want to thank you, Madam
3572 Chairwoman, for this hearing. This, as we know, is
3573 consequential to not only our physical and mental recovery,
3574 but also to our economic recovery. And this is such an
3575 important moment for us.

3576 And I am glad also, Dr. Tan, that you mentioned rural
3577 communities. I represent the entire State of Delaware. We
3578 are small, so we only have one congressperson. And so I am -
3579 - we are representing urban, suburban, and rural communities.
3580 And so us being creative, and innovative, and finding these
3581 different ways in multiple entry points is going to be very

3582 important, not just for today, but also, as you mentioned,
3583 for the future of our health care and our health
3584 infrastructure. So thank you so much.

3585 And I yield back the balance of my time.

3586 *Ms. Eshoo. The gentlewoman yields back.

3587 I think you are the only senator in the House of
3588 Representatives, so we love you.

3589 It is a pleasure to recognize the gentleman -- oh, I am
3590 sorry, another one of our great doctors on the subcommittee,
3591 Dr. Joyce from the State of Pennsylvania.

3592 You are recognized for five minutes.

3593 *Mr. Joyce. Thank you for the kind words. And thank
3594 you, Chair Eshoo and Ranking Member Guthrie, for convening
3595 this hearing. And thanks to the witnesses for appearing
3596 today on such an important topic.

3597 The COVID-19 pandemic has caused disruptions in almost
3598 every aspect of Americans' daily lives over the last 15
3599 months. And thanks to President Trump's Operation Warp
3600 Speed, we have seen multiple vaccines authorized for use in
3601 record time, and a return to normal life. Children have been
3602 greatly affected by the pandemic, as we have seen school
3603 closings, loss of activities, and limiting of routine social
3604 interactions, which have drastic impact on learning, on
3605 mental health, and on the social development of our children.
3606 With the authorization of the COVID-19 vaccine for children

3607 12 and up, all of these activities must resume in full.

3608 Now I would like to take -- turn to another matter of
3609 vaccines in children, and the troubling drop that we saw last
3610 year in routine childhood vaccinations, particularly early in
3611 the pandemic. These were especially prevalent in the DTaP
3612 and the MMR vaccine rates, which prevent several highly
3613 communicable -

3614 [Audio malfunction.]

3615 *Mr. Joyce. My question first is for Dr. Maldonado.

3616 Thank you for your testimony earlier, when you laid out
3617 some of these issues, and for highlighting the Strengthening
3618 the Vaccines for Children Program Act of 2021, which was
3619 introduced by my fellow physician, Representative Kim
3620 Schrier, myself, and our colleagues, Representative
3621 Butterfield and McKinley.

3622 In particular, I did want to focus on an issue that
3623 impacts doctors participating in the Vaccine for Children
3624 program.

3625 Dr. Maldonado, can you please discuss how the current
3626 program reimburses physicians for vaccines that protect
3627 against these multiple communicable diseases, and how this
3628 poses challenges?

3629 *Dr. Maldonado. Yes, thank you so much, Representative
3630 Joyce, for that question.

3631 So currently, the -- it really depends on at what level

3632 the provider works. So, for example, if they are in a large
3633 practice or a large health system, they are largely protected
3634 from the day-to-day work, but they still have quite a bit of
3635 paperwork to do. It only gets exacerbated if you are in a
3636 smaller practice, or in a rural area where you might be the
3637 only provider for many, many miles, for a large geographic
3638 region.

3639 What happens is these requirements are really broken
3640 down between Federal and state requirements, because there
3641 are separate payment stream fund flows -- funds flow for
3642 payments. So you may have private-insured patients, you may
3643 have state-funded patients, you may have Federal-funded
3644 patients. And the ability to streamline these processes
3645 would really take a big bite out of the time that providers
3646 have to spend after seeing their patients in completing all
3647 of the paperwork, hiring back office individuals to just do
3648 that work, which keeps them from seeing more patients and
3649 providing the care that they need.

3650 So the administrative and bureaucratic issues that --
3651 streamlining VFC and CHIP, for example, really would go a
3652 long way to reducing the financial burden, the administrative
3653 burden. It would increase the ability of pediatricians and
3654 other providers, such as family practitioners, as well, to
3655 see patients face to face, rather than to spend time doing a
3656 lot of the paperwork that is necessary to get this

3657 reimbursement.

3658 *Mr. Joyce. Thank you for bringing that into the
3659 discussion. The area that I represent in south-central and
3660 southwestern Pennsylvania you described. There are many
3661 small practices in rural areas, and these individual
3662 pediatricians and family practice physicians are obligated to
3663 take care of these children, and provide them with the
3664 necessary vaccinations.

3665 Finally, do you believe that the bill, Strengthening the
3666 Vaccines for Children Program Act of 2021, will alleviate the
3667 concerns that you just laid out?

3668 *Dr. Maldonado. I do believe that this will make a --
3669 take a -- take us a long way into addressing issues that we
3670 have been bringing up for many years now around the alignment
3671 of funds flow into practices, especially those that were
3672 already impacted even before the pandemic, and which has been
3673 exacerbated by current fiscal constraints that the pandemic
3674 has imposed on practices around the country.

3675 So this would have an immediate, immediate impact on the
3676 ability of practices to really gear up and get back into the
3677 business of taking care of children, and keeping them safe
3678 and healthy.

3679 And then the long-term impacts would be important in
3680 keeping -- in enticing more providers, as I mentioned, to
3681 come into VFC and be allowed to participate in providing more

3682 care for children, giving them those medical homes that they
3683 really need.

3684 *Mr. Joyce. Thank you so much for your answer.

3685 Chair Eshoo, thank you. I see my time has expired, but
3686 this is such an important issue, I definitely appreciate your
3687 indulgences in allowing us to continue this conversation.
3688 Thank you.

3689 *Ms. Eshoo. We appreciate you on the subcommittee,
3690 Doctor. So -- and thank you for yielding back.

3691 It is a pleasure to recognize a great new member of our
3692 subcommittee, the gentlewoman from Minnesota, Ms. Craig, for
3693 your five minutes of questions.

3694 *Ms. Craig. Thank you so much, Madam Chairwoman, for
3695 holding this important hearing today. And thank you to our
3696 panelists, who have stuck in there for the majority of the
3697 day today.

3698 With over 309 million doses administered within the
3699 United States, we have made historic progress in developing
3700 and delivering vaccines. Earlier this year I was proud to
3701 vote for the American Rescue Plan, which provided \$7.5
3702 billion to CDC for vaccine distribution and administration.

3703 However, as we all know and we heard today, those
3704 persistent gaps persist. In Minnesota, the statewide
3705 vaccination rate among Black, indigenous, and Hispanic
3706 Minnesotans is around 50 percent, compared to 62 percent

3707 among White residents. In rural areas, the vaccination rate
3708 among Black, indigenous, and Hispanic individuals is even
3709 lower. The most recent racial and ethnic data from CDC
3710 includes 57 percent of people who have received at least 1
3711 dose of the vaccine. While the national data indicates a
3712 narrowing in those disparities in vaccination rates among
3713 Hispanic, Black, and Asian communities, we still do not have
3714 state-level data.

3715 Earlier this year, I introduced H.R. 979, the Vaccine
3716 Fairness Act, which would direct HHS to provide regular
3717 updates on their efforts to ensure the COVID-19 vaccine
3718 reaches the groups most at risk. It would require HHS to
3719 report disaggregated data vaccine distribution data by age,
3720 race, ethnicity, and zip code. I want to thank the committee
3721 for including H.R. 979 in today's legislative hearing, and
3722 allowing me to raise awareness about vaccine equity in
3723 Minnesota.

3724 With that in mind, I wanted to ask you, Ms. Coyle, about
3725 the critical role immunization information systems play in
3726 how we respond to outbreaks like COVID-19. We also know how
3727 difficult it is to address racial, ethnic, and geographic
3728 barriers to care without robust and accurate data. Can you
3729 expand on the ways that outdated Immunization Information
3730 Systems inhibit states' ability to collect demographic data,
3731 and respond appropriately?

3732 *Ms. Coyle. Sure, and thank you for your question. So
3733 I think, you know, in terms of equity, it is very important
3734 to understand how all of that is calculated.

3735 One of the significant challenges that we faced going
3736 into this pandemic is really the emphasis on trying to
3737 capture some of that race and ethnicity data. Some of that
3738 data hasn't typically flown into an IIS before, through data
3739 exchange, for a variety of reasons: one, perhaps the clinic
3740 is not actually collecting that information; two, perhaps the
3741 system doesn't actually submit that information. Or I think
3742 even more troubling is that our actual systems -- and this
3743 includes EHRs -- don't actually capture the broad depth of
3744 which we need to capture for race and ethnicity data. It is
3745 very limited in nature to about seven fields, whereas we know
3746 race and ethnicity is very -- more complex than that.

3747 So the way that we have been able to see this, I think,
3748 sort of morph, and the attention placed on all of this, we
3749 saw all of our states, all of our jurisdictions be able to
3750 capture that information, and be able to save that
3751 information with the patient. Right now we are at a little
3752 over 50 percent of all of the COVID-related data containing
3753 race or ethnicity information. But we recognize that there
3754 is still a long ways to go, and it is a shared responsibility
3755 between those capturing the information, the medical clinics,
3756 and then, also, for the systems to maintain that information.

3757 *Ms. Craig. Ms. Coyle, just as a follow up, if we were
3758 able to capture that data more accurately, what are the ways
3759 that we can leverage that data to improve vaccine equity?

3760 How would we put that into practice?

3761 *Ms. Coyle. Certainly. Well, with access to data it
3762 certainly can highlight some of the areas that may need
3763 additional focus. We know that sometimes, with certain
3764 populations, they need an outreach that is conducive to their
3765 cultural or -- ways of thinking. And it is one of those
3766 things where, the more data you have at your hands, the more
3767 specific you can be in your response.

3768 And I think that is truly the best tool for these IIS,
3769 is that you have that complete knowledge and that complete
3770 look, then being able to leverage that to target your
3771 interventions.

3772 *Ms. Craig. Thank you very much, and thank you again to
3773 all of our panelists here today.

3774 And Chairwoman Eshoo, with that, I will yield back.

3775 *Ms. Eshoo. The gentlewoman yields back, yielding back
3776 some extra time, we thank you for that.

3777 Now the -- it is a pleasure to recognize the gentleman
3778 from Texas, Mr. Crenshaw, and we are so happy that you are
3779 with us, and hope that you are feeling really well.

3780 [Pause.]

3781 *Ms. Eshoo. You need to unmute.

3782 [Pause.]

3783 *Mr. Crenshaw. Working now.

3784 *Ms. Eshoo. There you are.

3785 *Mr. Crenshaw. Yes. I was unmuted, but the settings
3786 weren't correct. I had to utilize my Millennial background
3787 to -- with troubleshooting.

3788 *Ms. Eshoo. I hope you are feeling really well. It is
3789 great to see you.

3790 *Mr. Crenshaw. Well, thank you. Thank you, Madam
3791 Chairwoman, and I do. I feel -- I am, basically, back to my
3792 sense of normal, which is a complicated normal, but I am,
3793 basically, back. So I really appreciate all the prayers and
3794 well wishes.

3795 And thank you to our witnesses for being here today,
3796 discussing the important issue of the vaccinations and the
3797 amazing efforts by American industry to create, manufacture,
3798 and distribute vaccines at a record pace.

3799 I want to just briefly discuss one of my bills here
3800 today. I was disappointed it was not included in the budget
3801 reconciliation. I know a lot of my colleagues on both sides
3802 of the aisle have the same concern on the topic of vaccine
3803 allocation and transparency.

3804 Every American who wants a vaccine can get a vaccine.
3805 We are fortunate to have an excess supply to share with the
3806 world. It really is an amazing thing to be an American. But

3807 I want to remind us of where we were in February. And by us,
3808 I particularly mean Texans. The Houston Chronicle ran a
3809 story with the headline, "Nobody is Getting Enough: Why
3810 Texas Ranks Near the Bottom for COVID-19 Vaccines Per
3811 Capita.'" Again, of course, that is comparing to other
3812 Americans and other states, not the world.

3813 I would like to submit that article for the record.

3814 This wasn't an aberration. It was captured in a moment
3815 in time on January 14th. The CDC was reporting that total
3816 allocations to Texas were 7,602 doses for 100,000
3817 individuals. On that day to the national allocation to the
3818 states was 9,339 per 100,000 individuals. Fast forward to
3819 March 12th, where reporting shows that Texas was allocated
3820 37,000 per 100,000 individuals, compared to the national
3821 average of just under 42,000 doses per 100,000 individuals.

3822 So the Administration set out to allocate the most basic
3823 metric out there with population, but even a population-based
3824 formula will still have variances, and that is why my bill
3825 would require HHS to make their methodology public. I would
3826 love to see this committee continue a robust debate on how to
3827 prepare for pandemics. And I do think this bill will ensure
3828 that allocation transparency should be standard practice in
3829 the future.

3830 In addition, I am submitting for the record my letter to
3831 the GAO, asking them to investigate allocations, as well as a

3832 bipartisan Texas delegation letter to the CDC on this issue,
3833 as well.

3834 Thank you, Madam Chair. I will yield back the remainder
3835 of my time.

3836 *Ms. Eshoo. The gentlemen yields back. It is a
3837 pleasure to recognize our resident pediatrician, whose name
3838 has been mentioned many times today by our witnesses.

3839 Dr. Schrier from the State of Washington, you have five
3840 minutes for your questions, and thank you for your great
3841 work.

3842 *Ms. Schrier. Thank you, Madam Chair, and thank you for
3843 those kind words. Thank you to all the witnesses who came to
3844 speak today.

3845 Yes, as both a pediatrician and a mom, I have been
3846 carefully watching the development and approval process for
3847 COVID vaccines in children, and also worrying about the drop
3848 in routine childhood immunizations during this pandemic. And
3849 this has been most dramatic in the tweens and the teens, many
3850 of whom are now missing the shots that protect them from
3851 pertussis, which is highly contagious, and HPV. So a big
3852 thank you, first, to my colleagues, and to you, Dr.
3853 Maldonado, for your support of the Strengthening the Vaccines
3854 for Children Program Act.

3855 We just saw updated data from the CDC that, although
3856 immunization rates are improving, they still haven't sped up

3857 sufficiently to achieve catch-up coverage. And since more
3858 than half of childhood vaccines are given through the VFC
3859 program, shoring up this already efficient program is
3860 critical, as we have all heard, to making sure all children
3861 get caught up on their shots.

3862 Also, given the drop in middle and high school
3863 vaccination rates, again, where it is most pronounced, I was
3864 really happy to see the CDC recommend that tweens and teens
3865 can get their COVID-19 shots together with their routine
3866 immunizations. It is absolutely the most expedient way of
3867 catching them up, and getting it all done at their next
3868 doctor's visit.

3869 Dr. Maldonado, I trained at Packard Children's, and it
3870 was exciting that you are studying COVID vaccines in younger
3871 children there. And I have been following the discussion
3872 about -- and even Dr. Burgess talked about this -- kind of
3873 how you weigh the risks and benefits of the COVID vaccines in
3874 younger kids, particularly as community spread of the
3875 disease, hopefully, continues to drop.

3876 With current rates of disease, my assessment is that the
3877 risk of the disease, whether it is the acute, or the multi-
3878 system inflammatory syndrome, or long COVID, far outweigh the
3879 remote risk of mild myocarditis that might be associated with
3880 the second dose of an mRNA vaccine. That calculation could
3881 change, though, if vaccinations -- if circulating levels of

3882 disease continue to drop. And so I was wondering if you
3883 could just talk about that balance, and how you view that.

3884 *Dr. Maldonado. Well, absolutely. And thank you,
3885 Representative Schrier, for all of the work you have done.
3886 And we recall your work, here at Packard, of course.

3887 So I have been involved with the vaccine efforts from
3888 the beginning. And we have been part of the ACIP and FDA
3889 meetings from the very beginning of the pandemic, as well,
3890 and we have been following the data. And I think the issue
3891 is, as you mentioned, always a risk benefit calculation. My
3892 sense is, as I mentioned earlier, that COVID is going to be -
3893 - continue to be a major risk for children, even more than
3894 the vaccine could be, given how safe and effective these
3895 vaccines have been, given, as you have heard, that millions
3896 and millions of doses have been given with minimal safety
3897 signals. And in children we have seen the signal of
3898 potential for myocarditis.

3899 At this time it looks like, at the at the moment -- and
3900 we will see an update from the ACIP on Friday -- it looks
3901 like it is a signal of about 16 cases per million doses of
3902 vaccine given. So if, in fact, it is associated -- and we
3903 don't know that yet, but if it is, the risk is extremely low.
3904 Not to undermine that at all, but when you consider how many
3905 children have been hospitalized and died from COVID itself,
3906 and if you consider what may be happening with the Delta

3907 variant, and the fact that the Delta variant has now been
3908 shown to actually increase the risk of hospitalization for
3909 people -- in adults, obviously -- we don't know the impact in
3910 unvaccinated children, because we won't have vaccines for
3911 kids under five for at least the end -- through the end of
3912 the fall, maybe even the winter.

3913 I do think that the risk benefit needs to be looked at
3914 very carefully. I would have full confidence in the FDA and
3915 the CDC in helping us calculate those risks, but continue to
3916 think that those will be low, and we did write a commentary
3917 on --

3918 *Ms. Schrier. Dr. Maldonado -

3919 *Dr. Maldonado. -- just a couple weeks ago.

3920 *Ms. Schrier. -- I have just quick, yes-or-no questions
3921 for you, because, doctor to doctor, I have been seeing a lot
3922 of rumors about vaccines, and I wondered if you could help me
3923 dispel some myths.

3924 One, do mRNA vaccines change your DNA?

3925 *Dr. Maldonado. Absolutely not.

3926 *Ms. Schrier. Does the mRNA vaccine even enter your
3927 nucleus?

3928 *Dr. Maldonado. No.

3929 *Ms. Schrier. Does taking the COVID vaccine make you
3930 magnetic?

3931 *Dr. Maldonado. No, not that I am aware of, but I would

3932 heartily say no.

3933 *Ms. Schrier. Will the COVID vaccine insert some sort
3934 of a microchip into your body?

3935 *Dr. Maldonado. No, no.

3936 *Ms. Schrier. Does the COVID vaccine decrease
3937 fertility?

3938 *Dr. Maldonado. No.

3939 *Ms. Schrier. Now, do any of the vaccines we give today
3940 have long-term effects, other than long-term protection from
3941 disease?

3942 *Dr. Maldonado. We are not seeing that signal. Of
3943 course, we don't have long-term data yet, but absolutely no
3944 long-term effects.

3945 *Ms. Schrier. Great. So I had no hesitation about
3946 getting my 12-year-old vaccinated. We are looking at a
3947 really fun summer, with sleepovers and summer camp. And
3948 thank you for all the work that you do.

3949 *Dr. Maldonado. Thank you, as well.

3950 *Ms. Schrier. Wonderful yes-no series of questions, and
3951 thank you.

3952 It is a pleasure to recognize the gentlewoman from
3953 Massachusetts, Mrs. Trahan, a terrific, new member of our
3954 committee.

3955 You are recognized for five minutes.

3956 *Mrs. Trahan. Well, thank you, Madam Chair, and thank

3957 you to the witnesses here today.

3958 It has recently been reported that there is not one
3959 community in the State of Massachusetts that is in the red
3960 zone. And that is a huge milestone for the state, as we
3961 continue to build back better. However, even in highly-
3962 vaccinated states, like Massachusetts, our job is not done.

3963 Dr. Ashish Jha, a physician and health policy
3964 researcher, and dean at Brown University, recently referred
3965 to Massachusetts as, "a tale of two cities when it comes to
3966 inoculation rates in the state's more affluent communities
3967 versus rates in historically underserved communities.'" And
3968 these disparities present themselves in my district, and are
3969 reflected in states across our country, and are clearly
3970 driven by education levels, income, and race, and are all
3971 related to access.

3972 Lawrence, Massachusetts is a gateway city in my
3973 district, where 80 percent of the city's residents are
3974 Hispanic or Latino descent, and 20 percent of the residents
3975 live at or below the poverty line. And throughout the
3976 pandemic, Lawrence has had to get really creative in their
3977 vaccination efforts. In March, Lawrence General Hospital
3978 launched a mobile vaccine program in an effort to bring
3979 vaccines directly to their residents. And this past weekend
3980 the city held a vaccine block party, with access to walk-up
3981 vaccines, music, free food, and family activities. One

3982 hundred and fifteen individuals received their first dose at
3983 this event.

3984 But despite all these efforts, inoculation rates in
3985 Lawrence are still trailing inoculation rates in other, more
3986 affluent communities across the state, a telling sign of the
3987 -- various cities like Lawrence still face.

3988 So, Dr. Tan, although Lawrence has taken creative steps
3989 in vaccine efforts to reach the most people, city officials
3990 have discussed with me and my team that having the mobile
3991 units and physical vaccines is one thing, but they still lack
3992 the appropriate resources for outreach, and education, and
3993 public health infrastructure to continuously put on
3994 vaccination events like the one they held this past weekend.
3995 Can you speak to how investments in a public health workforce
3996 and public health infrastructure in gateway cities like
3997 Lawrence is essential to getting through this pandemic, and
3998 preventing a future one from occurring?

3999 *Dr. Tan. Oh, thank you so much for that question. And
4000 absolutely, I think in these gateway cities like Lawrence,
4001 that you are talking about, I think it is absolutely
4002 essential that we have a very strong public health department
4003 that is able to drive some of these -- and sustain is the
4004 critical word -- some of these innovative practices into the
4005 community.

4006 I don't think it is a one-time intervention. I don't

4007 think you can just drive a mobile van into a community and be
4008 done. I think it requires multiple efforts. So I think any
4009 kind of resources that we can give to these local public
4010 health departments to sustain some of these efforts is
4011 critical to maintaining this.

4012 And I build upon what we said earlier, and this idea
4013 that, once we do this, we are preparing ourselves for future
4014 immunization efforts, and also for future pandemics, heaven
4015 forbid, should they show up again. So I think, absolutely,
4016 that is an important thing to think about.

4017 The public health infrastructure -- I think Dr. Anne
4018 Schuchat in a New York Times piece said recently this was
4019 always the little engine that could, until COVID happened,
4020 then it was the little engine that couldn't anymore. I think
4021 we need to make sure that this little engine is no longer a
4022 little engine, but a big engine that can deliver all these
4023 lifesaving vaccines to -- across the lifespan to our public.
4024 So thank you for the question.

4025 *Mrs. Trahan. Oh, and thank you for the response.

4026 You know, certainly another group I want to make sure is
4027 adequately covered -- and always is with Dr. Schrier on the
4028 committee -- is our children and adolescents. You know, my
4029 own 7 and 11-year-old daughters are too young to get
4030 vaccinated at this time. However, we too are counting down
4031 the days until they are each able to get their COVID-19

4032 vaccines.

4033 Due to the COVID-19 pandemic, routine vaccination rates,
4034 as well as pediatric visits, have declined. And with school
4035 starting back up in just a few short months, the last thing
4036 we need coming out of the pandemic is an outbreak of another
4037 preventable virus. According to CDC, after initially
4038 decreasing in early 2021, adolescent hospitalization rates
4039 for COVID-19 increased during March and April. So clearly,
4040 children are not immune to the serious effects of the
4041 coronavirus.

4042 So, Dr. Maldonado, as we get more creative in the way we
4043 are reaching folks with vaccinations, can you speak to the
4044 role that pediatricians and family physicians can play in
4045 educating families, boosting vaccine confidence, and reaching
4046 our children with vaccines?

4047 *Dr. Maldonado. Well, as you probably know -- thank you
4048 so much for this question, but, as you probably know, when
4049 polled, it turns out that families trust their providers,
4050 their pediatric providers, almost more than any other person
4051 in their community. Pediatricians are really bonded
4052 together, in terms of keeping children's health at the
4053 forefront.

4054 The American Academy of Pediatrics provides resources
4055 free to all providers. They actually provide resources on
4056 their website to families, toolkits, information, webinars.

4057 It is a constant supply of information. Pediatricians are
4058 extremely responsive to what the Academy does for them, and
4059 they have full confidence in that information.

4060 And of course, we work with CDC and FDA and other
4061 partners to make sure that our information that we get from
4062 them is accurate, and that we give them our concerns, as
4063 well.

4064 So keeping the pediatricians engaged, and keeping them
4065 enrolled, for example, with VFC, and getting them to provide
4066 as many vaccines to as many children as possible, is not only
4067 a good way to prevent diseases, but also, as I mentioned
4068 earlier, to make sure that they can address other
4069 noninfectious issues that arise in these troubling times,
4070 when children have had -- suffered social, developmental, and
4071 mental health issues as a result of the pandemic.

4072 So thank you for that question.

4073 *Mrs. Trahan. Thank you, Doctor.

4074 I am sorry for going over my time, Madam Chair. I yield
4075 back.

4076 *Ms. Eshoo. You are welcome. It is a pleasure to
4077 recognize yet another one of our terrific doctors on our
4078 committee, the gentleman from California, Dr. Raul Ruiz.

4079 You are -- you have five minutes for your questions.

4080 *Mr. Ruiz. Thank you, Madam Chair. I am so proud that
4081 equitable access to COVID testing and vaccines have been

4082 highlighted by this committee throughout the duration of this
4083 pandemic.

4084 And I must say that this is a very good set of vaccine
4085 equity bills that we are putting forward. In particular, the
4086 bills by our very own pediatrician, Representative Schrier,
4087 Representative Kuster, Representative Barragan, and
4088 Representative Soto, those bills, in particular, will go a
4089 long way in reducing health care disparities in our nation.

4090 When the first vaccines became available, there was
4091 concern that Black and Hispanic individuals would have
4092 greater amounts of vaccine hesitancy than White individuals.
4093 But that is not what I am seeing on the ground. I have gone
4094 into the hardest-hit, hardest-to-reach Hispanic farm worker
4095 communities in my district to administer the vaccine, and I
4096 have heard their stories. The problem is not hesitancy; it
4097 is access. It is not about whether someone wants to get the
4098 vaccine; it is whether there are barriers preventing them
4099 from doing so.

4100 And I applaud the work of the Biden Administration to
4101 give vaccines to -- into the underserved areas of our
4102 communities through programs like direct distribution to
4103 retail pharmacies and FQHCs. It has made an enormous impact.
4104 And I know, firsthand, after organizing retail pharmacy
4105 mobile clinics, taking vaccines to the people in my district.

4106 The thing is, many of my constituents do not have a car,

4107 with limited access to public transportation. So, for many
4108 of my constituents, even getting to a pharmacy five miles
4109 away is difficult, as many cannot afford to take a lot of
4110 time off of work to get to a vaccination site.

4111 So today I want to talk about H.R. 3013, the COVID
4112 Vaccine Transportation Access Act, which authorizes grants to
4113 communities to provide transportation to vaccination sites.
4114 The bill was introduced by congressional Hispanic Caucus
4115 member Congresswoman Barragan, and I was proud to join her as
4116 one of the lead sponsors.

4117 Dr. Maldonado, can you address this issue, and talk
4118 about the importance of removing last-minute barriers like
4119 the lack of transportation?

4120 *Dr. Maldonado. Thank you, Representative Ruiz, for
4121 that question.

4122 I, too, helped organize some of the first testing sites
4123 here, in our Santa Clara County area, for our federally-
4124 qualified health centers, as well as setting up vaccination
4125 sites and testing sites for some of our migrant farm worker
4126 camps in the area. So I know how important this work was,
4127 early on, in getting people vaccinated, and making them aware
4128 of this disease. So I do think that it is a really important
4129 issue. We need to really underscore the importance of
4130 getting access to our population.

4131 The other thing that I noted, when I was taking care of

4132 patients, we have now since shut down our tents. They are
4133 bringing our patients in to clinics. But initially, it was
4134 impossible to find transportation for sick people to come in,
4135 because of COVID restrictions. And especially for those who
4136 didn't have access to their own cars, we almost could not
4137 bring people in for treatment. It is a critical issue for
4138 children, as well as for adults. And the issue of equity is
4139 critical for all of us, not just for those populations,
4140 because, as long as this virus circulates anywhere in our
4141 communities, anywhere in the world, it will affect each and
4142 every one of us.

4143 So I absolutely agree that bringing equity to this issue
4144 is so important to keeping the entire world healthy and safe.
4145 And --

4146 *Mr. Ruiz. Thank you --

4147 *Dr. Maldonado. I can't overscore that -- underscore
4148 that issue. Thank you so much -

4149 *Mr. Ruiz. Thank you. Right now, our focus is on the
4150 critical issue of COVID-19 and vaccinations. But let's look
4151 beyond this immediate crisis, and take some of the lessons we
4152 have learned from it, and apply that to the future for all
4153 vaccines. Routine vaccinations are also critical for our
4154 public health, and these same barriers that exist for COVID
4155 vaccine access will continue to exist after the public health
4156 crisis is over.

4157 Dr. Maldonado, as a pediatrician, can you address the
4158 importance of access to routine vaccines for children, in
4159 particular, and how a grant program like this with
4160 transportation could help reduce those barriers?

4161 *Dr. Maldonado. Absolutely. Transportation is an
4162 important piece of all of the puzzle pieces that it takes to
4163 keep children healthy and safe.

4164 And again, here at Packard Children's, we do have vans.
4165 We have access to vans that can go and transport children in
4166 and out, if we need them. But not everybody has that
4167 ability -

4168 *Mr. Ruiz. Thank you.

4169 *Dr. Maldonado. -- to schedule a van, and we -- it is
4170 critically important.

4171 *Mr. Ruiz. Thank you. Well, as a student and an
4172 advocate for health equity to reduce disparities, my --
4173 almost my entire life, I am so enthusiastically waiting to
4174 vote these bills out of committee, and send them to the House
4175 floor to make a lasting difference, once and for all.

4176 Thank you, I yield back,

4177 *Ms. Eshoo. The gentleman yields back.

4178 Thank you, Dr. Maldonado, for raising the issue of the
4179 farm workers. Most people don't think, or wouldn't even
4180 guess, that we have farm workers as part of the Silicon
4181 Valley district that I represent. And yet they are there,

4182 and that they have your care is a great, great blessing.

4183 And speaking of blessings, the gentlewoman from
4184 California, Ms. Barragan, is recognized for your five minutes
4185 of questions.

4186 *Ms. Barragan. Thank you, Chair Eshoo, for holding this
4187 important hearing, and including my bill, the COVID Vaccine
4188 Transportation Access Act, in the discussion.

4189 I also want to thank my committee colleagues,
4190 Representatives Cardenas, Clarke, Ruiz, and Soto, for
4191 cosponsoring this legislation.

4192 Our bill will create a grant program in HHS to remove
4193 transportation barriers in underserved communities, so people
4194 can not only get to COVID vaccine appointments, but also
4195 future access for -- appointments for boosters. This will
4196 help reduce disparities in access to care.

4197 Vaccinations are how we will finally defeat this
4198 pandemic. However, I have heard from many people in my
4199 district who want to get their COVID shots, but don't have an
4200 easy way to get to the sites. One man told me about having
4201 to take three buses, and travel for hours to get his vaccine.
4202 It is common sense. Removing barriers that prevent people
4203 getting to and from vaccine sites will increase the number of
4204 people who can get vaccinated.

4205 We have spoken about this a little bit, but Dr. Tan, can
4206 you discuss the continued need to provide underserved

4207 communities with help to get to and from vaccination
4208 appointments?

4209 Also, do you believe it is important to continue
4210 providing resources to these communities, beyond what
4211 Congress has already allocated, so that people in these
4212 communities are able to access COVID vaccine boosters --
4213 shots, as they become available?

4214 *Dr. Tan. Oh, yes, absolutely. And I think, you know,
4215 beyond the communities of color that you have discussed, and
4216 the communities of low socioeconomic status, I want to add
4217 older adults to that list, as well. I think we all know that
4218 transportation to a COVID-19 vaccination clinic can be
4219 challenging for those communities that we discussed.

4220 In particular, I think you want to think about issues
4221 that face these patients, such as, you know, do they -- if
4222 you are older and vulnerable, do you want to be getting into,
4223 let's say, you know, Uber or Lyft van with someone who may
4224 not necessarily be protected?

4225 And I think finding alternative ways to get COVID-19
4226 vaccination sites, the patients -- to get patients to these
4227 COVID-19 vaccination sites is incredibly important. So I
4228 actually agree with you that, if we can provide
4229 transportation solutions, we will also improve immunization
4230 coverage rates.

4231 *Ms. Barragan. Thank you, Doctor. This next question

4232 is for you, as well.

4233 A recent report from the CDC released on May 28 found
4234 that, despite our best efforts, there are growing disparities
4235 in terms of COVID vaccination rates between communities that
4236 are affluent and those that are low-income, and communities
4237 of color. Thus, communities that are more likely to be
4238 enrolled in the Medicaid are not achieving adequate
4239 vaccination levels, even through Medicaid, even though
4240 Medicaid covers the vaccine, its administration, and is the
4241 only publicly-financed health insurance that guarantees non-
4242 emergency medical transportation to the vaccine site.

4243 Due to these disparities, wouldn't it make sense to
4244 incentivize states to remove barriers to non-emergency
4245 medical transportation, and affirmatively reach out to
4246 Medicaid patients to schedule and transport them to a
4247 vaccination site, by enhancing the Federal match rate to 100
4248 percent for transportation to the vaccine site, as we have in
4249 the American Rescue Plan for Medicaid vaccine purchase and
4250 administration?

4251 *Dr. Tan. So, yes. I think one of the things that we
4252 have always talked about is how do we get patients who are of
4253 lower socioeconomic status into vaccination access points.

4254 I think one of the challenges we face with that is,
4255 actually, not necessarily a transportation issue. So I think
4256 we need to look bigger than just transportation. We need to

4257 look at this idea that, with lower socioeconomic status
4258 families, it is also about time and resources. You know, who
4259 is going to take care of my child, if I have to go in and get
4260 vaccinated?

4261 So I think transportation is, indeed, one very important
4262 component, but I think it is one component of a bundle of
4263 challenges that we face with these populations in order to
4264 get them into vaccination clinics, even if the vaccine is
4265 free, even if the administration fee is -- there is no copay.
4266 I think we need to think and recognize that there are more
4267 broader challenges, of which transportation is indeed one of
4268 them.

4269 *Ms. Barragan. Thank you very much for that, and for
4270 all of our panel today. It is important that we continue to
4271 work on ways to reduce the disparities, and removing the
4272 barriers, including transportation.

4273 So thank you for having this hearing. And with that,
4274 Madam Chairwoman, I yield back.

4275 *Ms. Eshoo. The gentlewoman yields back, and we thank
4276 her for her important work.

4277 Last, but not least, the gentleman from Georgia, the
4278 pharmacist on the committee.

4279 You are recognized --

4280 *Mr. Carter. Thank you, Madam Chair. I appreciate the
4281 opportunity. I appreciate all the panelists. This has been

4282 a good hearing --

4283 *Ms. Eshoo. You are not in your car.

4284 *Mr. Carter. I am not in my car. I am not, thank
4285 goodness.

4286 First of all, let me say that, you know, the
4287 Administration has supported waiving the World Trade
4288 Organization's trade-related aspects of intellectual property
4289 rights. And that is very concerning to me. My fear is that
4290 the Administration lacks the understanding of this complex
4291 science, and goes into biopharmaceutical innovation, or the
4292 economics, and -- encourage private investment in new biotech
4293 products and vaccines.

4294 As a practicing pharmacist for over 30 years, I have
4295 seen what has gone into research and development. And I know
4296 how important intellectual property is to companies. And
4297 this really concerns me, that the Administration is proposing
4298 to give the intellectual property of the vaccine to China --
4299 China, who -- we know that this virus originated in China.

4300 My question to you, Ms. Arthur, do you agree that a
4301 TRIPS waiver for COVID vaccines would discourage innovation
4302 and future investment in new cures and vaccines?

4303 *Ms. Arthur. I do agree that this is not the right
4304 solution for bringing more doses to more people around the
4305 world. It would actually hinder the ability for companies to
4306 safely partner outside of the country with these new

4307 technologies. And it could also hinder companies'
4308 willingness to respond to the next pandemic, with all the
4309 great innovations that we have been working on.

4310 *Mr. Carter. I couldn't agree with you more, Ms.
4311 Arthur.

4312 I mean, you know, the fact that these pharmaceutical
4313 manufacturers -- and I know we talk about the price of
4314 pharmaceuticals being too high, I get that, and I happen to
4315 have the belief that it is -- that a lot of the problem, most
4316 of the problem, is with the middlemen, with the PBMs, the
4317 pharmacy benefit managers, who are bringing no value
4318 whatsoever to the healthcare system, but are responsible for
4319 what has been estimated to be 47 percent of the cost of
4320 medications.

4321 But in order for these pharmaceutical manufacturers to
4322 continue to invest in research and development, they need to
4323 know that their intellectual property is going to be safe. I
4324 mean, we have had 200 years of a patent system here in
4325 America that has worked, and has led to nothing short of
4326 miracles in the way of drug development. And certainly, what
4327 we have witnessed here with the vaccine, I think, will go
4328 down -- and Operation Warp Speed will go down as being one of
4329 the great medical achievements of our generation. And for us
4330 to even consider -- or for this Administration, I say, I
4331 should say -- to consider to give the intellectual property

4332 away, that is just insane, to me.

4333 Ms. Arthur, what would be a better way for us to be able
4334 to get that -- the vaccines to people who need it?

4335 I am okay sharing it. I am okay sharing. As long as
4336 Americans are taken care of first, we have access, then I am
4337 okay with that. What do you think would be the best way, Ms.
4338 Arthur?

4339 *Ms. Arthur. So I think, first, we applaud the
4340 Administration for doing one of the things we absolutely
4341 suggested, which was starting to donate. You just brought
4342 this up, Mr. Carter. And I think donating doses has been
4343 pivotal, particularly as we try to wait for the resolution of
4344 the crisis in India, which actually hampered some of the
4345 production that companies counted on to deliver doses to low
4346 and middle-income countries. So we have to recognize this is
4347 a global system. And the more we can have high-income
4348 countries support donations of their doses to COVAX and other
4349 countries, the better off will be.

4350 And in the interim, the other thing we can do is
4351 absolutely get a free flow of goods, get the supplies we
4352 need, and manufacture doses both here and America and abroad,
4353 through the great partnerships that are already happening in
4354 manufacturing. There is -- over 250 partnerships that
4355 industries entered into with developing-country manufacturers
4356 all over the world to deliver doses as quickly as we can.

4357 And they are projected to make about 11 billion doses this
4358 year. That, coupled with the great donations promised by the
4359 G7 this week, should really help to get more doses to more
4360 people as soon as we can.

4361 *Mr. Carter. And thank you for mentioning that. The
4362 obvious solution is to ramp up production here, in the United
4363 States. That is the quickest way we can get it out there.
4364 It saves American jobs. It makes all the sense in the world
4365 to me. So thank you for bringing that up.

4366 Very quickly, Dr. Tan, I wanted to ask you -- health
4367 savings accounts, they include vaccines as a reimbursable
4368 expense, and commercial insurance plans also cover --

4369 [Audio malfunction.]

4370 *Voice. I am sorry --

4371 *Mr. Carter. -- how high deductible health plans,
4372 coupled with health savings accounts, encourage and cover
4373 vaccines, and how we can apply those lessons to public
4374 programs like Medicare?

4375 *Dr. Tan. I am so sorry, Representative Carter, I think
4376 you cut out on me a couple of times, so I didn't catch your
4377 whole question. I heard something about health spending
4378 accounts.

4379 *Mr. Carter. Yes, commercial and private plans that are
4380 covering vaccines, and in combination with health savings
4381 accounts, don't you -- I just wanted you to speak to how

4382 high-deductible health plans, when they are coupled with
4383 health savings accounts, and how they can encourage and cover
4384 vaccines.

4385 *Dr. Tan. I think that is certainly a wonderful option
4386 for those who have those accounts. I think we are -- we also
4387 have to be aware that, you know, the access to those kind of
4388 accounts are not available to a lot of adults who are
4389 vulnerable to vaccine-preventable diseases. And so part of
4390 the great -- the greatness of these two bills that we are
4391 looking at, you know, the Seniors Act, as well as HAPI, is to
4392 try to actually remove those -- the payment that is required
4393 there.

4394 I think, even with health service -- HSAs, as well as
4395 high-deductible plans, there is, obviously, that initial
4396 copayment. And unfortunately, a lot of times, what happens
4397 then, again, as we have discussed many times, you know, even
4398 someone who is on those plans may not see that as the best
4399 investment of their copay dollars, if you get what I mean.

4400 So I think this is about equalizing it across, for all
4401 adults.

4402 *Mr. Carter. Great. Well, I am over, Madam Chair,
4403 thank you for your indulgence, and thank all the panel for
4404 your testimony today, as well.

4405 Thank you, and I will yield back.

4406 *Ms. Eshoo. The gentlemen yields back.

4407 I want to pay all the tribute that I possibly can to our
4408 witnesses today. You have been -- you spent early morning,
4409 mid-morning, late morning, early afternoon, now almost mid-
4410 afternoon with us. So you have missed at least a couple of
4411 meals.

4412 But you have really advanced and broadened the case,
4413 relative to vaccines, whether it is for adults, whether it is
4414 for younger people or children, where are -- the shortcomings
4415 are in our country, how we maintain innovation, but address
4416 the issues where there are shortcomings. I think this has
4417 just been a superb hearing, and it was because of you.

4418 And you gave us wonderful validation of the legislation,
4419 because today's hearing was a legislative hearing. And so
4420 you gave us excellent input on the legislation that we are
4421 considering. So on behalf of every member of the Health
4422 Subcommittee, I salute you, and I thank you for your work.
4423 It really is your life's work, and our country is better
4424 because of you. And I couldn't mean that more. You are a
4425 blessing to our country, a true blessing to our country, so
4426 thank you. Thank you. Thank you. Thank you.

4427 And I know that you will respond to the questions that
4428 members submit to you in writing. Many of them made
4429 reference to that. And if you can do so in as timely a
4430 manner as possible, we will all be better for that.

4431

4432 [The information follows:]

4433

4434 *****COMMITTEE INSERT*****

4435

4436 *Ms. Eshoo. So thank you to each one of you. Dr. Tan,
4437 Dr. Maldonado -- I am just bursting with pride, I mean it,
4438 because she is my constituent. They are all so wonderful.
4439 But of course, we always have a special sense of pride when
4440 someone is testifying that we represent. And Ms. Coyle and
4441 Ms. Arthur, just A-plus, A-triple-plus. Gold stars. I am
4442 trying to think of what the nuns would always put on my
4443 papers if I did well. You deserve it all. So thank you to
4444 you, really. You moved the needle today. You moved the
4445 needle today.

4446 And now I have a unanimous consent request. To my
4447 friend, our wonderful ranking member, we have 10 documents,
4448 Mr. Guthrie. And there isn't anything in here that is, I
4449 don't think, objectionable. And we just handwrote some in
4450 that Mr. Crenshaw gave to us. So if you would like me to
4451 read them all out, I would be glad to, but --

4452 *Mr. Guthrie. There is no need to read. And I don't --
4453 we do not object.

4454 And I just want to echo what you said to our witnesses.
4455 And the vaccines is certainly an example. Operation Warp
4456 Speed was Congress working together with the Administration,
4457 both administrations, as we have switched administrations.
4458 And so when we work together, we do big things. So thank
4459 you, and thanks for our witnesses for being here.

4460 *Ms. Eshoo. And thank you for being such a wonderful

4461 partner.

4462 For the members that are still on board -- maybe they
4463 are all gone -- I want the members of the subcommittee to
4464 know that I am doing everything I possibly can to take up as
4465 many bipartisan bills in our subcommittee. Mr. Pallone is
4466 probably long gone from the hearing, but he can attest to the
4467 fact that I, during this period of time that we were at home,
4468 I would call him every single day, with the exception of
4469 Saturdays and Sundays, I gave him a break. But otherwise, I
4470 was like gum stuck to his shoe to move these things.

4471 So we are doing everything -- I am doing everything I
4472 can to take up as many bills as possible. Members, I think,
4473 deserve that kind of consideration of their bills.
4474 Certainly, the American people deserve the results of these
4475 of these bills, legislation that then becomes law, and the
4476 words walk right into their lives, into their daily lives.

4477 So thank you to all of the members for your marvelous
4478 questions and participation. And again, to the witnesses,
4479 absolutely superb and outstanding. And on behalf of all of
4480 the members, I once again thank you.

4481 So having -- you have -- members, of course, have 10
4482 days to submit additional questions for the record. And I
4483 have already asked the witnesses to respond as promptly as
4484 possible when they receive them.

4485 And without anything else here on my desk, I thank the

4486 -- do I have something to hit my desk with here? My cup on
4487 the desk, how is that?

4488 The subcommittee will now adjourn, thank you.

4489 [Whereupon, at 2:23 p.m., the subcommittee was
4490 adjourned.]