

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

1 Diversified Reporting Services, Inc.

2 RPTS EUELL

3 HIF333140

4

5

6 UNDERSTANDING HOW AI IS CHANGING HEALTH CARE

7 WEDNESDAY, NOVEMBER 29, 2023

8 House of Representatives,

9 Subcommittee on Health,

10 Committee on Energy and Commerce,

11 Washington, D.C.

12

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

14 in Room 2322 Rayburn House Office Building, Hon. Brett

15 Guthrie [chairman of the subcommittee] presiding.

16

17 Present: Representatives Guthrie, Burgess, Latta,

18 Griffith, Bilirakis, Johnson, Bucshon, Hudson, Carter, Dunn,

19 Pence, Crenshaw, Joyce, Harshbarger, Miller-Meeks, Obernolte,

20 Rodgers (ex officio); Eshoo, Cardenas, Ruiz, Dingell, Kuster,

21 Kelly, Barragan, Craig, Schrier, Trahan, and Pallone (ex

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

22 officio).

23

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

24 Staff present: Sean Brebbia, Chief Counsel; Jolie
25 Brochin, Clerk; Abigail Carroll, Detaille, FDA; Corey
26 Ensslin, Senior Policy Advisor; Kristin Fritsch, Professional
27 Staff Member; Tara Hupman, Chief Counsel; Alex Khlopin, Staff
28 Assistant; Peter Kielty, Member Services Director, Emily
29 King, Members Services Director; Chris Krepich, Press
30 Secretary; Molly Lolli, Counsel; Karli Plucker, Director of
31 Operations (shared staff); Lydia Abma, Minority Policy
32 Analyst; Shana Beavin, Minority Professional Staff Member;
33 Waverly Gordon, Minority Deputy Staff Director and General
34 Counsel; Tiffany Guarascio, Minority Staff Director; Stephen
35 Holland, Minority Senior Health Counsel; Una Lee, Minority
36 Chief Health Counsel; Katarine Morgan, Minority Health
37 Fellow; and Avni Patel, Minority Health Fellow.

38

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

39 *Mr. Guthrie. The subcommittee will come to order, and
40 the chair will recognize himself for an opening statement for
41 five minutes.

42 I will spend my first little bit to say we had news on
43 our ranking member, and we exchanged messages over
44 Thanksgiving weekend, but what a wonderful lady, what a
45 wonderful person, and someone who really puts this committee,
46 this subcommittee, the institution of Congress and _ first
47 and foremost. So we are _ you are going to _ we have another
48 year to work together.

49 *Ms. Eshoo. Thank you. That is right.

50 *Mr. Guthrie. But you are just going to be sorely
51 missed _

52 *Ms. Eshoo. Thank you.

53 *Mr. Guthrie. _ in this committee.

54 [Applause.]

55 *Ms. Eshoo. Thank you. Thank you. Thank you. Thank
56 you. Oh my goodness.

57 [Laughter.]

58 *Ms. Eshoo. Oh, goodness. Look at that. Isn't that
59 lovely. Thanks, Cathy. Thank you.

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

60 *Mr. Guthrie. But we still have a year to get things
61 done _

62 *Ms. Eshoo. That is right.

63 *Mr. Guthrie. _ and we are going to get things done.
64 We're _

65 *Ms. Eshoo. Yeah.

66 *Mr. Guthrie. So I would just like to thank our
67 witnesses and _ for being here today, and you will get a
68 chance to holler _ speak when _ now I got to get my statement
69 in in four minutes, but that is good _ that _ I can do it.

70 [Laughter.]

71 *Voice. Sorry.

72 *Mr. Guthrie. But that was important to do. No, that
73 is perfect. I shouldn't use all my time.

74 So thank you for our witnesses for being here today.
75 This hearing cannot be timelier as our committee, and the
76 Congress as a whole, looks at issues regarding artificial
77 intelligence. It is important that we shine a light
78 specifically on the role that AI could play in solving some
79 of our most significant healthcare problems. These emerging
80 technologies are already changing the way in which clinicians

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

81 care for their patients and how researchers conduct clinical
82 trials.

83 As AI continues to drive innovation in healthcare, it is
84 essential that Congress examine the meaningful benefits that
85 any potential unintended consequences that these technologies
86 could have. The potential benefits from artificial
87 intelligence are seemingly without limit. Future
88 technologies could help our healthcare system save lives by
89 better predicting potential diagnoses and could help us
90 reduce redundancies in our system.

91 We have already seen this play out in real time over the
92 past several years and have watched unimaginable advances in
93 healthcare as a result of generative AI. For example, there
94 are already numerous success stories in using AI for
95 pharmaceutical research and development to get treatments to
96 the market sooner. This was the case in the AI-assisted
97 research by MIT scientists that found the drug Halicin could
98 be used as an effective antibiotic.

99 We now have multi-cancer screening diagnostic tools that
100 use AI to help detect early-stage cancers, and AI is being
101 used in operating rooms to augment existing processes to

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

102 improve patient outcomes.

103 However, this is not to say that we should let the use
104 of these technologies go without guardrails. Over the next
105 several months years _ and years, policymakers and those in
106 the health industry will need to answer some fundamental
107 questions regarding the role AI will play in our healthcare
108 system, including are the technologies trained with
109 supervised AI using human-generated inputs to drive outcomes,
110 are these technologies trained with unsupervised AI, this
111 generating outcome is based off human behavior to ease
112 everyday decision making for healthcare consumers, or are
113 these technologies trained with reinforced AI which humans
114 are rewarding the systems for the outputs generated.

115 Those are very complex and difficult things that we have
116 to explore as we move forward. And in each of the _ these
117 use cases it is important to remember that every decision
118 comes with a cost, both human and financial. Wearable
119 devices that are constantly monitoring someone's heart rate,
120 caloric intake and outtake, and sleep patterns in addition to
121 other metrics can help lead to healthier lifestyles and in
122 some cases to predicting extreme cardiac event or even

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

123 strokes.

124 In the event of using user data to predict better
125 lifestyle habits, how are we ensuring this data is secure and
126 ensuring that consumers has full control over this
127 information and it is not being used or sold without their
128 consent. In the event of predicting a major health event,
129 are there protocols that should be considered to ensure
130 individuals aren't taking unnecessary trips to the emergency
131 room and potentially incurring significant healthcare debt as
132 a result.

133 In closing, I support the real possibilities AI can
134 bring to our healthcare system and in most _ and most
135 importantly to patients. We should give the technology the
136 license to coexist alongside clinicians, patients, and
137 innovators as well as regulators while also remaining
138 vigilant of how this technology is being used.

139 I look forward to the discussion today.

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

141

142 *****COMMITTEE INSERT*****

143

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

144 *Mr. Guthrie. And I will yield back. And to continue
145 my praise for the ranking member, I will recognize the
146 gentlewoman from California, and as I said, we have a year to
147 work together, and when you were chair and I was ranking
148 member, you treated with me most respect, and I really
149 appreciate in the areas where we don't _ didn't agree, you
150 challenged my thinking sometimes, and sometimes we had to
151 move forward in different, sometimes we couldn't, but it was
152 always with the utmost respect.

153 *Ms. Eshoo. Thank you.

154 *Mr. Guthrie. So with that, I will recognize the
155 ranking member for five minutes for her opening statement.

156 *Ms. Eshoo. Well, thank you very much, Mr. Chairman.
157 Your words mean a great deal to me, and I am deeply moved and
158 touched by the expression of all of the members of this
159 subcommittee. You know how much I love this committee, and
160 we have gotten so many important things done, gotten them
161 over the finish line. Let's optimize our time and _ so that
162 we can continue that tradition. So thank you to each one of
163 you.

164 You are all my friends, my fellow Americans, my fellow

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

165 colleagues, and _ well, there's so much that I want to say.
166 There _ really there aren't words to express how deeply,
167 deeply grateful I am, and the messages that poured in, I just
168 _ I have kept them all and I reread them before I go to sleep
169 at night.

170 [Laughter.]

171 *Ms. Eshoo. And they are really beautiful. It is like
172 falling asleep on this magnificent cloud of good will, so
173 thank you from the bottom of my heart.

174 So here we are to discuss AI and healthcare, and the
175 nexus between the two is really a very, very, very important
176 one. It represents an incredible opportunity for our
177 country, and it has the potential to make our healthcare
178 system more efficient, improve patient experiences, and
179 reduce burdens on physicians.

180 And new ways to use AI in the healthcare setting are
181 consistently in the news. I think all of you see this in
182 your national clips as you read them at the end of every day.
183 New York Times in October of this year, "New AI Tool
184 Diagnoses Brain Tumors on the Operating Table.'" Forbes in
185 August of this year, "AI is a Game Changer for Toughest Areas

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

186 of Drug Discovery.' ' The Wall Street Journal in November of
187 last year, "U.S.-Backed Researchers Use AI to Probe for
188 Weaknesses in Drug Supply Chains.' '

189 And despite this incredible promise, AI, we know and
190 some of the fathers and mothers of AI have instructed us on
191 the potential that AI has to _ at the other part of the
192 spectrum to worsen patient outcomes and exacerbate inequities
193 that we have in our healthcare system if it is not deployed
194 with adequate guardrails.

195 Earlier this month, reports found, and a lawsuit now
196 alleges, that United Health Group, one of the largest
197 insurers in our country, used an AI algorithm to wrongfully
198 deny care to Medicare Advantage beneficiaries. The AI
199 algorithm made decisions about patient care that went against
200 the recommendations of the patient's own physicians. Another
201 example is our Nation's children are being left behind as AI
202 in medical imaging rapidly expands. And to date, there are
203 no computer-aided detection, computer-assisted triage, or
204 computer-aided diagnosis radiology products authorized for
205 pediatric uses.

206 And these pediatric radiologists are working with

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

207 children. You can't experiment on children. So the _ you
208 know, in many _ in many areas the red lights are blinking,
209 and we need to pay attention to that because children are not
210 little adults.

211 I am working on a proposal to address this gap for
212 pediatric patients. And in my view and the view of both
213 Republican and Democratic members of both the House and the
214 Senate have created legislation that would democratize AI.
215 Today the resources, the massive resources are really in the
216 hands of a handful of very large high technology companies,
217 but we have many sectors in our country, and the health
218 sector, the medical sector needs to be a partner in this as
219 well.

220 So this legislation, and I am so proud that there are
221 members of this committee, including Mr. Obernolte, that are
222 original cosponsors of that legislation, and I would urge
223 those of you that are not on it to take a look at it so we
224 can get that over the finish line in this Congress.

225 So I am pleased that the witnesses are here. I am happy
226 to be with each one of you and my colleagues. I think that
227 this committee can lead the effort on AI as it applies to

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

228 healthcare. In fact, we must. I don't think this is, you
229 know, comme-ci comme-ca. It is not on the one hand but on
230 the other hand. We have to rise to this challenge, and I
231 think that we have the capacity to do so.

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

233

234 *****COMMITTEE INSERT*****

235

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

236 *Ms. Eshoo. So thank you, Mr. Chairman, and I yield
237 back.

238 *Mr. Guthrie. Thank you. The gentlelady yields back,
239 and the chair will now recognize the chair of the full
240 committee, Chair Rodgers, for five minutes for an opening
241 statement.

242 *The Chair. Thank you, Mr. Chairman. First, my
243 heartfelt warm wishes to the ranking Democrat, Anna Eshoo.
244 You know, she has been a trailblazer for so many members,
245 including me, and I am grateful for your outstanding
246 leadership and your friendship these years.

247 This is now the fourth hearing that the Energy and
248 Commerce Committee has held across our subcommittees on the
249 subject of artificial intelligence. Artificial intelligence
250 has the potential to transform every aspect of our lives, for
251 better or for worse. It's critical that America, not China,
252 is the one addressing AI's challenges and leading in this
253 technology's development and deployment.

254 The best way to start is by laying the groundwork to
255 protect people's information with a national data privacy
256 standard. This is a foundational first step towards a safe

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

257 and prosperous AI future in healthcare and beyond. I look
258 forward to continuing to discuss how we can improve privacy
259 protections for Americans as we incorporate AI tools into our
260 lives. And I am proud of each of our subcommittee chairs for
261 leading on this important issue.

262 AI has a unique role to play in the future of
263 healthcare. AI could help find the next breakthrough cure or
264 improve our ability to catch deadly diseases earlier, and we
265 are already seeing that artificial intelligence can be used
266 to aid in the assessment of medical imaging, which is one of
267 _ which one of our witnesses will discuss in detail.

268 Additionally, AI is reducing administrative burdens on
269 healthcare providers. We have all heard from providers in
270 our districts about the burden of necessary but cumbersome
271 paperwork, how often this leads to burnout for doctors and
272 nurses, and how it eats up time that they could be spending
273 providing actual patient care.

274 For just about my entire tenure in Congress, one of the
275 top issues that we have struggled with has been finding ways
276 to cut paperwork and redundancy in our healthcare system so
277 that we can let doctors do what doctors do best, treat their

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

278 patients. For years we have nibbled around the edges of this
279 issue, but the future of AI could be transformative and will
280 hopefully let doctors be doctors instead of administration
281 staff. We will hear more Dr. Schlosser from HCA on how this
282 is being tested out in hospitals.

283 To be clear, AI will not solve all of the problems with
284 America's healthcare system. One concern we have been _ we
285 have frequently heard is the potential of human biases to be
286 implicitly baked into AI technologies.

287 The first piece of healthcare legislation that this
288 committee advanced this year was my bill to ban the usage of
289 quality adjusted life years, or QALYs, which are
290 discriminatory measures that are used by federal payors to
291 deny healthcare services to people with disabilities and
292 chronic illnesses. If AI is reliant on QALYs or other
293 similar measures when assisting in clinical decision making,
294 our most vulnerable will be left behind. No one here wants
295 to advocate for discrimination, and we need to be conscious
296 of how federal programs and AI technologies incorporate these
297 types of biases and what we should be thinking about in this
298 area.

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

299 I will close by saying that I am optimistic about these
300 technologies. I think these technologies can make a
301 difference in the lives of patients, and this committee needs
302 to lead the way in supporting innovation. For America to
303 lead, we must strike the right balance with AI, one that
304 gives businesses the flexibility to remain agile as they
305 develop these cutting-edge technologies while also ensuring
306 responsible use.

307 A national standard for the collection and handling of
308 data will provide businesses, healthcare providers, and every
309 American with clear and understandable protections wherever
310 they are. Today's hearing will hopefully shed more light on
311 the current landscape of AI in healthcare and hopefully
312 provide us with further insight on the next steps that we
313 should take to support patients.

314 [The prepared statement of the Chair, Mr. Guthrie,
315 follows:]

316

317 *****COMMITTEE INSERT*****

318

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

319 *The Chair. I yield back.

320 *Mr. Guthrie. The gentlelady yields back. The chair
321 will now recognize the gentleman from New Jersey, Ranking
322 Member Pallone, for five minutes for an opening statement.

323 *Mr. Pallone. Thank you, Mr. Chairman. And I want to
324 start out by thanking our two Democratic members of the
325 subcommittee who have announced their retirements at the end
326 of next year. Of course I told them both they should change
327 their minds and they said they don't want to.

328 But let me start with Ranking Member Eshoo who served as
329 the top Democrat on this subcommittee for the last five
330 years, including four years as chair, and she led this
331 subcommittee through the COVID-19 pandemic. She played a
332 critical role in our successful efforts to reauthorize user
333 fees and to create ARPA-H, but that is just in the last
334 session. She has been so much involved in all healthcare
335 issues on this committee for a long time.

336 But I also think a lot of you don't know that I have
337 worked with Anna even before the Energy and Commerce
338 Committee, and she has played a critical role outside of the
339 committee in many ways, particularly with Armenian causes.

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

340 If it was not for Anna, the House would never have recognized
341 the Armenian genocide, which was such an important thing in
342 the history of Armenians that that happened and that we did
343 that. So thank you, Anna.

344 And then Tony _ I have to say Tony Cardenas has been a
345 long-time leader on this subcommittee. He has also served as
346 the vice chair of our Consumer Protection and Commerce
347 Subcommittee for four years. He has led several of our key
348 efforts to put consumers first, including a new law that
349 protects babies from dangerous sleeping products.

350 But again, you know, I want to emphasize Tony's role
351 outside of the Energy and Commerce Committee with the
352 Hispanic Caucus, with Bold Pack. He has just played a
353 tremendous role in promoting not only Latino members but also
354 the issues that are important to the Latino community.

355 So in both cases, in Anna's case as well as Tony's case,
356 what they accomplished here is important for our committee
357 but really goes beyond the committee. So thank you both.
358 But I have to say, we still have another year left, so I want
359 to thank them for their contributions, but there is still
360 more to be done, as they have already said.

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

361 So let me go if I can to the issue that we are dealing
362 with today, and we are exploring how artificial intelligence
363 is changing healthcare now and potentially in the future.
364 This is an important hearing because the integration of AI
365 presents opportunities to enhance patient care and streamline
366 processes to bring more efficiency to the health sector. At
367 the same time, Congress must recognize and address the
368 complex ethical, legal, economic, and social concerns raised
369 by the specter of greater deployment of AI in our healthcare
370 system.

371 As we are going to hear today, access to patient medical
372 data is often central to the use of AI and the delivery of
373 healthcare. As the patient's medical data passes between
374 physicians through these AI products, protecting individual's
375 information and privacy becomes even more important. So I
376 remain concerned that the expanded use of AI in healthcare
377 has generated significant risk. It is critical that
378 safeguards are in place to protect the privacy and security
379 of the patient's data.

380 And I have said at each of our AI hearings this year, I
381 strongly believe that as the bedrock of any AI regulation, we

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

382 must enact strong federal data privacy protections for all
383 consumers. AI cannot function without large quantities of
384 data, and we must ensure that this increased data demand does
385 not come at the expense of consumers' right to privacy, and I
386 am going to continue to push for a comprehensive national
387 federal privacy standard. I know the chair is just as
388 concerned.

389 I believe it is the only way we can limit the
390 unscrupulous data collection and selling practices of Big
391 Tech and third-party entities. It is also the only way we
392 can ensure all of our personal medical information is
393 protected online and protected against algorithmic bias or
394 security breaches. AI's role in the adjudication of medical
395 claims specifically poses a great concern to me. Despite
396 potential to revolutionize the healthcare landscape, AI in
397 certain instances could result in the denial of medical care
398 potentially worsening health inequities.

399 Right now there is a class action lawsuit against one
400 major insurer's use of AI to deny medical claims. AI systems
401 allegedly played a role in the denial of over 300,000 payment
402 requests within a two-month period. The average time spent

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

403 supposedly reviewing each of these claims was a mere 1.2
404 seconds.

405 Now AI tools can aid and support healthcare providers,
406 but the recommendation should not serve as a substitute for
407 the nuanced judgment of our healthcare professionals. AI has
408 potential to supplement medical decisions. However, when A _
409 when healthcare companies driven by efficiency implement AI
410 suggestions without subjecting them to critical scrutiny, I
411 worry that patient safety could be put at risk.

412 So there is a lot of work to be done here, and I want to
413 thank the chairman of the subcommittee and the chair of the
414 full committee for prioritizing this. Thanks again.

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

416

417 *****COMMITTEE INSERT*****

418

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

419 *Mr. Pallone. I yield back.

420 *Mr. Guthrie. If the gentleman will yield me a couple
421 of seconds?

422 I didn't see that Tony Cardenas had come into the room
423 when I _

424 *The Chair. Yeah.

425 *Mr. Guthrie. _ talked about Anna. I want to say the
426 same thing. There has been several issues, but specifically
427 one I remember that we had to plow through a lot of issues to
428 get through to help small businesses that were affected, and
429 we were focused on working together and coming to common
430 ground, and that was a great experience. And so,
431 congratulations to you, and we got another year to work
432 together moving forward.

433 So the gentleman yields back, and I will yield back.
434 And so thanks, and we will have more time to congratulate as
435 we move forward this year. To party? Is that what you said?

436 *Ms. Eshoo. Right.

437 *Mr. Guthrie. Okay.

438 [Laughter.]

439 *Mr. Guthrie. That sounds _ we will see what happens,

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

440 right?

441 So now we will _ that concludes member statements, and
442 we will move to our witness's opening statement, and I will
443 introduce each one of you then call on you _ introduce you as
444 a group and then call on you to give your opening statement.
445 And those of you who have not testified, I think some of you
446 have, some of you may not have, is that you will have a green
447 light. I think it goes for four minutes?

448 *Voice. Five.

449 *Mr. Guthrie. Five _ the green light's for five
450 minutes?

451 *Voice. Okay.

452 *Mr. Guthrie. They have five minutes to testify. Four
453 minutes you will have a green light, then you will get a
454 yellow light, and once you have the yellow light, that shows
455 you got a minute left, and when the red light hits, it is
456 time to wrap up and we will move forward.

457 So today I will first rec _ introduce Dr. Michael
458 Schlosser, Senior Vice President of Care, Transformation, and
459 Innovation at HCA Healthcare; Dr. Benjamin Nguyen, and you
460 said that was a proper pronunciation of your name, Senior

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

461 Product Manager, Transcarent; Mr. Peter Shen, Head of Digital
462 Health, North American Siemens Healthineers; Dr. Christopher
463 Longhurst, Chief Medical Officer, Chief Digital Officer, and
464 Association Dean, US (sic) San Deigo Health; and then also
465 Dr. David Newman-Toker, Director, Division of Neuro-visual
466 and Vestibular Disorders, Department of Neurology, Professor
467 of Neurology at Johns Hopkins University School of Medicine.

468 I appreciate you all for being here and taking the time
469 to be here today. This hearing's important. And I will
470 begin by recognizing Dr. Schlosser. You are recognized for
471 five minutes for your opening statement.

472 *Dr. Schlosser. Thank you. Thank you _

473 *Mr. Guthrie. Make sure your microphone is either on
474 and then push _ and then _

475 *Dr. Schlosser. Here we go.

476 *Mr. Guthrie. Yeah, up to your _ yeah, if you will lift
477 it up. It should bend towards you. There you go.

478 *Dr. Schlosser. Thank you.

479

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

480 STATEMENT OF MICHAEL SCHLOSSER, MD, MBA, SENIOR VICE
481 PRESIDENT OF CARE TRANSFORMATION AND INNOVATION, HCA
482 HEALTHCARE; BENJAMIN NGUYEN, SENIOR PRODUCT MANAGER,
483 TRANSCARENT; PETER SHEN, HEAD OF DIGITAL HEALTH - NORTH
484 AMERICA, SIEMENS HEALTHINEERS; CHRISTOPHER LONGHURST, MD,
485 CHIEF MEDICAL OFFICER, CHIEF DIGITAL OFFICER, AND ASSOCIATION
486 DEAN, UC SAN DIEGO HEALTH; AND DAVID NEWMAN-TOKER, MD, PhD,
487 DIRECTOR, DIVISION OF NEURO-VISUAL AND VESTIBULAR DISORDERS,
488 DEPARTMENT OF NEUROLOGY, PROFESSOR OF NEUROLOGY, JOHNS
489 HOPKINS UNIVERSITY SCHOOL OF MEDICINE

490

491 STATEMENT OF MICHAEL SCHLOSSER

492

493 *Dr. Schlosser. Thank you, Subcommittee Chairman
494 Guthrie, and Ranking Member Eshoo, as well as Chairman
495 McMorris Rodgers, and Ranking Member Pallone, and esteemed
496 members of this committee for inviting me to testify here
497 today.

498 I am Dr. Michael Schlosser, Senior Vice President for
499 Care Transformation and Innovation at HCA Healthcare. I have
500 a background in neurosurgery, in hospital operations, and

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

501 deep involvement in healthcare in AI technology and so
502 excited to share my perspectives in how HCA is approaching AI
503 in healthcare.

504 At HCA Healthcare, our commitment to integrating AI into
505 healthcare is driven by a vision to enhance patient care and
506 operational efficiency and effectiveness. Our initial use
507 cases are focused largely on removing administrative burden
508 from clinicians, providers, and leaders so we can return
509 precious time to them, allowing them to focus on patients,
510 critical decision making, and other high-risk activities like
511 transitions of care. Allowing these colleagues to function
512 at the top of their license will create expanded healthcare
513 workforce with the time and tools to deliver a superior
514 standard of care.

515 To achieve these goals, our first step was to develop a
516 responsible AI program involving a robust governance
517 structure to ensure our AI applications are fair, robust,
518 accountable, and continuously evaluated for safety and
519 effectiveness. The stated goal of the program is to both
520 govern and enable the use of AI across our organization.
521 Ensuring the technology is used responsibly but also ensuring

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

522 we take full advantage of these innovations and the benefits
523 they can provide to our care teams and our patients.

524 When it comes to privacy and security, we have several
525 decades of experience in protecting patient data that has
526 positioned us well to meet the challenges of deploying AI in
527 a secure and private manner. Building on our experience
528 managing patient data under the HIPAA standard, we ensure
529 that all our AI applications adhere to these stringent
530 standards. Patient data and the output of any AI model that
531 could include protected health information about our patients
532 as well as the models themselves are all protected in the
533 same way. Private and secure is also a key feature of our
534 responsible AI program.

535 Finally, we are deploying a new data architecture to
536 support AI _ our AI agenda which focuses on deidentified
537 datasets the primary _ as the primary source of training
538 data. This allows for the use of large datasets to develop
539 models in advanced analytics without having to expose
540 individual patient PHI.

541 Another safeguard that we have implemented is a human-
542 centric approach to AI. In all our AI applications, we

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

543 emphasize a human-in-the-loop approach. This ensures that
544 when we leverage AI for efficiency and accuracy, we do not
545 compromise on safety and responsibility. The human-in-the-
546 loop models also allow for ongoing model development through
547 direct feedback provided inside the workflow for those using
548 the models. The more the models are used, therefore, the
549 better they become.

550 Finally, when it comes to AI-driven decision support
551 tools, these are the models where they are directly advising
552 on the treatment or diagnosis of patients, we believe this is
553 an existing opportunity for AI in the future, but an area
554 that requires significant testing and research before they
555 can be deployed safely.

556 So with my final time, let me add just three examples of
557 how we are using AI in healthcare across HCA. The first is
558 enhancing clinical documentation. We have a system in a
559 partnership with Augmedics where AI can listen to a provider
560 interview a patient in the emergency room, this is live in
561 four ERs, and then transcribe the event, and then using
562 natural language processing and large language models turn
563 that into structured clinical documentation, moving

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

564 documentation into an AI assistant mode rather than the
565 doctor as a data entry analyst.

566 The second is streamlining nurse handoff. Nurse handoff
567 occurs almost 400,000 times every week across our 183
568 hospitals. It is a risky time during a transition of care.
569 We have taught a large language model to read our EHR data
570 and therefore be able to interpret that data and create a
571 handoff tool that the nurses, after they review it
572 themselves, can use to drive that conversation. This will
573 bring standardization and safety to a highly variable and
574 risky time during care delivery.

575 Finally, we are using AI for staffing and scheduling.
576 We have taught an AI algorithm to understand the data
577 surrounding how our care teams are deployed in our hospitals.
578 Care teams are our most valuable resource and ensuring we
579 have the right team in the right place at the right time with
580 the assistance of an AI algorithm is proving to be able to
581 create more balanced, fair, and equitable schedules for our
582 care team members.

583 So in conclusion, at HCA Healthcare, we are dedicated to
584 exploring and leveraging AI to enhance patient care and

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

585 experiences, improve operational efficiency, and uphold the
586 highest standards of privacy and security. We are committed
587 to ongoing dialogue with Congress and with this subcommittee
588 to help ensure the pathway forward provides all the
589 opportunities that our patients deserve.

590 [The prepared statement of Dr. Schlosser follows:]

591

592 *****COMMITTEE INSERT*****

593

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

594 *Mr. Guthrie. Thank you. Thank you for your opening
595 statement.

596 The chair now recognizes Dr. Nguyen. You are recognized
597 for five minutes for your opening statement.

598 *Dr. Nguyen. Thank you; thank you. Chairman Guthrie _

599 *Mr. Guthrie. You have to turn your microphone on.

600 *Dr. Nguyen. Oh.

601 *Voice. And point it up towards you.

602 *Dr. Nguyen. How is that?

603 *Mr. Guthrie. Yes.

604 *Dr. Nguyen. Better?

605 *Mr. Guthrie. Turn yours off, Doctor. There we go.

606 *Dr. Nguyen. Oh, that is why. Can you hear me now?

607 *Mr. Guthrie. We are good now.

608 *Dr. Nguyen. Okay, all right. Thank you.

609

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

610 STATEMENT OF BENJAMIN NGUYEN

611

612 *Dr. Nguyen. Chairman Guthrie, Ranking Member Eshoo,
613 Chairwoman McMorris Rodgers, and Ranking Member Pallone,
614 distinguished members of the committee, it is my pleasure to
615 appear before you today to discuss how artificial
616 intelligence is changing healthcare.

617 And my name is Dr. Benjamin Nguyen. I am a Senior
618 Product Manager at Transcarent, leading our AI team, which is
619 tasked with expanding the Transcarent affiliated clinic suite
620 of AI tools while maintaining the highest standards for
621 patient safety. I have worked at the intersection of
622 technology and care delivery throughout my career, with a
623 special focus on artificial intelligence.

624 Transcarent was founded to make it easy for people at
625 access high-quality, affordable healthcare and to offer
626 greater choice and control for healthcare consumers, our
627 members, and employer-sponsored group health plans, our
628 clients. Transcarent is not a stand-alone health plan,
629 rather our services make the healthcare journey for our 4.4
630 million members a more informed and easy one. We help make

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

631 their existing health medical plan easier to understand and
632 use.

633 Our platform is personalized for each member, guiding
634 them to appropriate care. We offer access to physicians, on
635 demand care teams in a connected ecosystem of in-person and
636 virtual care point solutions. Our affiliated virtual clinic
637 provides chat and video-based telemedicine visits for a wide
638 spectrum of urgent and primary care needs, and in the face of
639 significant demand for virtual care, we use AI tools to
640 improve the experience for our members while reducing the
641 administrative burden on clinicians.

642 When a patient comes to the virtual clinic, an AI
643 assistant immediately begins to gather information from them
644 about the reason for their visit so that by the time the
645 clinician greets the patient, they have a detailed and
646 relevant summary of the patient's symptoms and history. They
647 can spend their time discussing the diagnosis, treatment
648 decisions, and follow-up care with the patient. AI is
649 already helping these clinicians reduce the administrative
650 burden and frees them up to spend more time on the patients
651 who need it the most without replacing their clinical

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

652 judgment.

653 But I want to paint a picture for how next gen AI used
654 thoughtfully can transform the way patients experience
655 healthcare. Imagine a single mother for whom English is a
656 second language with limited health literacy. For us, maybe
657 the 10 to 15-minute doctor visit is enough, but she may need
658 30 to 60 minutes to ask all the questions she rightfully has
659 about her son's care, and there is nothing wrong with that,
660 but current constraints make this kind of engagement very
661 challenging in a modern medical practice. There are patients
662 in the waiting room and there aren't enough practitioners.

663 But thoughtfully built AI systems using next gen
664 technology can help. Imagine an AI chatbot built in
665 partnership with clinicians that can simplify information to
666 her level of comfort or even fluently translate into any
667 language she prefers. In this very near future, she can
668 spend as much time as she wants and needs to. Well-designed
669 systems like this can help us move from a one size fits all
670 approach to a many sizes for many needs approach.

671 A few years ago it would have been immensely difficult
672 and expensive to build an AI chatbot so perfectly tailored to

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

673 this mother's needs, but recent leaps in AI technology have
674 made it easier to do this. This kind of technology,
675 generative AI, is of a different nature than AI systems you
676 may be familiar with. It can be applied in many domains, but
677 its most common application is in large language models
678 powering chatbots.

679 Chatbots powered by this new AI technology are not
680 human, but they act human-like. They can converse with
681 users, grasp complex, nuanced topics, engage in reasoning,
682 and write in a way that sound _ sounds indistinguishable from
683 a human. To use an analogy, the technological leaps in AI
684 that happened in the five years past to enable this are so
685 great that they are akin to going from locomotives to powered
686 flight. And like the move to powered flight, this leap
687 brings with it many opportunities and dangers.

688 Because generative AI is not perfect and it is prone to
689 certain shortcomings, even amongst AI companies and experts,
690 there isn't consistent agreement on the best practices for
691 measuring capabilities and safety risks of these new
692 generative technologies, much less how to mitigate them.
693 Healthcare's unique challenges and opportunities mean that we

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

694 also need to develop our own internal expertise in generative
695 AI. This won't come from the outside; it has to come from
696 within.

697 This brings me to my last point which is there is a
698 significant and growing gap in AI talent in the healthcare
699 industry. We need more doctors and nurses at the bedside who
700 are as comfortable speaking the language of AI as they are
701 the language of medical care. And the same goes for our
702 healthcare leaders. Having gone to medical school, I know
703 that this doesn't come naturally to our institutions, which
704 are rightfully focused on teaching the science and art of
705 bedside medicine.

706 But ensuring that AI products serve all Americans
707 equitably demands active participation from all levels of the
708 healthcare system. We need the incentives, frameworks, and
709 collective effort to create these opportunities if we want to
710 ensure that AI achieves its potential in changing the
711 healthcare system for the better.

712 Thank you for the opportunity to testify, and I would be
713 happy to answer any questions you may have.

714 [The prepared statement of Dr. Nguyen follows:]

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

715

716 *****COMMITTEE INSERT*****

717

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

718 *Mr. Guthrie. Thank you. Thank you for your testimony.

719 Mr. Shen, you are now recognized for five minutes for

720 your opening statement.

721

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

722 STATEMENT OF PETER SHEN

723

724 *Mr. Shen. Chairman Guthrie, Vice Chair Bucshon,
725 Ranking Member Eshoo, and members of the subcommittee, on
726 behalf of Siemens Healthineers and our nearly 17,000
727 employees in the United States and approximately 71,000
728 employees globally, thank you for the opportunity to testify
729 today on the topic of artificial intelligence in healthcare.

730 My name is Peter Shen. I am the North America Head of
731 Digital Health for Siemens Medical Solutions USA,
732 Incorporated, also known as Siemens Healthineers. My career
733 focuses on the introduction of new and emerging technologies
734 in the healthcare market, including artificial intelligence.

735 Siemens Healthineers is a leading medical technology
736 company with more than 120 years of history and experience
737 bringing breakthrough innovations to market that enable
738 healthcare professionals to deliver the best care for
739 patients. Our core portfolio includes imaging, diagnostics,
740 and therapies augmented by digital technologies and
741 artificial intelligence. We partner with more than 90
742 percent of the leading providers in healthcare to address

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

743 issues around population growth and chronic disease
744 management, healthcare workforce shortages, and the lack of
745 access to care in underserved areas.

746 We have the distinction of being the only medical
747 technology company capable of end-to-end cancer care from
748 diagnosis and screening to treatment and survivorship. This
749 is a responsibility we take very seriously as we keep
750 patients at the center of everything that we do.

751 Siemens Healthineers has been working on applying
752 artificial intelligence in medical technology for more than
753 20 years. At our AI office of Big Data in Princeton, New
754 Jersey, we have built one of the most powerful supercomputing
755 infrastructures dedicated to developing AI in healthcare.
756 This allows our research scientists to collect, prepare, and
757 organize correct and secure medical data needed to train and
758 deliver accurate AI algorithms.

759 From its inception, we create and maintain a transparent
760 quality assurance process which involves clinical validation
761 to guarantee the data being used to train the AI algorithms
762 is accurate for diagnosis and treating disease. This
763 training data is based on a balanced cohort of people of

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

764 different ages, genders, and ethnicities, thus ensuring we
765 develop reliable, accurate, and unbiased AI algorithms that
766 are reflective of the patient populations that they will be
767 applied towards.

768 The patient journey is at the heart of Siemens
769 Healthineers' AI work, and AI has the ability to help improve
770 care and outcomes for the patient. AI helps patients
771 undergoing a CT scan for lung cancer screening by optimizing
772 the resulting generating images while minimizing the time the
773 patient spends in the scanner. Radiologists reviewing those
774 images can utilize our AI-guided computer software as a
775 companion to identify small nodules and other suspicious
776 abnormalities that they previously weren't able to visualize
777 without the assistance of AI.

778 Suspicious lung nodules diagnosed to be cancerous by the
779 clinician can potentially be treated by radiation therapy
780 which includes the very tedious task of manually drawing
781 these unique contours of the cancerous tumor to target
782 radiation while preserving healthy tissue. Our AI-enabled
783 auto-contouring software can automatically detect these
784 contours of the cancerous area, significantly speeding up the

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

785 patient's time to treatment and potentially eliminating
786 unwarranted radiation.

787 At Siemens Healthineers, commercial AI algorithms have
788 gone through a regulatory approval process with the FDA. We
789 follow all AI ML-enabled medical device regulatory
790 requirements for the pre-market review and post-market
791 surveillance to ensure the safety and efficacy of our
792 devices. We believe with the rapid acceleration in
793 development and innovation of AI medical devices, the need
794 for a regulatory environment to be able to have _ be balanced
795 in innovation and adoption is going to be critical.

796 While we believe the current regulatory framework is
797 sufficient to support innovation in AI, we support the
798 continuation of flexibility in the approval process as well
799 as efforts to facilitate global harmonization and the
800 development of appropriate international consensus standards.

801 While CMS has recognized the value and the complex
802 nature of AI, the agency's reimbursement decisions have not
803 uniformly and consistently ensured appropriate levels of
804 payment for these AI products. This inconsistent,
805 unpredictable approach stifles adoption and limits access to

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

806 patients benefitting from AI technologies across our
807 healthcare system, especially in rural and underserved areas.
808 We support a solution that ensures a predictable and
809 consistent approach to CMS, an approach that recognizes the
810 cost of AI and reimburses AI analysis with a temporary and
811 separate payment system until more data can be evaluated.

812 Siemens Healthineers believes AI has the greatest
813 potential to improve access to care, diagnose the disease
814 faster, and enable physicians to make more precise treatment
815 decisions. As a market leader, we are excited to see what
816 the future folds for AI in healthcare.

817 Again, thank you for the opportunity to testify before
818 you today, and I look forward to your questions.

819

820

821

822 [The prepared statement of Mr. Shen follows:]

823

824 *****COMMITTEE INSERT*****

825

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

826 *Mr. Guthrie. Thank you. Thank you for your testimony.

827 Dr. Longhurst, you are recognized for five minutes for

828 your opening statement.

829

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

830 STATEMENT OF CHRISTOPHER LONGHURST

831

832 *Dr. Longhurst. Good morning. Thank you, Chairs
833 Rodgers and Guthrie, Ranking Members Pallone and Eshoo, and
834 members of the subcommittee for the opportunity to speak with
835 you today about our experience at UC San Diego Health using
836 machine learning and AI models to improve healthcare
837 delivery.

838 My name is Chris Longhurst. I am a practicing
839 pediatrician, and I have the privilege of serving as the
840 Chief Medical Officer, Chief Digital Officer, and Associate
841 Dean at UC San Deigo Health. At our institution, we have
842 been carefully evaluating and implementing machine learning
843 models to enhance quality and safety for over five years, and
844 we believe our experience can be helpful as the committee
845 considered the implications of healthcare AI.

846 As a leader at the intersection of care delivery and
847 technology, it has been disappointing to see so little
848 progress in patient safety over the last two decades, with a
849 recent study from Boston suggesting that one in four patients
850 admitted to the hostel _ hospital continue to experience an

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

851 adverse event, many of which are preventable. Healthcare
852 organizations are complex sociotechnical systems and these
853 new AI tools may be the key to finally bending the patient
854 safety curve in a better direction.

855 One instructive example of our use of this technology at
856 UCSD arose early in the pandemic. Because Marine Corps Air
857 Station Miramar served as one of the first two sites for
858 evacuation of Wuhan ex-patriots, we hospitalized some of the
859 first COVID patients in the country back in February 2020.
860 This early experience led us to broadly deploy an imaging AI
861 tool which helped to identify COVID pneumonia on chest x-
862 rays. Remember this is months before widespread testing
863 became available.

864 We published the results of our outcomes evaluation
865 which showed that this tool impacted clinical decision making
866 for one in five patients in our emergency department over the
867 course of the summer of 2020. However, after processing over
868 60,000 chest x-rays, we turned the tool off at the end of
869 2020 because it was no longer useful to our clinicians when
870 testing became ubiquitous, which demonstrates the importance
871 of ongoing monitoring to ensure that AI tools continue to be

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

872 both safe and effective.

873 The study was recently cited in review of all research
874 about COVID and AI which found our publication was one of _
875 was one of just four out of over 9,000 which actually
876 demonstrated an impact on clinical outcomes. This
877 demonstrates another key point which is the huge gap between
878 the creation of algorithms and the actual implementation and
879 measurement to benefit patients, what we refer to as the AI
880 hype cycle.

881 A second instructive example comes from our use of AI to
882 support earlier identification and treatment of a blood
883 infection called sepsis. UC San Diego has chosen to develop
884 a local model using local data, and we even trained it to
885 tell our users, I don't know, when predictive confidence was
886 low. This was implemented with significant clinical process
887 redesign such as notifying a central team and not just the
888 frontline clinicians.

889 The results have been associated with a decreased risk
890 of death among patients with sepsis in our emergency
891 department. And this case study highlights the importance of
892 not only creating these algorithms but ensuring the

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

893 algorithms are transparent in their predictions to generate
894 trust, and doing the hard work then of integrating these into
895 clinical workflows where they can impact meaningful outcomes
896 and care quality.

897 A final example is our recent use of generative AI to
898 help our busy clinicians answer patient messages which have
899 reached unprecedented levels with the rise in virtual care.
900 UC San Diego authors published a study earlier this year
901 showing generative AI could draft high-quality and empathetic
902 responses to patient questions, perhaps even higher quality
903 than some physician responses.

904 On the tale of these results, UCSD became one of the
905 first sites in the Nation to implement generative AI to help
906 our clinicians respond to patient messages. But importantly,
907 we chose to ensure full transparency with our patients by
908 ensuring every message has an addendum disclosing that this
909 message was automatically generated and reviewed by your
910 doctor. These messages cannot be sent to patients without a
911 clinician review and our preliminary results have shown this
912 has been well-received by clinicians and patients and may
913 save cognitive burden. This case study illustrates the

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

914 importance of both transparency and keeping a human in the
915 loop at all times.

916 Now from a privacy and security perspective, I want to
917 note that in all three cases no protected health information
918 has left our HIPAA-protected environment. In fact, we
919 recently founded the first Center for Healthcare
920 Cybersecurity with an ARPA-H grant and a focus on continuing
921 to improve our digital protections and resiliency.

922 So to summarize, as a health system engaged in the
923 procurement, development, and use of large-scale machine
924 learning models that can perform a wide variety of tasks, we
925 commit to pursuing these technologies' benefits while
926 mitigating their risk and protecting patient privacy. For
927 almost five years our health AI committee has been evaluating
928 all machine learning models proposed for implementation from
929 an ethical and health equity framework to ensure safety,
930 security, and trust, which is well-aligned with the model
931 proposed by the Office of the National Coordinator for Health
932 IT to ensure fair, appropriate, valid, effective, and safe
933 use of AI, or FAVE.

934 Now while some advocate for a centralized testing

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

935 process, our experience suggests that local audits could be
936 more effective in the hospital setting for sure _ ensuring
937 alignment with these principles, as these models must be
938 evaluated within the context of the care they support.

939 Finally, with the generous support of Joan and Erwin
940 Jacobs, Center for Health Innovation, we see an opportunity
941 for moving this industry forward together engaging with you
942 and the administration on responsible AI use. I look forward
943 to answering any questions you may have. Thank you.

944 [The prepared statement of Dr. Longhurst follows:]

945

946 *****COMMITTEE INSERT*****

947

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

948 *Mr. Guthrie. Thank you, we appreciate your opening
949 statement.

950 And the chair now recognizes Dr. Newman-Toker, five
951 minutes for your opening statement.

952

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

953 STATEMENT OF DAVID NEWMAN-TOKER

954

955 *Dr. Newman-Toker. Chairman Guthrie, Ranking Member
956 Eshoo, and members of the committee, thank you for the
957 opportunity to address Congress on this critically important
958 topic of artificial intelligence in healthcare.

959 My name is David Newman-Toker, and I am a physician
960 scientist with doctoral-level training in public health and a
961 research focus on improving medical diagnosis, including the
962 development and deployment of novel diagnostic technologies
963 such as AI. I have been a faculty member at Johns Hopkins
964 School of Medicine for more than two decades where I am
965 currently a Professor of Neurology and Director of our AHRQ-
966 funded Center for Diagnostic Excellence. I am also past
967 President of the Society to Improve Diagnosis in Medicine.

968 My testimony today will focus on opportunities and
969 challenges for AI in healthcare from a public health
970 perspective with a special emphasis on AI to improve medical
971 diagnosis. I would like to state for the record that the
972 opinions I express here today and my written testimony are my
973 own and do not necessarily reflect those of the Johns Hopkins

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

974 University.

975 AI is the branch of computer science concerned with
976 endowing computers with the ability to simulate intelligent
977 human behavior. The most complex cognitive task in medicine
978 is the act of diagnosing the cause of a patient's symptoms.
979 Errors in diagnosis account for an estimated 800,000 deaths
980 or permanent disabilities each year in the U.S., more than 80
981 percent of which are associated with cognitive errors or
982 clinical reasoning failures. This creates a unique quality
983 improvement opportunity for AI-based systems to save American
984 lives at public health scale.

985 Potential benefits of AI include better health outcomes
986 for patients at lower costs, greater access to and efficiency
987 of care delivery, especially for those currently underserved
988 and disadvantaged, and decreased healthcare cost _ decreased
989 healthcare workforce burnout. However, none of these
990 benefits will be realized without tackling foundational data
991 challenges facing AI. The rate-limiting step for developing
992 and implementing AI systems in healthcare is no longer the
993 technology, it is the sources of data on which the technology
994 must be trained.

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

995 There are three critical data problems. First, using
996 data that are wrong, often called the garbage in/garbage out
997 problem; second, relying on the wrong kinds of data,
998 sometimes called the looking where the light is best problem;
999 and third, not having the right kinds of data at all,
1000 especially health outcomes such as inaccurate diagnoses,
1001 unexpected adverse events, or reduced quality of life.

1002 Data quality in healthcare is non-uniform, even for
1003 diagnosis. The most reliable and complete digital datasets
1004 exist in radiology and laboratory medicine. Here, good AI
1005 diagnostic systems are already being built. The least
1006 reliable and most incomplete digital data are from routine
1007 clinical encounters. Key details about patient symptoms or
1008 clinical examination findings in the electronic health record
1009 are often missing or inaccurate. Here, good AI diagnostic
1010 systems must wait for a radical shift in the way we capture
1011 diagnostic information about patients.

1012 AI systems that learn on faulty data will generally make
1013 the same mistakes that humans make. Put simply, if available
1014 electronic health record datasets are used to train AI
1015 systems, the best we can hope for is AI systems which

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

1016 replicate and formalize implicit human biases, and the worst
1017 we can expect is AI systems that are frequently wrong in
1018 their recommendations. If AI-based systems are deployed
1019 without adequate testing, the quality of healthcare will
1020 drop.

1021 The biggest public health gains from well-designed AI
1022 can reasonably be expected in parts of the healthcare system
1023 where there are large quality gaps that could be closed for
1024 many individuals, diagnostic errors, lack of access to care
1025 in underserved areas, and health disparities.

1026 For AI and healthcare to maximally benefit the health of
1027 all Americans, the following are essential. First, AI
1028 systems must be trained on gold-standard datasets that are
1029 unbiased and include complete information on both clinical
1030 inputs and care outputs. Second, AI systems must be
1031 effectively integrated into clinical workflows, leveraging
1032 the strengths of computers and humans together to produce a
1033 better result that could be achieved by either alone. And
1034 third, wherever AI is used, systems to monitor, maintain, and
1035 even enhance clinician skills, including diagnostic ones,
1036 should be co-deployed so the clinicians and AI systems will

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

1037 continue to fact check each other.

1038 I have three primary policy recommendations for the
1039 committee. First, AI systems must be held to a high
1040 regulatory standard that must be demonstrated scientifically
1041 to improve care quality over current care. Second, new
1042 payment incentives will be needed to ensure AI systems are
1043 unbiased and health outcomes are being monitored. Special
1044 incentives will likely be needed for AI-based diagnostic
1045 tools since diagnosis is generally unaffected by current
1046 disease-based payment models. And third, targeted research
1047 funding to address known barriers is essential.

1048 Special consideration should be given to funding
1049 programs that support development of large gold-standard
1050 datasets from which high quality AI systems for diagnosis can
1051 be trained.

1052 In summary, AI has great potential to transform
1053 healthcare for the better, but absent carefully crafted
1054 regulations, innovative payment incentives, and targeted
1055 research resources, risks will dominate. The guiding
1056 principle for policy changes should be public health impact,
1057 including an emphasis on the equitable distribution of

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

1058 benefits and risks across the population.

1059 Thank you for this opportunity. I will be pleased to
1060 answer any questions you may have.

1061 [The prepared statement of Dr. Newman-Toker follows:]

1062

1063 *****COMMITTEE INSERT*****

1064

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

1065 *Mr. Guthrie. Thank you. I thank you for your
1066 testimony. That concludes opening statements for all
1067 witnesses.

1068 I was just going to say this generically because I know
1069 _ I think, Dr. Nguyen, you said this is your first trip to
1070 D.C. so I know you haven't testified before, so welcome to
1071 our Nation _ all of you, is that you guys have a lot of
1072 information and we have a lot of curiosity, so each of us are
1073 going to get five minutes, and so I know that it is going to
1074 be hard to answer some of your questions succinctly, but if
1075 one us say, I am sorry, I am going to move to the next
1076 question because we have things we want to get to, we are not
1077 being rude, we just want to make the best of our five
1078 minutes. I will say that moving forward.

1079 And there _ some of my colleagues, some more than
1080 others, they will ask you a really detailed question with
1081 five seconds left in their time. So I will let you answer as
1082 much as we can, but if I gavel you down, it is not being
1083 rude, it is getting things done so we can appreciate your
1084 time as well.

1085 So I will say that I will begin by _ the five minutes by

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

1086 recognizing myself for five minutes for questions.

1087 So, Dr. Nguyen, you mentioned in your testimony the
1088 various types of AI and how generative AI is often the focus.
1089 Can you walk us through how you might deploy the various
1090 forms of AI, supervised, unsupervised, reinforced? And if
1091 these aren't the main drivers of how you deploy AI, then
1092 please walk me through your approach.

1093 *Dr. Nguyen. Absolutely. So I think it is very helpful
1094 to think about AI at a high level in two different
1095 categories. One is I will call it narrow AI, right, these
1096 are narrow, specialized AI tools. And they typically are
1097 built to do very specialized, very specific jobs, and they
1098 are very good at those if we train them well and train our
1099 bias, right?

1100 Tools like this are things such as a predictor tool,
1101 right, to predict the risk of a cardiac event in a patient,
1102 right? Now that is a narrow type of AI, right? You want to
1103 apply those types of narrow AI systems when you have high-
1104 risk, right, highly important tasks, right, that you must get
1105 right. So things such as supporting diagnoses, right, making
1106 predictions on a patient's deterioration, right, those are

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

1107 what you want those narrow systems for.

1108 The other half, right, and this is a little newer, these
1109 kinds of systems are more in the news, are generative AI
1110 systems. These systems are much more flexible. They are not
1111 built for specific specialized tasks. You see them most
1112 often in technologies like the very well-known chatbot,
1113 ChatGPT. They are built to be very flexible, right, they are
1114 built to do things like take a language's input and output
1115 written language in response, right?

1116 They are very good at flexible tasks, like assisting
1117 with administrative burden, right, generating educational
1118 content, right? These are tasks where you need the
1119 flexibility, right, rather than the specialized nature of the
1120 other systems. So those are the two ways.

1121 *Mr. Guthrie. Okay, thank you, appreciate that.

1122 And, Mr. Shen, I will move to you. For healthcare,
1123 especially ensuring that patients _ there are guardrails in
1124 place for AI, we want to make sure we protect patient safety
1125 while promoting better outcomes and safeguarding taxpayer
1126 dollars. So my question is how do you believe we can strike
1127 the proper regulatory balance on the front end to ensure

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

1128 there are safeguards in place without stifling the innovation
1129 and the growth of AI?

1130 *Mr. Shen. Yeah. Thank you very much for the question.
1131 For _ as it relates to our work with the FDA, our algorithms
1132 as _ go through a regulatory process with the FDA. We follow
1133 all the AI machine learning enabled medical device regulatory
1134 requirements for both pre-market review and post-market
1135 surveillance to make sure that those solutions are safe for
1136 patients and effective for them as well.

1137 We also have regular dialogue with the FDA regarding AI
1138 and machine learning and provide feedbacks on ways that they
1139 can ensure continued safe and effective application of these
1140 technologies. I think also what is a great example is that
1141 we worked very closely with the FDA on the implementation of
1142 the predetermined change control plans for AI, and I thank
1143 this committee as well for their support in this particular
1144 effort. Those help us ensure that we can continue to
1145 innovate in this area while having the right regulatory
1146 components in place.

1147 At the same time I think where the challenge is right
1148 now is around adoption of artificial intelligence and for

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

1149 providers and physicians to take advantage of all the great
1150 benefits that myself and the other colleagues here have
1151 talked about here. Right now, again, CMS con _ really needs
1152 to create kind of a consistent and predictable approach for
1153 the payment of these AI solutions that are FDA approved
1154 rather than the current ad hoc approach that we have seen to
1155 date where certain technologies receive a separate payment
1156 based on manufactured supply costs, but other ones don't
1157 receive that payment.

1158 That confusion leads to uncertainty for providers as to
1159 whether they should actually make an investment into
1160 artificial intelligence. And, unfortunately, because of that
1161 uncertainty, the patients get lost in terms of their ability
1162 to take advantage of these technologies.

1163 *Mr. Guthrie. Okay, thank you.

1164 And I want to move a question to Dr. Newman-Toker. Some
1165 of my concerns as we are looking at all the data that goes
1166 into AI, some of the _ what we need to be aware of and what
1167 could come out of _ so the regulatory and policy challenges
1168 that we need to consider. And I guess an example would be to
1169 make sure _ we have talked about quality adjusted life years

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

1170 in _ on this subcommittee quite often, and we want to make
1171 sure that a data system isn't _ to factor that in to see if
1172 people are qualified for care.

1173 So how do _ what are the _ kind of the unforeseen
1174 challenges that you think we need to be aware of moving
1175 forward, that being an example?

1176 *Dr. Newman-Toker. There are significant data
1177 challenges for AI systems, particularly where _ when we look
1178 at clinical data. So, for example, there are great data in
1179 laboratory and imaging datasets that are digitized. The
1180 clinical data, which are in electronic notes, actually have
1181 lots of errors and problems in them, and I do think that to
1182 some extent that is a key focal point where we should be
1183 making sure that we are not over-relying on faulty data
1184 sources in order to _ as we try to move forward to AI systems
1185 that are helping us.

1186 *Mr. Guthrie. Yeah, I didn't leave you much time to
1187 answer, so thanks for _ and we will _ hopefully we can
1188 explore that more to this hearing and/or through _ in writing
1189 as we move forward.

1190 So I will yield back, and I will recognize the ranking

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

1191 member for five minutes for her questions.

1192 *Ms. Eshoo. Thank you, Mr. Chairman, and thank you to
1193 each one of you, our witnesses today.

1194 As I was listening, I was listening hard, you know, to
1195 absorb what you were saying, and I have to admit that there
1196 were different parts of your testimony where I really didn't
1197 understand what you were talking about. That is not, you
1198 know, to be interpreted as you being less than perfect, I
1199 mean, that's is a _ it is a condition for the entire of
1200 humanity.

1201 But I think that we are really very hungry to hear in
1202 pedestrian terms, if you will excuse that terminology,
1203 exactly how this is going to work and how you think it is
1204 working now. I recall the book written by John Doerr. I
1205 think all of you know who he is. If you don't on the
1206 committee, Google him because he is one of the great minds of
1207 our country.

1208 But the title of the book was "Measure What Matters'",
1209 and that is what I am trying to extract from your testimony.
1210 I don't know if some of this is meant for administrators. I
1211 mean, we talk about administrative burden. What does that

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

1212 mean? I mean, what is AI going to do about that? What does
1213 it mean in terms of patients at their bedside?

1214 At their _ I mean, in real life. Not only important
1215 information that medical specialists can have access to to
1216 enlarge their understanding, as you said Dr. Longhurst, and
1217 so wonderful that you took everything _ all of your
1218 experience at Lucille Packard Children's Hospital to UC.
1219 They are first cousins, right? Stanford and University of
1220 California.

1221 So my questions are really more about the practical, the
1222 real, practical advantages of AI. I mean, I would ask just
1223 the entire panel if you can answer this. Without any
1224 congressional statutes yet, how do you guarantee the _ all
1225 the positives that you presented to us today?

1226 *Dr. Schlosser. I'll be happy to take a stab.

1227 *Ms. Eshoo. Yeah, just briefly but _

1228 *Dr. Schlosser. Yeah.

1229 *Ms. Eshoo. Yeah.

1230 *Dr. Schlosser. To address _

1231 *Ms. Eshoo. I mean, because you are all saying that
1232 this is _ and I believe in the potential of this, but I think

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

1233 that we need to think long and hard about how this is
1234 actually going to work.

1235 *Dr. Schlosser. Yeah.

1236 *Ms. Eshoo. So if you are doing it right now and _ with
1237 your systems _

1238 *Dr. Schlosser. Let me see if I can briefly give you a
1239 very factual answer. So when we say administrative burden,
1240 we are talking about the anywhere between 25 and 50 percent
1241 of time during a day that a clinician, a doctor or a nurse,
1242 spends on activities that don't directly relate to patient
1243 care. They are entering data into a system, they are
1244 searching for data in multiple different systems, they are
1245 bringing all that information together, they are writing it
1246 down, they are organizing it, they are communicating with
1247 other physicians, with pharmacy, with the other departments
1248 in the hospital. All of that just so they can have the right
1249 information and be able to make good decisions for their
1250 patients.

1251 That is a space that AI, in particular large language
1252 models, is almost custom built for where it became an _

1253 *Ms. Eshoo. So is it _ are you using it today?

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

1254 *Dr. Schlosser. Yeah.

1255 *Ms. Eshoo. And having measured what matters, what is
1256 the outcome?

1257 *Dr. Schlosser. Yeah.

1258 *Ms. Eshoo. What are your doctors saying?

1259 *Dr. Schlosser. So _

1260 *Ms. Eshoo. Does it reduce their burdens by 50 percent,
1261 20 percent, five percent? What are they saying?

1262 *Dr. Schlosser. So for our _

1263 *Ms. Eshoo. What are they telling you?

1264 *Dr. Schlosser. For our ER doctors, for example, that
1265 are using this to help with their documentation, yeah, they
1266 are seeing, you know, upwards of 20, 30 percent of their time
1267 returned to them so that they can focus on patients, so they
1268 can spend more time with the patient and communicating with
1269 the patient and not having to do the documentation
1270 themselves.

1271 *Ms. Eshoo. Mm-hmm. Anyone else?

1272 *Dr. Newman-Toker. I think there is an important
1273 distinction to be made between the direct benefits of AI to
1274 patient health and the sort of indirect benefits. What we

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

1275 have been discussing is sort of the indirect benefits _

1276 *Ms. Eshoo. Indirect, right.

1277 *Dr. Newman-Toker. _ of having _

1278 *Ms. Eshoo. Mm-hmm.

1279 *Dr. Newman-Toker. _ additional time with _ you know,
1280 less time for clinicians spent on unnecessary tasks and more
1281 time spent on the task at hand of taking care of the patient.
1282 I think the future of AI that we want to look towards is one
1283 where AI is actually helping improve health for patients
1284 directly through, for example, the prevention of medical
1285 errors _

1286 *Ms. Eshoo. Absolutely. Uh-huh

1287 *Dr. Newman-Toker. _ by improving the accuracy of
1288 diagnoses _

1289 *Ms. Eshoo. Uh-huh.

1290 *Dr. Newman-Toker. _ and the _ improving the accuracy
1291 of the application of correct treatments, avoiding adverse
1292 events from mistakes made in the delivery of healthcare. And
1293 I think those are the kinds of things that you are getting at
1294 when it _ you are talking about measures that matter. We
1295 want to improve patient health through AI.

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

1296 *Ms. Eshoo. Is it happening now?

1297 *Dr. Newman-Toker. I would say that it is not happening
1298 at that level as yet, but it is a place where we need to
1299 focus our attention.

1300 *Ms. Eshoo. Mm-hmm. Well you all are going to get my
1301 specific other questions that I had planned to ask but went
1302 right off script. So thank you for your testimony today and
1303 for, you know, the expertise that you are bringing to this.
1304 We need it and I hope that you would all weigh in in some
1305 way, shape, or form about the CREATE Act. I would like to
1306 know where you are on that. I think it is important for us
1307 to pass it. Thank you again.

1308 *Mr. Guthrie. Thank _ the gentlelady yields back. The
1309 chair recognizes Chair Rodgers for five minutes for her
1310 questions.

1311 *The Chair. Dr. Schlosser, as you may know, this
1312 committee has worked on a national data privacy standard, and
1313 I believe that that is the first step that Congress should
1314 take as we think through the guardrails that are needed in
1315 regard to artificial intelligence. Your testimony states the
1316 importance of data privacy in using and developing AI in

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

1317 healthcare.

1318 Would you share any comments on this issue and the
1319 importance of privacy in artificial intelligence?

1320 *Dr. Schlosser. Yeah. Privacy is critical to
1321 everything we do with patient data, even prior to the advent
1322 of artificial intelligence. And as a healthcare provider, we
1323 have been operating under the HIPAA standard now for decades,
1324 and I think that is actually given us a great roadmap to
1325 understand how to do a really good job in protecting our
1326 patients' data.

1327 AI strategy is a data strategy. The two are
1328 intrinsically linked, and so we need good, quality data,
1329 diverse data sources, large datasets to train and fine-tune
1330 these models. And so we have to think about both sides of
1331 this, which is how we do we keep the data private and secure,
1332 which I a hundred percent agree we need to, but also do it in
1333 a way that enables us to use the data to train these models
1334 to get smarter, to get better. If we want to achieve the
1335 outcomes my colleagues and I have mentioned, the data is the
1336 fuel for that.

1337 So we completely agree that a _ that data has to be kept

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

1338 private and secure. We obviously would be happy to work with
1339 the committee and yourself on the approach to data privacy
1340 you mentioned in that act. But I would just add that I think
1341 as a provider, we have a lot of deep experience in how to do
1342 this and a lot of insight into how to do this well, and AI
1343 now is just another software application that we have to put
1344 under that umbrella of HIPAA so we make sure that we continue
1345 to protect our patients' data the way we have.

1346 *The Chair. Thank you.

1347 Mr. Shen, recognizing the growing interest in medical
1348 products that incorporate AI, it is critical that FDA keeps
1349 pace with how these innovative technologies are being
1350 utilized and the benefit and risk involved. FDA must ensure
1351 patients and providers have timely access to safe and
1352 effective products while facilitating innovation by providing
1353 industry with predictable, regulatory pathways and rules of
1354 the road.

1355 Can you discuss how FDA's current regulatory process
1356 works for AI-enabled medical technologies, and are there any
1357 improvements in mind?

1358 *Mr. Shen. Yeah.

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

1359 *The Chair. Mm-hmm.

1360 *Mr. Shen. Thank you for the question, Chairwoman. So
1361 for _ as it relates to the FDA, the FDA actually provides
1362 several different pathways for AI solutions to go get their _
1363 their regulatory approval. And these pathways include
1364 different rigors that are available there to be able to prove
1365 _ for organizations to prove that they are both ethical,
1366 safe, and secure in terms of how they are treating the
1367 patient data, and then also how that application is going to
1368 be applied towards the patient population going forward. So,
1369 in fact, the way that the construct that the FDA has today
1370 actually provides good ways for how software can be updated
1371 and AI algorithms can be updated going forward.

1372 Where we see some of the challenges as it relates to
1373 regulation is not in terms of the approval of FDA solutions,
1374 but as mentioned earlier, the adoption of these FDA solutions
1375 and leveraging things like CMS to be able to provide ways to
1376 encourage adoption of AI solutions amongst the different
1377 providers that are mentioned here.

1378 *The Chair. Thank you.

1379 I want to ask each of you in the time remaining to speak

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

1380 to this question because AI is being used in different fields
1381 to improve healthcare for patients and _ and we hear the
1382 examples of improved diagnostics, better care for providers,
1383 and as we move forward and continue to incorporate AI in
1384 healthcare, it is going to be important to make sure that
1385 providers and patients are aware when decisions involve AI.

1386 So just starting with Dr. Schlosser, would you just
1387 speak to what Congress should be thinking about in this
1388 regard as we _ to make sure that it isn't lost as AI
1389 technology continues to evolve?

1390 *Dr. Schlosser. Well, I would comment that transparency
1391 is incredibly important when it comes to AI in general across
1392 all use cases that patients and providers deserve to be _ to
1393 understand exactly when AI is being used, what datasets were
1394 used to train it, what decisions it is being enabled to make.
1395 I think that is foundational to an AI strategy.

1396 *The Chair. Thank you.

1397 Dr. Nguyen?

1398 *Dr. Nguyen. Absolutely. I think it is of the
1399 paramount _ the most paramount importance that patients
1400 always have the right to understand who is treating them and

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

1401 if AI is involved, right?

1402 *The Chair. Okay.

1403 *Dr. Nguyen. There must be transparency around the use
1404 of those tools. Providers as well must understand the
1405 limitations of those tools.

1406 *The Chair. Okay. Mr. Shen?

1407 *Mr. Shen. Yeah, I would add to the transparency topic.
1408 It is not only transparency in terms of how the AI is created
1409 but also transparency in terms of understanding how the AI
1410 has derived its clinical decision. So being able to educate
1411 the users of the AI to understand how is the AI actually
1412 making this clinical decision or clinical recommendation.

1413 *The Chair. Thank you. Thank you, everyone.
1414 Unfortunately, my time is expired, so I will have to look for
1415 another opportunity get the input from the rest you. Thanks.

1416 I yield back.

1417 *Mr. Guthrie. Thank you. The chair yields back, and
1418 the chair recognizes the ranking member for five minutes for
1419 opening _ for questions.

1420 *Mr. Pallone. Thank you, Mr. Chairman.

1421 My questions initially are Dr. Longhurst. I am

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

1422 concerned that the rapid deployment of AI tools means that
1423 there is an enormous incentive to collect, use, and share
1424 vast quantities of patient and other consumers' health
1425 information to train AI models, and this raises serious
1426 privacy and data security concerns, particularly as it
1427 relates to data collected and transferred outside of the
1428 HIPAA related _ regulated environment.

1429 So do you share my concerns in this respect and
1430 particularly potential sale of health data by third parties,
1431 including mobile applications, and that that is not
1432 sufficiently regulated under any federal privacy law,
1433 including HIPAA?

1434 *Dr. Longhurst. Thank you, Ranking Member Pallone, for
1435 the great question. We absolutely share your concern. As.
1436 Dr. Schlosser just described in his points, commitment to
1437 transparency is key. Transparency requires privacy. Health
1438 systems and payors who have been subject to HIPAA for over
1439 two decades now understand what that means, but these third-
1440 party apps that are collecting health information directly
1441 from consumers are not today subject to HIPAA, and that is
1442 deeply concerning to us as a industry that there are growing

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

1443 databases of patient data provided in my many cases by
1444 patients themselves that will be unwittingly and
1445 inadvertently used for other purposes.

1446 *Mr. Pallone. All right. So let me ask you, in your
1447 testimony you mentioned several examples of AI tools used at
1448 the University of California at San Diego. Do you know what
1449 data was used to train those tools and was it all data
1450 protected by HIPAA?

1451 *Dr. Longhurst. Yeah. Thank you again for another
1452 great question. The first two examples I gave about imaging
1453 and sepsis were absolutely tools created with our own
1454 datasets about the patients that we serve. They were created
1455 in the HIPAA-protected environment and our protected health
1456 information never left that environment.

1457 The third example I shared was the generative AI using
1458 these tools to help respond to messages. This was a general
1459 tool that is not accessing our patients' protected health
1460 information, it is not being trained on our patients' data,
1461 and it does exist in our HIPAA-protected environment. So in
1462 all three cases, they are subject to HIPAA regulations.

1463 But as you point out, these third-party consumer apps

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

1464 which collect data directly from patients are building
1465 databases and creating algorithms without that level of
1466 transparency or data protection.

1467 *Mr. Pallone. Well, thank you.

1468 Let me go to Dr. (sic) Shen from Siemens. You have
1469 testified about the vast amounts of medical data needed to
1470 train the tools, the AI tools, that Siemens is creating. Is
1471 all the consumer data that you use to train those tools
1472 regulated under HIPAA?

1473 *Mr. Shen. Yeah, thank you for the question, Ranking
1474 Member Pallone. So at Siemens Healthineers, we are deeply
1475 committed to safeguarding patient data and data privacy upon
1476 upholding the data protection standards that are set forth by
1477 HIPAA. I think it is essential to recognize that the data
1478 that is utilized to train these algorithms goes through a
1479 rigorous process of de-identification. So we actually use
1480 methods to remove all personal identifiable information, or
1481 PII, and any protected health information as well, and that
1482 is all done prior to doing any sort of AI algorithm training,
1483 and that ensures that all of that data security and privacy
1484 is respected for that patient.

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

1485 *Mr. Pallone. Well, you mentioned the importance of
1486 strong data security, so elaborate a little bit on why it is
1487 important, particularly in the context of consumers'
1488 sensitive healthcare data, of you will.

1489 *Mr. Shen. Yeah, absolutely. Another great follow-up
1490 question, Ranking Member Pallone. So what is very critical
1491 here is making sure that we want to _ we want to make sure
1492 that we have a healthy dataset that is utilized to train
1493 these algorithms, but at the same time we have to recognize
1494 and respect the data privacy and the patient confidentiality
1495 that has been established between the patient and the
1496 provider themselves. So when we work with our clinical
1497 partners to utilize data for algorithm training, we respect
1498 that _ those legal constricts that are already in place with
1499 the different providers that are there.

1500 On top of that, what we do within Siemens Healthineers
1501 is we also make sure we double check that the data that we
1502 received that has been said to be de-identified, we double
1503 check that that data is truly de-identified. So we go
1504 through the extra rigor to make sure that that data has been
1505 removed of all _ any PII or PHI that is there.

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

1506 *Mr. Pallone. Let me just _ thank you.

1507 Just quickly, only 30 seconds, but, Dr. Newman-Toker,
1508 what do you recommend on how AI developers can proactively
1509 identify and mitigate potential biases to prevent
1510 unintentional perpetuation of racial disparities in
1511 healthcare algorithms?

1512 *Dr. Newman-Toker. Sure.

1513 *Mr. Pallone. 15 seconds.

1514 *Dr. Newman-Toker. I will just that there _ you know,
1515 they are reasonable questions about how best to address
1516 genetic differences in human physiology that may correspond
1517 to macroscopic racial groups, but one this is clear, we
1518 should not be converting human racial biases into hard and
1519 fast AI-determined rules. I think that is a critical
1520 feature, and it is going to require that we adopt larger
1521 datasets that are represented _ representative of all the
1522 population with oversampling for minorities.

1523 *Mr. Pallone. Thank you.

1524 Thank you, Mr. Chairman.

1525 *Mr. Guthrie. Thank you. The gentleman yields back,
1526 and I know we had a markup since _ and we were able to talk a

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

1527 little bit, but Dr. Burgess also has announced he is not
1528 running for reelection, and I will say on our side of the
1529 aisle, probably in the entire Congress, there is nobody that
1530 has a more encyclopedic knowledge of healthcare policy. But
1531 more important of his just ability to absorb the facts and
1532 move forward is his passion for making sure that the
1533 healthcare system works the best and his compassion that it
1534 works for people that have the least ability to make it work
1535 for themselves, and someone who has become a dear friend of
1536 mine, and somebody I have a tremendous amount of respect for.
1537 And we have another year, but we are absolutely going to have
1538 an empty seat at this table next year from somebody who is so
1539 good at what he does.

1540 So, Dr. Burgess, you are recognized for five minutes.

1541 *Mr. Burgess. Thank you, Chairman, and thank you for
1542 those kind remarks. Probably kinder than I deserve.

1543 When you look at AI in the context of the existing
1544 ecosystem, if I can use that word in healthcare, it is not
1545 new and it is not unique. We have all had some experience
1546 with it, and like anything in healthcare, there is rarely a
1547 day that goes by _ or there is never a day that occurs where

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

1548 someone comes in to me and says, you know, I don't think we
1549 are regulated enough in healthcare. So I want to balance
1550 those two things, but we do need to be sensitive in finding a
1551 balance when we discuss improving the regulatory process and
1552 make sure that innovation is not clobbered in the process.

1553 So let me ask Dr. Schlosser and Mr. Shen both this
1554 question. If you can discuss the importance of clarifying
1555 the role of AI as a support tool rather than a primary factor
1556 in decision making and sort of extrapolate on what makes this
1557 distinction so significant in practice.

1558 *Dr. Schlosser. Yeah, thank you for the question. And
1559 I think this is an incredibly important distinction. The
1560 concept of human-in-the-loop, which I mentioned in my
1561 testimony, I think is a critical safeguard that we can use
1562 that will allow us to accelerate the use of AI and learn more
1563 about the capabilities of these tools, in particular these
1564 new versions of AI, the large language models, but do it in
1565 such a way that we still have a trusted physician or
1566 clinician between that AI model and the patient who
1567 ultimately is impacted.

1568 So the tool becomes an assistant that can provide

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

1569 decision support, advice, summarize data, bring new insights,
1570 but we rely on that physician or clinician to be the ultimate
1571 decision maker for that patient, and I think that gives us a
1572 level of safety that will allow us to continue to experiment
1573 and understand how to use AI going into the future.

1574 *Mr. Burgess. Very good.

1575 Mr. Shen?

1576 *Mr. Shen. Yeah, thank you, Congressman Burgess. And
1577 just to echo what Dr. Schlosser said, we also believe that
1578 artificial intelligence is here to be a companion for the
1579 clinician. So we fully understand the value of the
1580 patient/clinician or the patient/doctor relationship there,
1581 and what we want the AI to do here for that clinician is to
1582 provide more information, more context for that clinician to
1583 make that more informed diagnostic decision or that more
1584 personalized treatment decision for the patient.

1585 So we are not looking for AI to actually replace what
1586 that clinician is trying to do from a diagnosis or a
1587 therapeutic standpoint, but actually to help inform that
1588 clinician to be _ to make that more informed diagnostic
1589 decision or that more personalized treatment decision.

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

1590 *Mr. Burgess. We don't have time to get into in this
1591 hearing, but I also hope, and I make ask this to respond in
1592 writing, where the technology will lead to long-term savings.
1593 Of course, we have to be concerned about the deficit and the
1594 healthcare spend is one of the primary drivers there.

1595 But, Mr. Shen, staying with you, what is your experience
1596 been like, and I know Chairman Guthrie asked you this a
1597 little bit, but you got to work with Center for Medicare and
1598 Medicaid Services, and they make coverage determinations and
1599 reimbursement determinations, so how has that been working
1600 out for you?

1601 *Mr. Shen. Yeah. We have been working very closely
1602 with CMS to try to determine again what is the appropriate
1603 reimbursement as it relates to artificial intelligence. And
1604 I think where we see the biggest concern again is around the
1605 adoption of these AI solutions, and what we are hearing from
1606 providers and physicians is that they are _ they have this
1607 strong desire to want to adopt these AI solutions because of
1608 all the great benefits that we have talked about here this
1609 morning.

1610 The challenge again is that the uncertainty on whether

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

1611 they _ if they make an investment in AI, the uncertainty on
1612 whether they will receive any reimbursement or not coming
1613 back for that investment. There is just inconsistency
1614 coming _

1615 *Mr. Burgess. Yeah.

1616 *Mr. Shen. _ from CMS today. Yeah.

1617 *Mr. Burgess. This is a safe space. You can talk about
1618 CMS all you want. We won't tell a soul.

1619 [Laughter.]

1620 *Mr. Burgess. Dr. Nguyen, let me just ask you, Dr.
1621 Schlosser went into some detail in his written testimony
1622 about the large language model that he is using, and then you
1623 talked about a generative model for large language models,
1624 and I just wonder if it is possible to set down the patient
1625 interaction in iambic pentameter, which after all is the
1626 language of Shakespeare? That is what you referenced in your
1627 written testimony.

1628 *Dr. Nguyen. Yes, just to clarify, are you asking if it
1629 is possible to set down the patient experience in iambic
1630 pentameter using these models?

1631 *Mr. Burgess. Well, I was just intrigued by your

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

1632 statement, using the language of Shakespeare. So let's focus
1633 a little bit on drug development. Is there a place where
1634 this can play a role in drug development?

1635 *Dr. Nguyen. Yeah, absolutely. Drug development is a
1636 very complex process, right, involving many moving parts.
1637 There are many ways in which AI can be _

1638 *Mr. Burgess. But some of those are predictable at the
1639 level of the FDA, so as far as collecting the data that you
1640 are going to need to submit, the timeliness of the
1641 submission _

1642 *Dr. Nguyen. Absolutely.

1643 *Mr. Burgess. _ it seems like that AI would be a place
1644 where that could be organized and _

1645 *Dr. Nguyen. Exactly.

1646 *Mr. Burgess. _ if something is going to fail, maybe it
1647 could fail a little earlier and save everyone some time and
1648 trouble.

1649 *Dr. Nguyen. Exactly. Selection of population data,
1650 synthesis, administrating of the study, right, and the busy
1651 work around that are very clearly things that AI could assist
1652 in reducing the burden on.

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

1653 *Mr. Burgess. Well, I thank you all for being here
1654 today. Very informative panel and we are not done with this
1655 discussion.

1656 *Dr. Nguyen. Thank you.

1657 *Mr. Burgess. Thank you.

1658 *Mr. Guthrie. Thank you. The gentleman yields back.

1659 The chair now recognizes Mr. Cardenas _ the gentleman from
1660 California, Mr. Cardenas, for five minutes for questions.

1661 *Mr. Cardenas. Thank you, Chair Guthrie and Ranking
1662 Member Eshoo, for holding this timely hearing, and thank you
1663 to our witnesses for sharing your expertise and your
1664 opinions.

1665 Emerging AI technologies show an incredible promise to
1666 improve and plug gaps in our existing healthcare ecosystem.
1667 Many of you have already mentioned that these novel
1668 technologies have the potential to expand healthcare access,
1669 address outstanding disparities, and support the healthcare
1670 workforce. I have been clear in my support for advancing
1671 technologies that increase access and quality of care for all
1672 Americans, but there is also the potential for harm if we are
1673 not intentional about how to proceed forward.

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

1674 AI should make healthcare systems more equitable not
1675 less equitable, and because AI is only as good as the data it
1676 trains on or _ I worry about the possibility that these
1677 technologies may perpetuate or even widen existing health
1678 disparities. We have a responsibility to ensure AI
1679 innovation in healthcare is developed carefully and reliably
1680 if we truly want to harness its full potential.

1681 I have a question for Dr. Newman-Toker. Dr. Newman
1682 (sic), you mentioned in your testimony that those in rural or
1683 underserved communities or those with social determinants of
1684 health associated with generally worse health outcomes may be
1685 most susceptible to suffering adverse consequences of
1686 inadequately regulated AI systems. Can you expand on the
1687 kinds of consequences we have already seen?

1688 *Dr. Newman-Toker. Yes. Obviously, we have populations
1689 that are at risk. These are individuals who do not
1690 necessarily have good access to healthcare in the first
1691 place, and on the positive side, we hope that AI will offer
1692 the opportunity to deliver higher quality care, greater
1693 access to expertise. On the downside, there are obviously
1694 concerns about whether AI systems will either be accessible

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

1695 to those individuals at all, for example, there may be
1696 broadband access problems or other issues that constrain
1697 their ability to even access technologies even if they are
1698 broadly available.

1699 And we have further issues about health literacy, the
1700 ability to use such tools, and beyond that, the issue of
1701 whether _ when AI systems do potentially fail or make errors,
1702 they may be less equipped to be able to deal with those
1703 problems.

1704 *Mr. Cardenas. Thank you. What should Congress keep in
1705 mind as we look to AI to improve health equity and protect
1706 against worsening disparities? Yes, go ahead.

1707 *Dr. Longhurst. I appreciate your question. We have
1708 talked on this panel about the importance of transparency and
1709 some of our vendor colleagues talked about submitting to the
1710 FDA the results of internal testing, but it is important for
1711 this subcommittee to recognize those are all self-reported
1712 tests, and so the Coalition for Health AI, or CHAI, has
1713 recently proposed a series of national labs that would serve
1714 as testing beds for vendor-supplied AI algorithms. I think
1715 that is something that should be reviewed in more detail

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

1716 because having an external testing is the way that we are
1717 going to mitigate these health equity kind of issues that
1718 come up from algorithms developed on biased datasets.

1719 *Mr. Cardenas. Thank you. One of the things that I am
1720 concerned about we have seen in the past with incredible
1721 innovations that make it easier for people to make
1722 conclusions. For example, back in the day when the term
1723 credit score didn't even exist. I was told at the time when
1724 I said, wait a minute, you are going to use this as the _ not
1725 the backdrop, but you are going to use this as a primary
1726 driver of who is going to get access to capital across
1727 America and now across the world.

1728 And they said, no, no, no, no, it is just a side tool.
1729 No, it is now the main tool. The old days of having a big
1730 file and having a whole review before they make a decision is
1731 gone. But my point is this, there are proprietary
1732 algorithms. The government of the United States doesn't even
1733 have a clue what those algorithms are. Nobody does but the
1734 actual proprietor, and it is protected. And I respect that
1735 protection because they have done a lot and invested much
1736 into that.

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

1737 So it is, in fact, proprietary, but the problem is this,
1738 nobody knows what is happening in that black box. That is
1739 one of my concerns with AI, especially when it comes to not
1740 only quality of life but whether or not who lives or dies
1741 based on an algorithm's decision as to what is going to be
1742 the outcome or the cure or if someone is even going to get
1743 access to healthcare because they say, no, yours is not an
1744 emergency situation so therefore you are not going to get
1745 cared for.

1746 *Dr. Longhurst. Yeah. We 100 percent agree with you,
1747 and we see the increasing rate of denials of payor claims and
1748 we know that that is being driven in part by AI processing
1749 these claims and very rapidly denying them in an inequitable
1750 way, and so we share your concerns.

1751 *Mr. Cardenas. Well, we already have concerns, we
1752 already have examples, and I hope that we in Congress
1753 actually do our job and actually try to move hopefully as
1754 fast as AI has in order to make a better future for us.

1755 Sorry that I went over my time, Mr. Chairman. I yield
1756 back.

1757 *Mr. Guthrie. The gentleman yields back. The chair

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

1758 recognizes the gentleman from Ohio, Mr. Latta, for five
1759 minutes.

1760 *Mr. Latta. Well thanks, Mr. Chairman, and thanks to
1761 our panel for being witnesses today. I _ it is very, very
1762 important because AI is something that I applaud our
1763 chairwoman of the full committee through all of our
1764 subcommittees that we have been having hearings on AI and how
1765 important this issue is as we go forward, especially when we
1766 are talking about on the healthcare side because this is _
1767 especially technology, that we do have to put those
1768 guardrails in place making sure that we protect the privacy
1769 of Americans and to also prevent other countries, especially
1770 countries like China, from abusing it.

1771 Also in this subcommittee it has also been interesting
1772 through the years, and it has been brought up in your
1773 discussion today, again we were trying to help the providers
1774 out there being able to do what they are supposed to do. You
1775 know, we have a shortage of healthcare providers, the docs
1776 that we have had before us today when I have asked them
1777 questions, I remember one panel especially said _ I think it
1778 was about as many as is at this table today, I said, how many

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

1779 of you spend _ how much time are you spending actually seeing
1780 your patients, and I don't think one of them said more than
1781 50 percent. And so when you have a shortage of doctors out
1782 there, and nurses, and everyone else, it is important that
1783 they are doing that job that is actually essential to get it
1784 done.

1785 Dr. Newman-Toker, in 2021 more than 100 drug and
1786 biologic applications included AI and machine learning
1787 components. Would you explain to the subcommittee if we
1788 continue to explore AI how this could lead to further
1789 breakthrough developments?

1790 *Dr. Newman-Toker. Thank you, Congressman, for the
1791 question. What I would say is that as we look to the space
1792 of drug development, you can imagine in the same way as in
1793 general with healthcare that there are opportunities for AI
1794 to help both in the process itself, that is the mechanics of
1795 working your way through the regulatory process as well as
1796 through the identification process of actual treatments. So,
1797 for example, if we have large datasets that allow us to
1798 identify drug therapies that are available to us, then I
1799 think that that will give us an opportunity to break new

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

1800 ground using existing data architectures.

1801 *Mr. Latta. Oh, well thank you very much.

1802 Dr. Schlosser, when I was reading your testimony, it was
1803 kind of interesting. I got a question because it _ I thought
1804 it was kind of interesting when you _ the technology uses the
1805 ambient speech models to transcribe the doctor/patient
1806 interactions and detects in emergency rooms. And because,
1807 you know, we all have the opportunity to visit our hospitals
1808 and especially because being on this subcommittee, I go
1809 through a lot of different emergency rooms and, you know, you
1810 _ the stress that happens there. How _ I am curious, because
1811 of the stress and everything that is there, how does the
1812 technology eliminate that stress to make sure you are getting
1813 the perfect absolutely a hundred percent of what you got to
1814 have to be transcribed for that patient?

1815 *Dr. Schlosser. Yeah. Well _ and thank you for the
1816 question. And I will go back to a comment I have made
1817 several times now which is the human-in-the-loop, and that we
1818 always have the physician and their opportunity to review the
1819 note as that last step before it would ever become part of
1820 the electronic health record so that they can ensure that it

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

1821 is a hundred percent accurate. The AI is not at the point
1822 yet where it can do that completely on its own.

1823 We are using the data through data sharing agreements to
1824 continue to improve the quality of the AI and it continues to
1825 get better and better, which means it saves them more and
1826 more time, they have to do less editing at the end of the
1827 event. But right now we do need those physicians to still be
1828 vigilant.

1829 As you identified, the emergency room is a chaotic and
1830 challenging environment. That is actually why we took that
1831 technology there in the first place. We feel like it has the
1832 most to offer in that space where precious time given back to
1833 the physicians so they can really tune into what is going on
1834 with that patient will actually yield meaningful quality
1835 results.

1836 *Mr. Latta. Well, thank you very much.

1837 Dr. Longhurst, you said something interesting in your
1838 testimony. You said that we have to have the ethical review
1839 of AI. Would you just delve into that ethical review of AI a
1840 little bit more, please?

1841 *Dr. Longhurst. Yeah. So our health AI committee,

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

1842 which has been around for some years, is staffed by legal,
1843 and compliance, and risk management, and clinicians. It is
1844 cochaired by several of our internal medicine physicians. It
1845 includes health equity researchers and bioethicists, and the
1846 reason for that is to look at things like what is the ethics
1847 of being transparent in this case, is that an ethically
1848 appropriate thing to do or are there ethically-challenged
1849 questions.

1850 And so that actually helped to raise for us when we
1851 first implemented generative AI to help our clinicians
1852 respond to patient messages, that question was raised by our
1853 ethicists, should we be transparent with our patients, and
1854 that generated the conversation that resulted in full
1855 transparency to our patients about the fact that we are using
1856 generative AI to help with our responses, even though there
1857 is still a human in the loop, even though those messages are
1858 still edited by clinicians at the end of the day.

1859 *Mr. Latta. Well, thank you very much.

1860 Mr. Chairman, my time is expired, and I yield back.

1861 *Mr. Bucshon. [Presiding.] The gentleman yields back.

1862 I now recognize Dr. Ruiz from California for five minutes.

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

1863 *Mr. Ruiz. Thank you, Mr. Chairman. Our healthcare
1864 system is strained by widespread healthcare workforce
1865 shortages, burnout, and barriers to care for patients. As
1866 members of Congress, we must work together to create a
1867 healthcare system that is sustainable, fair, and always puts
1868 the patient first. It is important to now only support
1869 advancements that improve patient quality of care and
1870 strengthen the workforce but also ensure that we are
1871 addressing barriers to care that affect underserved
1872 communities, communities that need the care the most due to
1873 the disparities of health and the burden of those disparities
1874 on those communities.

1875 As the witnesses here today have underscored, innovation
1876 in AI has the potential to address these concerns and improve
1877 patient care. However, these technologies also pose
1878 potential risks that we must carefully consider and mitigate
1879 as the technology continues to develop. As an emergency
1880 medicine physician, I am all too familiar with the
1881 administrative burden that physicians face and the negative
1882 impact that can have on patient care.

1883 Dr. Schlosser, how is AI currently helping physicians

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

1884 cut down on administrative burdens so they can focus their
1885 efforts on patient care, and how does this affect the quality
1886 of patient care?

1887 *Dr. Schlosser. Thank you for the question, Mr. Ruiz.
1888 And I agree completely with your comments about the burnout
1889 and administrative burden that our clinicians are seeing. As
1890 I just mentioned and mentioned in my testimony, we focused in
1891 two areas. One is around documentation improvement.
1892 Documentation takes up an inordinate amount of our
1893 clinicians' time, and if we can return that time to them so
1894 they can focus on patients, on underserved patient
1895 populations, we believe we can actually create an expanded
1896 healthcare workforce using just the clinicians we already
1897 have by simply automating and removing some of those tasks.

1898 We are also looking at AI as an assistant to our nurses.
1899 Our nurses are under the same kind of pressure our physicians
1900 are from shortage and burnout, and so giving them tools that
1901 helps them do their job, like the nurse handoff tool we
1902 talked about in the testimony where we can automate a piece
1903 of their workflow, making it easier for them to spend time at
1904 the bedside with patients, we think both of those will lead

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

1905 to improved experience and bring some of the joy back into
1906 caring for patients.

1907 *Mr. Ruiz. Thank you.

1908 Dr. Nguyen, your testimony mentioned specifically how
1909 Transcarent uses generative AI in your virtual clinic. What
1910 safety mechanisms are in place to protect patient safety when
1911 using generative AI in health settings?

1912 *Dr. Nguyen. Absolutely. Absolutely, yes. To clarify,
1913 generative AI is still being prototyped internally at
1914 Transcarent. We do use non-generative AI in our clinic.
1915 Safety mechanisms, though, to consider when you are building
1916 generative AI or any AI applications really involve safety at
1917 every layer, right, so when you are building these systems,
1918 you need to think about the data layer first, right, and
1919 ensure that you don't have a garbage in/garbage out system _
1920 problem in your system.

1921 You also need redundant safety mechanisms. I mentioned
1922 earlier the use of narrow versus general AI systems. You
1923 want to build redundant safety mechanisms that can detect
1924 things like patients asking questions that indicate they
1925 might have a medical emergency, right? You want those

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

1926 specialized systems in place ensuring, right, that you have a
1927 high degree of likelihood that you are going to catch issues
1928 like that. And so, you know, you want those redundant layers
1929 in order to ensure the highest level of patient safety.

1930 *Mr. Ruiz. Dr. Newman-Toker, what would be the
1931 ramifications of AI biases in healthcare if it is not
1932 addressed at this point in AI development, and what strategy
1933 should we be _ should be implemented to detect and mitigate
1934 biases in AI models used for healthcare?

1935 *Dr. Newman-Toker. It is a great question. Thank you,
1936 Congressman. What I would say is that obviously we don't
1937 want to concretize the racial biases that we see in _ and
1938 other demographic biases that we see in human behavior today
1939 in the form of mathematical algorithms. To prevent that, we
1940 need to do work both on the side of developing the AI tools
1941 using appropriate datasets. We also need to deal with at the
1942 back-end monitoring for these kinds of problems, both using
1943 sophisticated tools to identify bias as has been done in a
1944 number of recent studies, and furthermore, to monitor for
1945 outcomes of healthcare associated with AI so that we can
1946 monitor for measures that matter for patients who are

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

1947 underserved.

1948 *Mr. Ruiz. Thank you, I appreciate that. Thank you all
1949 for your insight into the benefits and potential risks of
1950 using AI in healthcare. This insight is especially important
1951 to ensuring this innovative technology is used to improve
1952 patient care, improve access to care, reduce healthcare
1953 disparities, reduce the barriers in underserved communities,
1954 and improve equity by giving resources and healthcare
1955 attention to locations that need them the most, while
1956 mitigating biases and potential risks to patients.

1957 And I yield back my time.

1958 *Mr. Bucshon. The gentleman yields back. I now
1959 recognize Mr. Griffith for five minutes.

1960 *Mr. Griffith. Thank you very much, Mr. Chairman. I
1961 appreciate it.

1962 Dr. Longhurst, I am going to pick on you first because I
1963 loved this book, "The Perfect Predator," which is written by
1964 one of your colleagues. And so my question is _ and for
1965 those who don't know, it is about phage therapy and the
1966 saving of her husband's life, Thomas Patterson, who also is a
1967 UC San Diego individual, by finding the right virus to attack

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

1968 the antibiotic-resistant bacteria that had attacked his body.

1969 It is a great story if anybody wants to read it.

1970 The question is, are you all using AI to try to find
1971 more of those phage therapy-type viruses, and if not, do you
1972 see any potential in that?

1973 *Dr. Longhurst. Great question, and thank you for
1974 referring to the book, "The Perfect Predator.'" It is an
1975 amazing story of a life saved by phage therapy.

1976 Something that was actually explored prior to the advent
1977 of antibiotics and now we have gone back with antibiotic
1978 resistances to looking for solutions outside of that domain,
1979 and so it started a whole movement across the world.

1980 We do have a center at UC San Diego pursuing expansion
1981 of phage therapy for treatment of serious bacterial
1982 infections. I am not aware that we are currently using AI to
1983 help with that center, but as previously mentioned, I think
1984 in general drug discovery will be augmented by the use of AI,
1985 and I am very optimistic that we are going to see large
1986 language model generated hypotheses about new ways of
1987 treating patients that we may not have previously examined
1988 hypothetically. So thank you.

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

1989 *Mr. Griffith. And that was a little bit off script. I
1990 am going to go back to script, but it is the _ I am going to
1991 flip the coin over on the other side.

1992 According to reporting, the use of artificial
1993 intelligence has the potential to allow for generative large
1994 language models like ChatGPT and other chatbots to revive old
1995 deadly pathogens. So we have talked about how it can help.
1996 It can also be used to revive old deadly pathogens or even
1997 create new deadlier ones. One example was done at MIT where
1998 students were able to get the large language models to
1999 suggest four potential pandemic pathogens within one hour by
2000 asking a series of questions to a generative large language
2001 model.

2002 Further, researchers in Cambridge, Massachusetts used
2003 open-sourced language _ excuse me _ open-sourced large
2004 language model asking it how to revive the 1918 Spanish Flu.
2005 Several participants found obtaining the 1918 virus Spanish
2006 Flu would be feasible for someone with basic wet lab skills
2007 while one participant got "very close" to learning all the
2008 steps needed to obtain the virus.

2009 So I am going to go to you, Dr. Nguyen. I was

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

2010 encouraged to see the White House put out an executive order
2011 to attempt to provide more oversight and security on this
2012 type of AI, but this still causes grave concern. Do you know
2013 if any AI technologies have security limits on what can be
2014 asked and what cannot be asked?

2015 *Dr. Nguyen. Thank you, Congressman, that is a very
2016 good question. In a broader sense even outside of
2017 healthcare, right, these AI technologies have extremely broad
2018 and wide capabilities, many of which we don't fully
2019 understand yet. While this is outside the realm of the kind
2020 of AI Transcarent uses, AI in general, especially generative
2021 AI in a large language model sense, the _ in that field there
2022 is the world of alignment research, right?

2023 The world of alignment research refers to the science of
2024 studying the malicious capabilities of these models and
2025 studying the ways in which we can defend against them. So in
2026 that world, right, it _ very, very important work is being
2027 done to find things such as what you are describing, right,
2028 which is vectors of malicious use. There is still a lot of
2029 work to be done in that world, and I think it is very
2030 important for us in the healthcare world to follow that,

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

2031 acknowledge it, for this committee to support that kind of
2032 work.

2033 *Mr. Griffith. So we want to look on the positive side,
2034 but one of the articles I was reading indicated that the
2035 proponent said maybe we need a _ some kind of a test ban
2036 treaty like we do with nuclear weapons. Do you think that we
2037 should be looking at some kind of a limitation on the test?
2038 I mean, we want the positives, but the negatives could also
2039 be very consequential.

2040 *Dr. Nguyen. Yeah, that is a very good question as
2041 well. I think it is very difficult to truly limit the
2042 progress, you know, of testing these systems and making them
2043 safe without using them, right, and trying to push them to
2044 their limits, right? So I think it requires a measured
2045 approach. The other risks, though, of course of test banning
2046 is that countries other than the United States will also,
2047 right _

2048 *Mr. Griffith. Right.

2049 *Dr. Nguyen. _ make progress _

2050 *Mr. Guthrie. Right. I am going to switch gears again.
2051 Back to you, Dr. Longhurst. You mentioned in your testimony

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

2052 the AI-based messaging system was helpful for virtual care
2053 visits and allowing doctors to provide more care to patients.
2054 The question is, did the patients trust the system and find
2055 benefit from those automated responses?

2056 *Dr. Longhurst. Thank you for your question. I know we
2057 are expired on time. I will say briefly that anecdotally we
2058 have gotten very positive feedback from patients, and we are
2059 submitting more quantitative data for publication.

2060 *Mr. Griffith. Thank you very much, and I yield back.

2061 *Mr. Bucshon. The gentleman yields back. I now
2062 recognize the gentlelady from Michigan, Mrs. Dingell, for
2063 five minutes.

2064 *Mrs. Dingell. Thank you, Mr. Chairman. We are living
2065 in an increasingly technological world and the emergence of
2066 new technologies, like AI, has the ability to reshape _ or
2067 shape the way, as you all have been talking about, address
2068 public health and improve patient outcomes. And as we keep
2069 talking about, and I have got many concerns like others have
2070 expressed here, on the other hand, AI does pose serious risks
2071 that left unchecked can harm patients and quite frankly our
2072 national security.

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

2073 But as this subcommittee has discussed, and COVID-19
2074 pandemic has taught us a lot about the fragility of our
2075 healthcare supply chains and how vulnerable they are to
2076 disruptions. It is really a national security issue, and we
2077 have learned that during COVID. How can we keep our Nation
2078 safe if we can't access the medicines, the devices, and
2079 protective equipment we need to protect communities from
2080 public threats?

2081 Earlier this month I joined a panel for a discussion on
2082 healthcare supply chains and what we think these supply
2083 chains will look like in the future. In addition to
2084 identifying ways to reduce our reliance on overseas
2085 manufacturers and bring these supply chains home, we all
2086 agreed we need to find ways to strengthen our existing supply
2087 chains to improve transparency and increased efficiency.

2088 Mr. Shen, I think AI has a role to play in all of this.
2089 How does AI support healthcare supply chain management?

2090 *Mr. Shen. Yeah. Thank you for the question,
2091 Congresswoman. I think for artificial intelligence here,
2092 artificial intelligence has the ability to be able to drive
2093 efficiencies as it relates to the supply chain here. So

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

2094 being able to leverage computing power to be able to simplify
2095 some of the processes that today are dependent on other
2096 components, maybe some of those that are outside the U.S.
2097 here, but being able to leverage artificial intelligence to
2098 be able to accelerate the ability to drive delivery and
2099 efficiency of supplies that are needed.

2100 We see this directly within the solutions that we make
2101 here at Siemens Healthineers that we try to leverage to
2102 computing power here to be less reliant on certain components
2103 that might not be accessible here, and we saw the success of
2104 that during the pandemic itself by being able to deliver
2105 still diagnostic equipment and therapeutic technologies to
2106 patients and providers during that time.

2107 *Mrs. Dingell. Drug shortages _ thank you for that _
2108 are a persisting challenge that threaten patient's health and
2109 wellbeing. This summer was really _ we saw very real
2110 shortages. We are still seeing them now. I don't know why I
2111 saw this summer.

2112 We continue to see shortage of critical cancer drugs,
2113 like cisplatin and carboplatin, but during last year's flu
2114 and RSV season, parents across the country had difficulty

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

2115 finding common over-the-counter pain relievers such as
2116 Tylenol and Advil for their kids as well as the antibiotic
2117 amoxicillin which is used to treat common infections.

2118 Mr. Shen, how are suppliers already using AI to address
2119 these drug shortages?

2120 *Mr. Shen. Yeah, again, thanks for the question again.

2121 *Mrs. Dingell. And it is real, serious.

2122 *Mr. Shen. Yes. Yes, it is. It is a challenge, but I
2123 think that is what is the exciting part about artificial
2124 intelligence and its ability here to be able to drive
2125 efficiencies within the processes that are established.
2126 Within Siemens Healthineers, we leverage artificial
2127 intelligence both _ not only to provide solutions to take
2128 care of patients, but we also use that to improve the
2129 processes that we have internally within our organization
2130 that allows us to be able to deliver diagnostic and
2131 therapeutic imaging solutions to our _ to providers, to
2132 physicians in a timely fashion and making sure that patients
2133 receive the latest technology available _ medical technology
2134 available to help them with their diagnosis.

2135 *Mrs. Dingell. Thank you. We got to keep working on

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

2136 it, though.

2137 During the pandemic we also saw tremendous need to
2138 ensure limited resources were strategically going to the
2139 communities and patients that needed them the most. Dr.
2140 Newman-Toker, how can AI help us determine how to best
2141 allocate our resources?

2142 *Dr. Newman-Toker. Thank you for the question,
2143 Congresswoman. Obviously, we have heard a little bit from
2144 Mr. Shen about the architecture of AI allowing us to improve
2145 the allocation of resources. I think one of the critical
2146 issues in this space is about having the right data
2147 architectures to be able to get to the point where AI can
2148 actually help us in those ways.

2149 So often the key problem is that we don't have the right
2150 kinds of information about where the shortages exist and how
2151 _ and where the mismatch is between supply and demand. So I
2152 think that is one of the critical pieces of the puzzle. If
2153 we want AI to work properly, we are going to have to create
2154 datasets that are digestible by AI for real-time use.

2155 *Mrs. Dingell. I am out of time. So, Mr. Chairman, I
2156 have more questions for the record and ask _ thank the

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

2157 witnesses for being here.

2158 *Mr. Bucshon. The gentlelady yields back. I now
2159 recognize the gentleman from Florida, Mr. Bilirakis, five
2160 minutes.

2161 *Mr. Bilirakis. Thank you, I appreciate it, Doctor.
2162 Mr. Shen, can you tell us about the role of generative
2163 AI, what it is and what its potential can be within the
2164 healthcare sector? I know it is a general question but _ and
2165 I know others have asked this question, but it is so very
2166 important. Please.

2167 *Mr. Shen. No, I appreciate that, Congressman.

2168 *Mr. Bilirakis. Yeah.

2169 *Mr. Shen. So certainly my colleagues have also talked
2170 about generative AI, so perhaps maybe I will talk about it as
2171 it relates to medical imaging and where we see the impact _

2172 *Mr. Bilirakis. Sounds good.

2173 *Mr. Shen. _ for patients. So with generative AI here,
2174 where we see the greatest potential is the ability for the AI
2175 to consume more information about the patient themselves. So
2176 when a patient actually goes to get an exam done to get a
2177 diagnosis, for example, leveraging generative AI gives them

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

2178 the ability to know exactly what precise diagnosis should we
2179 be looking for. Yeah. So not just doing a test just for the
2180 sake of doing a test on that patient but actually doing a
2181 test because we are seeking a particular diagnosis that is
2182 happening there.

2183 So that actually, if you think about it, helps the
2184 patient not go through _ avoid going through multiple exams
2185 just trying to look for what the issue is here. So that is
2186 potentially one area.

2187 The other area where generative AI has some benefit from
2188 a medical imaging standpoint is actually the interpretation
2189 of the images themselves. So the ability to be able to take
2190 all this complicated medical language and convey the
2191 diagnosis to layman's terms for the patient themselves so the
2192 patient gets a better understanding of what is going on and
2193 the test results that they have had from that exam.

2194 *Mr. Bilirakis. Oh, that is great stuff. We appreciate
2195 _ very exciting.

2196 Mr. Shen, I appreciate that your testimony mentions the
2197 use of predetermined change control plans. And I was proud
2198 to lead the effort in the House last Congress to authorize

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

2199 the use of the PCCPs through my bill that got enacted into
2200 law last year. Can you describe the PCCP pathway and explain
2201 to us how this can allow for a more efficient regulatory
2202 framework and why it is so important to ensure that FDA
2203 implements this bill effectively.

2204 *Mr. Shen. Yeah. Thank you. Thank you, Congressman.
2205 And again, thank you very much for the PCC effort. Yeah, so
2206 enactment of the Predetermined Change Control Plan allows
2207 organizations like Siemens Healthineers to include in our
2208 initial FDA product application a description of how the
2209 software will be updated rapidly based on new data as it
2210 comes about. So without the need to have to resubmit back to
2211 the FDA any sort of application or supplement every single
2212 time an update happens. So this really helps accelerate and
2213 go in conjunction with all the rapid development around a
2214 technology like artificial intelligence.

2215 The PCC itself, we have to include a description of the
2216 modifications, the methodology that we are using so we
2217 provide that transparency that is needed, that we have talked
2218 about here today, as it relates to that technology here. And
2219 again, we are very, very pleased that the _ with your help

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

2220 there that we were able to _ that we are able to move forward
2221 and make sure that PCCP is part of the FDA process going
2222 forward.

2223 *Mr. Bilirakis. Thank you. Excellent.

2224 One question for Dr. Schlosser. Can you elaborate on
2225 the potential that large language models have in reducing
2226 provider burden within the hospital settings, please?

2227 *Dr. Schlosser. Yeah, absolutely. Thank you for the
2228 question, Congressman. So as I mentioned in my testimony, I
2229 think there are numerous opportunities where our current
2230 healthcare system has created what we refer to as
2231 administrative burden, added tasks to physicians, nurses,
2232 pharmacists, other healthcare providers that don't directly
2233 add value to the patient where they are acting as data entry
2234 analysts or transferring information between different
2235 providers or different systems.

2236 And large language models are actually really good at
2237 those types of tasks. If we can train them to understand the
2238 data, which is part of the challenge, they can search for
2239 information, read complex medical charts, find information
2240 from multiple disparate sources, synthesize and understand

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

2241 it, and then serve it up to the healthcare providers in their
2242 workflow. And then because they are language models, you can
2243 actually interact with them in a natural language way. You
2244 can ask questions and get feedback.

2245 And so it is a really powerful tool to make the universe
2246 of healthcare information around a patient simple and easy to
2247 access.

2248 *Mr. Bilirakis. Very good. Good stuff.

2249 I yield back the rest of my time, Mr. Chairman.
2250 Appreciate it.

2251 *Mr. Bucshon. The gentleman yields back. I now
2252 recognize the gentlelady from Illinois, Ms. Kelly, for five
2253 minutes.

2254 *Ms. Kelly. Thank you, Chair Guthrie and Ranking Member
2255 Eshoo, for holding today's critically important hearing.

2256 The integrating of AI in the healthcare system offers a
2257 potential to be a transformative solution to address long-
2258 term disparities in access issues. Many in both the
2259 healthcare and technology fields have promoted AI as a means
2260 to create a more accessible and equitable healthcare
2261 landscape, particularly in minority, underserved, and rural

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

2262 communities.

2263 Dr. Newman-Toker, I am hopeful about the potential
2264 synergy of AI's ability to improve clinical trial diversity
2265 by scanning multiple databases for clinical site placement
2266 and patient populations with the hopes that diverse patient
2267 populations can be matched with clinical trials, thus
2268 resulting in a more efficient and diverse recruitment
2269 process.

2270 What incentives or regulations need to be considered
2271 regarding AI's use to improve clinical trial diversity?

2272 *Dr. Newman-Toker. Thank you for the excellent
2273 question, Congresswoman. Clearly diversity in clinical
2274 trials is an essential component of eliminating health
2275 disparities. We have seen that a large number of treatments
2276 that we have studied over the course of time have only been
2277 studied in white men or very restricted populations with
2278 minorities, and I do think that the potential of AI to
2279 identify locations and places where patients can be recruited
2280 is a strong one.

2281 In terms of the regulatory framework, I do think that
2282 some of the existing architectures around clinical trial

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

2283 requirements for diversity are _ I think are important. I
2284 think we are going to have to make sure that we further
2285 bolster that as we get deeper into the AI space in order to
2286 make sure that we are having overrepresented groups of
2287 minorities so that we can do proper subgroup analysis across
2288 demographic groups.

2289 *Ms. Kelly. Thank you. Additionally, this body has
2290 worked in a bipartisan manner to decrease the length of time
2291 for prior authorization to Medicare populations, so while I
2292 am supportive of the use of AI to improve the timeliness of
2293 prior authorizations, I am concerned about multiple recent
2294 articles on the use of AI in prior authorizations and the
2295 association with high rates of claim denials.

2296 So, again, Dr. Newman-Toker, the reliance on AI for
2297 crucial medical decisions introduces the risk of patient
2298 harm. Rigorous testing and validation are imperative to
2299 ensure the safety and efficacy of these technologies
2300 preventing errors or misinterpretations that could have
2301 severe consequences for patient wellbeing. In your review of
2302 these AI systems embedded in prior authorizations, can you
2303 explain why we are currently seeing such disappointing

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

2304 outcomes and what can we do to help mitigate these
2305 troublesome findings?

2306 *Dr. Newman-Toker. Thank you for the excellent
2307 question, Congresswoman. I do think part of the problem here
2308 is that this is _ there is a preexisting arms race in the
2309 space around claims with insurers generally trying to find
2310 ways to reduce their expenditures and deny more claims and
2311 providers trying to increase their claims and the revenue
2312 that is generated associated with this, and now we are seeing
2313 that escalate into the AI space.

2314 I think when we think more broadly about the issue of
2315 regulation here, what _ we have been talking a little bit
2316 about AI used in the context of healthcare with patients. I
2317 think what you are alluding to is all of the AI that may
2318 exist out in the periphery, around the problem, and that is a
2319 totally unregulated space, and that is a potentially
2320 dangerous area because we have no idea even what systems are
2321 being used for controlling the process of healthcare or
2322 access to healthcare, or even direct to patients in the form
2323 of symptom checkers and otherwise. All of these things exist
2324 outside of our regulatory frameworks, and I do think we need

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

2325 to start bringing some of those into the regulatory
2326 framework.

2327 *Ms. Kelly. Thank you.

2328 Dr. Longhurst, I have to give you a chance to comment
2329 because you are shaking your head.

2330 *Dr. Longhurst. Well, your questions I think are
2331 incredibly pertinent and not only do we need to think about
2332 the diversity of clinical trial participants and ensuring
2333 equity in how this is impacting the healthcare system and
2334 care of patients, we also need to think about our workforce
2335 and ensuring that we are creating diversity in the AI
2336 workforce. Previous comments suggested we need to train our
2337 medical students and other young professionals in these new
2338 technologies, and I think that is absolutely correct, and I
2339 think we are at risk of making these technologies only
2340 available to those who can afford them.

2341 And so I want to use this opportunity to express my
2342 strong support for the bipartisan proposed legislation Create
2343 AI, creating resources for every American to experiment with
2344 Artificial Intelligence Act of 2023 which would establish the
2345 National Artificial Intelligence Research Resource or NAIRR.

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

2346 Both UC San Diego and the University of California Office of
2347 the President strongly endorse this Create AI proposal
2348 because it would provide the opportunity for academic
2349 researchers to develop better methods and knowledge on the
2350 systems. But it is not just for academics, right, it is for
2351 small businesses, nonprofits, and other organizations.

2352 So thank you for that proposed legislation.

2353 *Ms. Kelly. Thank you, and I yield back. Thank you.

2354 *Mr. Bucshon. The gentlelady yields back. I now
2355 recognize Mr. Johnson from Ohio, five minutes.

2356 *Mr. Johnson. Thank you, Mr. Chairman, and thanks to
2357 our panelists for being here today. You know, artificial
2358 intelligence or AI is creating quite a buzz around Capitol
2359 Hill. That is to say the least. Even across the country.
2360 It has been met with both excitement and concern. Whether
2361 the American people realize it or not, AI is already
2362 prevalent in many sectors, particularly in the healthcare
2363 space.

2364 I have always been an advocate for innovation and
2365 development of new technologies, and AI is no different in
2366 this regard. I worked with AI when AI literally was just a

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

2367 buzz word back in the early 1980s when I was in graduate
2368 school at Georgia Tech, so I am very familiar with the
2369 technology. But simply put, AI is a tool that our medical
2370 professionals and scientists can use to not only further the
2371 development of care and therapeutics resulting in better
2372 outcomes for patients but hopefully lower cost to families
2373 and the taxpayer.

2374 Unlike the vast majority of Congress, I _ as I
2375 mentioned, I actually have a tech background, and in my time
2376 in the military as well as the time spent in the private
2377 sector. I worked in information technology, and I understand
2378 the benefits and challenges of AI. It has been around for
2379 decades.

2380 Take electronic health records, for example. As
2381 Congress continues to incentivize adoption, and rightfully
2382 so, we are saddling healthcare systems with an immense amount
2383 of data. From patient notes to imaging, doctors and nurses
2384 are expected to utilize all this information to best treat
2385 their patients. That is a lot easier said than done. It is
2386 a lot of information.

2387 This is a perfect example of how AI can be utilized in

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

2388 reading and deciphering all this data. They can make these
2389 health records more digestible and ultimately increase
2390 outcomes for everyone. Not to mention lessening the
2391 administrative burden for physicians, nurses, and healthcare
2392 systems nationwide.

2393 Generative AI has gotten a lot of attention, a result of
2394 ChatGPT, and Claude, and other public-facing technologies
2395 that have been widely used over the last year. However,
2396 generative AI has been used in healthcare for years through
2397 patient engagement technologies and clinical decision support
2398 models.

2399 So my first question. Dr. Schlosser, do I have that
2400 right? Am I saying that right?

2401 *Dr. Schlosser. That is right.

2402 *Mr. Johnson. Thank you. What are some of the other
2403 promising ways you see generative AI integrating into the
2404 healthcare system?

2405 *Dr. Schlosser. Yeah, thank you for the question, Mr.
2406 Johnson. And there is numerous opportunities. I think the
2407 one you highlighted around making the vast universe of data
2408 that clinicians and physicians have to access more easy to

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

2409 access is one we are incredibly excited about.

2410 We are working right now with one of our partners on
2411 what is essentially an AI assistant in your pocket so that
2412 you can interact with the electronic health record as well as
2413 the entire information health exchange through a natural
2414 language interface allowing you to search for and look for
2415 information that otherwise it would take a long time and it
2416 is very burdensome. If you ever have seen a CCD, which is
2417 the output of the HIE, it is this giant list of data that is
2418 the way that information is provided, it is incredibly
2419 difficult to use.

2420 But these models actually are capable of doing more than
2421 just read and understand information. We have taught a model
2422 to look at our staffing schedules across an entire hospital
2423 and are able to ask it questions like how do we better
2424 balance Friday nights. And so we can deploy our labor
2425 workforce in a much more efficient and effective way by
2426 harvesting the intelligence contained within these large deep
2427 learning models to solve complex problems that previously
2428 were put on nurse leaders or others that just struggle to
2429 have the information and to deliver the outcomes we are

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

2430 looking for.

2431 *Mr. Johnson. Let me get to a second question. What
2432 about rural and underserved populations like Eastern Ohio and
2433 Appalachia where I live? What can Congress do to facilitate
2434 more adoption of these technologies across smaller and rural
2435 practices to make our healthcare system more personalized and
2436 ensure every patient and provider has access to the highest
2437 quality healthcare technology?

2438 *Dr. Schlosser. Yeah, that is another great question.
2439 And so we learned through the pandemic that there is
2440 basically a one-to-one relationship between having enough
2441 healthcare providers and the patients that you need to take
2442 care of, that ultimately providers deliver care. And so the
2443 way we see AI helping solve this problem is by literally
2444 freeing them up from tasks that are not focused on caring for
2445 those populations so that we can in a sense increase the size
2446 of our healthcare workforce without actually needing more
2447 bodies, but just through AI.

2448 *Mr. Johnson. Yeah. Can _ one final question before my
2449 time expires here. Can you _ and you can answer this for the
2450 record if you would get back to me because my time has

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

2451 expired. How can we facilitate _ what can Congress do to
2452 facilitate more private investment into these technologies to
2453 make them more useful to the healthcare system?

2454 *Dr. Schlosser. Yeah, thank you for the question.

2455 *Mr. Johnson. If you would get back to me, I would
2456 appreciate it.

2457 *Dr. Schlosser. I will.

2458 *Mr. Johnson. I yield back, Mr. Chairman.

2459 *Mr. Bucshon. The gentleman yields back. I now
2460 recognize the gentlelady from Washington, Dr. Schrier, for
2461 five minutes.

2462 *Ms. Schrier. Thank you, Mr. Chairman. Thank you to
2463 all of our witnesses today for this interesting conversation.

2464 Artificial intelligence and machine learning are already
2465 transforming how we study and practice medicine, and as we
2466 continue to grow these capabilities and to make further
2467 breakthroughs, it is really important that Congress keeps up,
2468 and I thank you for this education.

2469 Last spring, Mr. Shen, I loved visiting Siemens
2470 Ultrasound Research and Development Center headquarters
2471 located in my hometown of Issaquah, Washington. And during

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

2472 my visit, I learned about and got to see pretty incredible
2473 innovations being done. One of them was the ability to
2474 diagnose non-alcoholic fatty liver disease in an ultrasound
2475 scan that took less than a minute, and to be able to catch
2476 this early. And the implications for morbidity, mortality
2477 are incredible.

2478 But, you know, every time we have a new advance, there
2479 is this question of cost, and as we integrate artificial
2480 intelligence and these more advanced algorithms and new
2481 technology, there are impacts on cost. There is development
2482 impacts, but there is also potential cost savings down the
2483 line if you are avoiding liver transplants.

2484 I was wondering if you could _ I have two questions, so
2485 just kind of partition your time _ kind of comment a little
2486 bit on AI development and cost.

2487 *Mr. Shen. Yeah. Thank you for the question,
2488 Congresswoman. And of course we were very happy to host you
2489 at our Issaquah facility.

2490 As it relates to artificial intelligence, as you
2491 correctly noted, we are trying to integrate AI tools directly
2492 into the types of exams or devices that are touching patients

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

2493 here. So here in this case for ultrasound, being able to
2494 integrate the AI and not have it as _ be a separate type of
2495 solution there. So doing that in itself reduces some of the
2496 costs. So rather than having _ trying to have a separate AI
2497 solution that has to be maintained, has to be procured or
2498 whatnot, we actually integrate those solutions directly into
2499 the medical devices that are treating the patient. So that
2500 is one aspect of it.

2501 And then as we looked at AI overall, we do want to look
2502 at not just the cost of procuring that AI but what is that
2503 downstream cost, what is that benefit, not just to the
2504 patient in terms of maybe fewer days that they have to spend
2505 at the hospital or maybe shorter time to diagnosis or to
2506 treatment, but also cost savings that could be realized by
2507 the provider themselves as well, so the _ that the provider
2508 by deploying this type of technology, is able to be more
2509 efficient, is able to be able to make that diagnosis faster,
2510 is able to see more patients because they now have more time
2511 to be able to take care of one patient and move quickly to
2512 the next patient.

2513 So these are all things that we think about as we

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

2514 develop AI algorithms.

2515 *Ms. Schrier. Thank you. I appreciate that.

2516 My next question, I want to talk to _ pivot to Dr.

2517 Longhurst, and this is really about the impact of AI on the

2518 physician/patient experience. Ranking member Eshoo talked

2519 about the patient experience. I would like to talk about _ a

2520 little bit about the doctor experience.

2521 And I can understand how nice it would be to have the

2522 latest research pop up as a suggested pathway for a given

2523 patient who I am seeing, who has maybe already filled out

2524 their whole history for me, but doctors are already burnt

2525 out. We are _ we have been compared in an OpEd to cogs in a

2526 wheel, to line workers after almost a decade of training

2527 post-university, and we are being asked to see more patients

2528 faster, do more things in a visit, and people _ they are _ we

2529 are burning out.

2530 And so I wanted to talk with you about kind of the

2531 physician/patient relationship, the trust that is there, how

2532 physicians feel when, you know, perhaps they are just

2533 becoming a check on a system where AI makes patient

2534 management decisions for them after that kind of training.

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

2535 Can you speak about that?

2536 *Dr. Longhurst. Yeah. Thank you, Dr. Schrier, and it
2537 is a real privilege to speak with a fellow pediatric graduate
2538 from Stanford.

2539 When I was at Lucille Packard Children's Hospital, we
2540 were in the process of implementing electronic health record,
2541 and as well all know, the electronic health record, if not
2542 the primary cause, has become a primary symptom of burnout.
2543 The many hours that our pediatricians, physicians in general
2544 spend documenting electronic health record is contributing to
2545 a national epidemic of what we call pajama time or after-
2546 hours work. We know that for every day spent in clinic, the
2547 average physician spends about two hours documenting
2548 electronic health record to ensure regulatory compliance,
2549 billing, and other things.

2550 And so where the electronic health record was a really
2551 important digital infrastructure for collecting data, for
2552 quality and population purposes, it has introduced these
2553 unintended consequences. I am incredibly optimistic about
2554 AI, particularly the AI scribes that Dr. Schlosser described
2555 as being a solution to help decrease the burden that was

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

2556 introduced by electronic health record. So we are seeing
2557 just incredibly positive results from pilots using these
2558 scribes.

2559 Unfortunately, the technologies are still quite
2560 expensive, but as they become commoditized and continue to
2561 demonstrate outcomes in privacy, I think this is going to
2562 help us to remediate some of the burnout that has happened
2563 over the last decade.

2564 *Ms. Schrier. Thank you. I appreciate that.

2565 And I yield back.

2566 *Mr. Bucshon. The gentlelady yields back. I now
2567 recognize myself for five minutes.

2568 While I am only just beginning to learn about how AI can
2569 contribute to healthcare, I recognize it has great potential.
2570 I was a cardiothoracic surgeon before I was in Congress. And
2571 I do believe that ultimately technology used properly will
2572 help us control cost. I really believe that.

2573 As an example, a top priority of mine is legislation
2574 that would allow real-time prior authorization decisions by
2575 Medicare Advantage plans and ultimately by all health plans.
2576 I recognize that AI would make real-time decision making far

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

2577 more feasible and expect that it would be used for this
2578 purpose.

2579 At the same time, we are hearing allegations that health
2580 plans are making coverage determinations using AI-powered
2581 tools that are ultimately shown to have high rates of errors,
2582 as was mentioned by Ms. Eshoo, the ranking member in her
2583 opening statement, resulting in patients paying more for
2584 healthcare or perhaps foregoing necessary medical
2585 interventions. Basically, these are improperly denied
2586 claims. Recent media articles have outlined the situation,
2587 which is unacceptable, and I would argue that this should be
2588 investigated by Congress.

2589 I say all of this to remind my colleagues that our
2590 approach needs to be balanced and to remind the companies
2591 using AI to do so responsibly. This is a statement, Mr.
2592 Schlosser. As long as the AI can properly populate the
2593 record to obtain appropriate reimbursement for the providers
2594 involved in the case, you will see wide acceptance of it if
2595 there are _ if _ even if their record is there, but it
2596 doesn't properly reimburse the provider for their care, then
2597 it will be a struggle, and I am assuming they will probably

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

2598 do that.

2599 That is a major issue for providers, the documentation
2600 that is required by the Federal Government for reimbursement.
2601 And honestly, in my view, it has been a problem for a long
2602 time. Another issue in our healthcare system will _ we will
2603 need to think about is using more AI in how we train and
2604 educate medical professionals to use it appropriately.

2605 I am going to address this Dr. Nguyen. Your testimony
2606 mentions using AI to train and educate medical professionals.
2607 There may be a risk that our future providers will become
2608 overly dependent on technology, resulting in less well-
2609 trained providers in the art of clinical decision making.

2610 I will give you an example. Google Maps. It is not
2611 direct, but any _ I have adult children who are in their 20s.
2612 I mean, they can't navigate anywhere without Google Maps. I
2613 mean, they literally don't know what direction they are
2614 going.

2615 [Laughter.]

2616 *Mr. Bucshon. And to go around the block, they map it.
2617 That _ I would call that an over-reliance on technology. It
2618 is not a direct correlation, but kind of.

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

2619 So how do we begin to train these professionals on the
2620 uses of AI and increase of the awareness of the pros and
2621 cons, and is that something that medical schools are
2622 beginning to think about, and if not, should we be?

2623 *Dr. Nguyen. Thank you, Dr. Bucshon. That is a very
2624 prescient example. I too have a lot of trouble navigating
2625 without Google Maps, so I fully understand that.

2626 I think that, you know, our institutions very rightfully
2627 so focus on the art and science of medicine, right? At the
2628 same time, I think it is very, very important that
2629 institutions leverage these new AI technologies to create
2630 learning experiences, first, to enhance the learning
2631 experiences and make them more efficient, enabling students
2632 to really hone in on the most important concepts that they
2633 need to know in the _ in an efficient amount of time.

2634 Second, I think it is very, very important that these
2635 institutions train and educate their students on the nuances
2636 of these technologies. It will be unavoidable that doctors
2637 of the future use these technologies, whether or not they are
2638 trained in them, and so the most important way to prevent
2639 overreliance is to educate them on the limitations of that

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

2640 technology.

2641 *Mr. Bucshon. I would agree with that. Don't get me
2642 wrong, I am a big supporter of technology and innovation in
2643 the healthcare space.

2644 I guess, Mr. Shen, you can talk about maybe, you know,
2645 real time, what is _ are we seeing medical professionals real
2646 time over-relying on AI as it relates to the evaluation of,
2647 for example, CT scans, MRIs, x-rays? Is there _ are the
2648 people coming up being properly trained I would say I guess
2649 on the positives and negatives of this situation? I mean,
2650 that is going to be really important, right?

2651 *Mr. Shen. Yeah. No, this is a great question, Vice
2652 Chair Bucshon. I think to echo what Dr. Nguyen was talking
2653 about, I _ what is critical here is transparency around the
2654 artificial intelligence. Not in terms of how you actually
2655 use the AI but how _ again, how is the AI making that
2656 clinical determination and educating these upcoming
2657 physicians on what _ how the AI is actually making that
2658 clinical determination.

2659 *Mr. Bucshon. Thank you both for the answer to that
2660 question. It is really important.

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

2661 Now I recognize Ms. Kuster from New Hampshire for five
2662 minutes.

2663 *Ms. Kuster. Thank you so much, Mr. Chairman, and thank
2664 you to all of you for sticking with us. We appreciate it.

2665 Today's hearing is an opportunity to understand how
2666 artificial intelligence can help patients, providers, and
2667 researchers. To fully realize this potential, we need to
2668 ensure that AI tools are safe and equitable. I want to use
2669 this hearing to discuss one opportunity and two concerns I
2670 have with AI health.

2671 For the opportunity, I will look to Dr. Newman-Toker.
2672 In your testimony, you described one potential benefit to AI
2673 is that it can improve patient outcomes through more accurate
2674 diagnosis. Could you give us some examples of how AI tools
2675 could benefit public health?

2676 *Dr. Newman-Toker. Yes. So as _ thank you very much,
2677 Congresswoman, for the excellent question. As I noted in my
2678 testimony, we have recently estimated that about 800,000
2679 Americans die or are permanently disabled each year from
2680 diagnostic error with serious medical illnesses like stroke,
2681 heart attack, pneumonia, sepsis, et cetera.

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

2682 There is an enormous potential public health impact of
2683 being able to close that gap, that quality gap with AI-based
2684 detection of using laboratory data and vital signs for things
2685 like sepsis, using video-based interpretation of eye
2686 movements for stroke diagnosis is some of the work that we
2687 have been doing, so I think there is tremendous potential in
2688 that space.

2689 And at the same time, to deal with some of the concerns
2690 raised earlier about costs, because when you realign _ when
2691 you actually improve diagnosis, what you do is you cut down
2692 on both false positives and false negatives at the same time,
2693 and by doing that you save lives by catching the cases you
2694 had missed and you cut costs by not over-investigating the
2695 patients that didn't need that investigation. So I think it
2696 is a tremendous public health opportunity.

2697 *Ms. Kuster. Good. Thank you. Two concerns. I am
2698 worried about bias in the data. Continuing with Dr. Newman-
2699 Toker, you also state in your testimony, for AI tools to be
2700 maximally beneficial, they must be properly validated and
2701 utilize gold standard datasets. What steps can companies and
2702 researchers take to ensure that the data that is being used

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

2703 to train AI systems is accurate and without bias?

2704 *Dr. Newman-Toker. Thank you for the wonderful
2705 question. I do believe that this is the foundational
2706 challenge that faces this whole area of AI in healthcare.
2707 The issue of creating gold standard datasets is not a _ there
2708 is not a simple solution to that problem. We actually have
2709 to do things in healthcare that we don't normally do, such
2710 as, for example, determine what actually happens to our
2711 patients downstream after an encounter.

2712 So we say, for example, that a patient leaves our care
2713 and they have X diagnosis, but we don't actually know if that
2714 is true. We often don't get that follow-up. They may go
2715 somewhere else, they may end up in a different health system.
2716 So we have to start coordinating data architectures and we
2717 have to start developing and curating good datasets that can
2718 be used at a large scale to train these AI models.

2719 So I do think that that is going to take a big effort
2720 and one that would be best coordinated federally.

2721 *Ms. Kuster. Helpful, thank you.

2722 And my final concern is about protecting patient data
2723 when we are developing AI tools. Dr. (sic) Shen, I

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

2724 appreciate Siemens Healthineers' commitment to protecting
2725 patient data. Unfortunately, we have seen an increase in
2726 healthcare cyberattacks, which have more than doubled from
2727 2016 to 2021. What steps does your team take to ensure
2728 patient data being used to train AI tools is protected from
2729 cyber criminals and just plain bad actors?

2730 *Mr. Shen. Yes, very, very timely question and I really
2731 appreciate that, Congresswoman. So here at Siemens
2732 Healthineers, we take data privacy and patient data privacy
2733 as a core component to how we approach the development of
2734 artificial intelligence. And to that respects as it relates
2735 to securing the data, once of the important aspects that we
2736 do is that any of the data that we utilize to train our AI
2737 algorithms is fully protected in our big data office that is
2738 there in Princeton, New Jersey. So there are physical
2739 limitations that are set already in place, the physical
2740 barriers that don't allow individuals or bad actors to gain
2741 access to that data center there.

2742 And then from a cyber standpoint, what our big data
2743 office does is that they actually control who has access to
2744 the data itself. And in terms of controlling internally the

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

2745 audit that is needed in terms of who are the users that can
2746 access that clinical data to do the algorithm training. So
2747 they have the ability to audit the user access and restrict
2748 the user access to only the individuals who need to be
2749 accessing that data.

2750 *Ms. Kuster. Great, thank you.

2751 I am all set. I will yield back.

2752 *Mr. Guthrie. [Presiding.] The gentlelady yields back,
2753 and the chair will recognize Dr. Dunn for five minutes for
2754 questions.

2755 *Mr. Dunn. Thank you very much, Mr. Chairman. I
2756 appreciate all the insights from our witnesses regarding the
2757 role of AI in the clinical setting. I believe there is an
2758 important debate to be had about the value add versus the
2759 risks of AI in the doctor's office and the hospital, and I
2760 agree with our witnesses about the promises of this
2761 technology in medicine. I also echo Dr. Nguyen's caution and
2762 careful consideration when AI is utilized for clinical
2763 decision making without close physician oversight.

2764 It is clear from the advances in AI from narrow AI to
2765 the generative and large language models that there are

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

2766 sweeping implications for the delivery of healthcare, and it
2767 presents clear opportunities and challenges. I am encouraged
2768 by the efforts to explore the role of AI in interpreting
2769 radiology and pathology. And although I think the current
2770 evidence demonstrates that this is not quite ready for
2771 primetime, I am certain that that will become more
2772 sophisticated over time.

2773 I am especially optimistic about the ability of AI
2774 platforms to reduce administrative burdens and simplify
2775 clerical tasks. I appreciate the questions that Dr. Schrier
2776 asked about _ on that _ in that Q, and that is a real problem
2777 as we all address burnout. Physicians are spending a quarter
2778 of their time or more on administrative tasks, so that is a
2779 huge _ I would have loved to have had that when I was
2780 practicing, quite honestly.

2781 I do have some concerns that the private practices may
2782 struggle with the upfront cost of adopting AI technology, and
2783 I urge the industry to think creatively about ways to provide
2784 access to that technology to the full spectrum of provider
2785 settings. And to echo Mr. Johnson's concerns with our rural
2786 communities, rural providers who will be further

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

2787 disadvantaged if they don't have access to that. If those
2788 technologies are only accessible to those with the resources,
2789 we may have an even worse shortage in rural medicine.

2790 So, Dr. Nguyen, can you briefly comment on any specific
2791 challenges that rural or private practices may face when
2792 trying to adopt something like Transcarent?

2793 *Dr. Nguyen. So _ yes, Congressman. So to address your
2794 question, I think there are always going to be challenges
2795 with rural and private practices who _ which are just simply
2796 smaller in size, smaller in staff, smaller in budget, right?
2797 The challenges come in many ways, shapes, and forms for any
2798 technology adoption, AI included, and that is the capacity to
2799 assess, right, the right tools to adopt and the budget to
2800 adopt them.

2801 I think it is very, very important, right, to continue
2802 to support the development of AI tools amongst the private
2803 industry in a safe and non-biased way because that is
2804 actually in my opinion the fastest way that ultimately a lot
2805 of these practices will experience and be able to use these
2806 generative AI tools is when the vendors and the tools that
2807 they use begin to incorporate those, right?

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

2808 When we began adopting EHRs, right, most of these
2809 private practices had access to EHRs once vendors began to
2810 build it for those practices specifically.

2811 *Mr. Dunn. You know, what I would like to do, I would
2812 like to, offline out of this hearing, have somebody from your
2813 company come tell me what is your pricing mechanism, you
2814 know, for different practices and how they can, you know,
2815 adopt that in their office, so that would be something we
2816 could do separately.

2817 Dr. Schlosser, briefly, what are some of the ways you
2818 have seen AI improve efficiencies for patients improve their
2819 experience?

2820 *Dr. Schlosser. Well, one thing that all the clinicians
2821 and probably everyone in the room will acknowledge is that we
2822 ask patients the same questions over and over again. We are
2823 constantly burdening them with delivering their entire health
2824 history and each interaction along a healthcare journey, and
2825 then if you change systems or go to a different physician,
2826 you start that entire process over.

2827 So I think the ability of AI to help us wrangle this
2828 entire universe of healthcare data that exists across

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

2829 multiple disparate EHRs into a longitudinal record of the
2830 patient that clinicians and patients can easily access _

2831 *Mr. Dunn. Just to access, you are right. So I spent
2832 more time as a patient than a doctor the last few years up
2833 here in Congress, and I have to tell you, I filled out my
2834 history probably a thousand times.

2835 *Dr. Schlosser. Yep.

2836 *Mr. Dunn. Just _ it just _ amazing experience to me.

2837 Dr. Longhurst, in your testimony you made reference to a
2838 study, I believe you were a coauthor on that study actually
2839 in which you said algorithm was rapidly deployed to analyze
2840 chest x-rays in COVID-19 patients. Every clinician I know
2841 has been reading chest x-rays for 40 years. What specific
2842 advantages did you confer to these physicians?

2843 *Dr. Longhurst. Yeah, great question, thank you. I can
2844 tell you the day that we rolled this algorithm out that I
2845 walked through the emergency department and asked if our
2846 attending physicians had used it, and one of them said, yeah,
2847 last night we got a chest x-ray on this woman who was in for
2848 cardiac symptoms. We didn't see a sign of pneumonia, the
2849 radiologist didn't call any pneumonia, but the AI showed some

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

2850 color and because of that we ordered a test. And I said,
2851 well what did the test show? And the answer was, well it
2852 takes 24 hours to come back.

2853 *Mr. Dunn. [Laughter.]

2854 *Dr. Longhurst. It turns out that test was positive.
2855 That patient was diagnosed with COVID early before symptoms,
2856 patient was proactively hospitalized, did not need critical
2857 care, went home safely. And to me that was a really great
2858 example of the AI finding a signal that we would not have
2859 found otherwise as a human, and that is the kind of promise I
2860 think the technology holds when deployed appropriately.

2861 *Mr. Dunn. Thank you, Dr. Longhurst.

2862 Thank you, Mr. Chairman, for your forbearance. I yield
2863 back.

2864 *Mr. Guthrie. The gentleman yields back. The chair now
2865 recognizes Ms. _ the gentlelady from Massachusetts, Mrs.
2866 Trahan, for five minutes for questions.

2867 *Mrs. Trahan. Well, thank you, Mr. Chair, for holding
2868 this hearing, and to all the witnesses here today.

2869 AI in healthcare has the potential to transform various
2870 aspects of the industry by offering new solutions, improving

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

2871 efficiency, and enhancing patient outcomes. However,
2872 Congress does have the responsibility to make sure that we
2873 establish appropriate guardrails around AI in healthcare in a
2874 way that works best for consumers and maintains patient and
2875 provider trust.

2876 According to a new Qualtrics survey of more than 28,000
2877 consumers across the globe, consumers are more hesitant about
2878 using AI to get advice about medical problems than they are
2879 for other uses like billing and customer service. As the use
2880 of AI in medicine becomes more commonplace, patients have
2881 raised logical comments around privacy, transparency, ethical
2882 considerations, human oversight, errors and misdiagnoses, and
2883 access issues.

2884 With this in mind, I just welcome the opportunity to
2885 discuss some of those issues today. Many of my colleagues
2886 have already brought up valid ethical considerations around
2887 AI, including biases in algorithms, potential discrimination,
2888 and AI's impact on vulnerable populations. As AI advances
2889 into healthcare and begins to play a role in making medical
2890 decisions, I am curious if there are differences among
2891 various patient demographics in their willingness to consent

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

2892 to AI decision making and whether those preferences may
2893 unintentionally skew algorithms.

2894 So, Dr. Newman-Toker, I am wondering how important is it
2895 to understand if there are patterns of patients who would or
2896 would not consent to use of AI in healthcare based on race,
2897 education level, geographic area, et cetera.

2898 *Dr. Newman-Toker. Thank you, Congresswoman, that is a
2899 fabulous question. I think _ I don't have any specific data
2900 about the demographic variability in trust with respect to AI
2901 specifically, but we have seen over and over again that trust
2902 issues are un _ inequitably distributed. So, for example, in
2903 Baltimore, there is a strong strain of lack of trust of the
2904 healthcare system in the black community, and this is a major
2905 problem for getting equitably distributed data from patients.
2906 So I do believe that you have pointed to a critical concern
2907 that trust gaps are a major issue and they may not be evenly
2908 distributed.

2909 *Mrs. Trahan. Thank you. The rapid _ I am going to
2910 switch gears, but we will definitely probe that further as we
2911 progress.

2912 The rapid evolution of AI in healthcare has exposed the

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

2913 need for federal coverage and payment policies that promote
2914 innovation and protect patients' interests. While the FDA
2915 has moved forward to regulate software as a medical device,
2916 CMS has yet to establish consistent methods for the coverage
2917 and payment of these technologies. Mr. Shen, what _ are our
2918 federal agencies like the FDA and CMS well-positioned to keep
2919 up with the rapid increase in innovative technologies such as
2920 software, algorithms, and AI, and if not, what additional
2921 capability or resources do those agencies need?

2922 *Mr. Shen. Yeah, thank you for the question,
2923 Congresswoman. I think as you correctly pointed out, you
2924 know, we work very closely with the FDA and CMS to try to
2925 bring forth these new and emerging technologies and make sure
2926 that they get into the hands of providers and the patients
2927 themselves. Where we are seeing the challenge here is
2928 unfortunately specifically around CMS and the reimbursement
2929 associated with artificial intelligence.

2930 Today, unfortunately, there is inconsistency and _ in
2931 terms of how this technology is being reimbursed, and that
2932 inconsistency and uncertainty translates to providers being
2933 unsure whether they should make the investment in artificial

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

2934 intelligence, not knowing whether they will actually get
2935 reimbursement or not for this. So we see this as actually
2936 inhibiting and creating a bit of an adoption problem and
2937 preventing the patients from ultimately benefitting from this
2938 technology.

2939 So we would love to see opportunities where working with
2940 this committee here, trying to figure out a better way to
2941 work with CMS to maybe establish some sort of payment that
2942 allows the different providers to move forward with investing
2943 in artificial intelligence and helping everybody understand
2944 what the true value of this technology is.

2945 *Mrs. Trahan. Great, thank you. I couldn't agree more.

2946 And while there is warranted skepticism around the use
2947 of AI in healthcare, you know, we are all excited for
2948 increased applications of AI and how they will positively
2949 impact patient outcomes. Dr. Longhurst, how are we already
2950 seeing AI used to enhance progress to treat diseases with no
2951 known cure like Alzheimer's and MS? Oh, I looked up. Where
2952 did he go? Did _ can anyone else answer that?

2953 *Dr. Newman-Toker. Dr. Longhurst had to step away. I
2954 will _ as the neurologist on the panel, I will take _ I will

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

2955 field that one.

2956 I think there is tremendous potential for AI to do early
2957 detection of disease, chronic disease in particular such as
2958 Alzheimer's disease. You can imagine if we can make
2959 diagnoses 10 years in advance through information coming out
2960 of wearables or eye movement analysis, we will be able to
2961 then apply early preventative therapy. So I think there is a
2962 lot of potential there.

2963 *Mrs. Trahan. Well, thank you, Dr. Newman-Toker. We
2964 appreciate _ Mr. Chair, I yield back.

2965 *Mr. Guthrie. The gentlelady yields back. The chair
2966 recognizes the gentleman from Georgia, Mr. Carter, for five
2967 minutes.

2968 *Mr. Carter. Thank you, Mr. Chairman, and thank all of
2969 you for being here. This is obviously a very hot subject on
2970 Capitol Hill, artificial intelligence, and particularly in
2971 the healthcare world. We are very concerned about it.

2972 And look, I am a big believer in telehealth. I
2973 represent a rural area and I have seen how it has benefited
2974 us in the rural areas. As you know _ all of you know that we
2975 have got a doctor shortage here in America, particularly in

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

2976 our rural areas. Telehealth has been a great savior for us.

2977 I have always said that there is a big difference
2978 between knowing something and realizing something, and during
2979 the pandemic I think we realized just how important
2980 telehealth can be. I think there was a article in the paper,
2981 in the New York Times, that said that telehealth had advanced
2982 more in one day than it had in the last 10 years, and it
2983 probably has. So I want to kind of focus on telehealth here.

2984 Dr. Nguyen, can you talk about how Transcarent is using
2985 AI within your telehealth solution and how that is allowing
2986 your doctors to be more efficient with their time so that
2987 they can see more patients?

2988 *Dr. Nguyen. Certainly, Congressman. Thank you for the
2989 question. I think it has been repeated on this panel, a
2990 common refrain you will hear is that a very important benefit
2991 of AI is enabling the doctors and nurses to do the doctoring
2992 and the nursing. What Transcarent does, right, is we really
2993 believe in freeing up the time of the doctor to spend with
2994 the patient and reducing the time required for administrative
2995 burden.

2996 So the way we use AI is in our clinic when a patient

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

2997 comes to the clinic, an AI assistant gathers information from
2998 them and synthesizes that information for the doctors. That
2999 enables the doctors to come into the visit and see all the
3000 information organized and spend time on that diagnosis and
3001 that treatment and really creating the plan with the patient,
3002 right? That frees up time and that frees up capacity to see
3003 more patients, including patients in rural areas, since we
3004 serve 4.4 million Americans across the entire United States.

3005 *Mr. Carter. Right. Good.

3006 Mr. Shen, let me ask you, I have heard that sometimes
3007 there is bias in AI and that that can actually be good. That
3008 is somewhat baffling to me, but nevertheless, can you explain
3009 to me how that might be and how bias can sometimes help
3010 improve the utility of AI in healthcare?

3011 *Mr. Shen. Yeah, that is an interesting question,
3012 Congressman. So I think what is very important here to make
3013 sure that we all emphasize is that as we train these AI
3014 algorithms, these algorithms have to be trained with data
3015 that is respective of the patient population that they are
3016 going to be serving, so it is important that we work with our
3017 different clinical collaborators to find the right type of

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

3018 patient data to train these AI algorithms, again, that are
3019 going to be applied towards that patient population and
3020 making sure that that patient population is reflected in the
3021 data that is actually training those algorithms themselves.

3022 *Mr. Carter. Okay. All right, I have got one last
3023 question, and I _ and it is kind of for all of you or any of
3024 you, if you will, and that is we have a Doctor's Caucus here
3025 in Congress, and I am a healthcare professional, a pharmacist
3026 by profession, and I have served in the state legislature on
3027 healthcare, and one of the things that I notice is that a lot
3028 of our healthcare costs have increased because of defensive
3029 medicine and doctors running unnecessary lab tests just
3030 really to protect themselves from litigious patients or
3031 situations.

3032 But how is that going to impact the practice of medicine
3033 if a physician doesn't use AI and then something happens and
3034 then, you know, all of the sudden they are sued because you
3035 didn't use something that was available that you should have
3036 used? It seems to me like this could potentially increase
3037 healthcare costs as well. I see the savings, yes, but I have
3038 also seen and tried to deal with it on a state level and now

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

3039 on the federal level. And I will open it up, whoever wants
3040 to comment, go ahead.

3041 *Dr. Schlosser. I will take a stab. So I think that we
3042 need to remind ourselves that healthcare decisions are made
3043 by physicians and practitioners, right? They should be the
3044 ultimate decider when it comes to coverage, when it comes to
3045 do you need to be admitted to the hospital, what treatment do
3046 you need. These need to be made by our trained healthcare
3047 physicians. AI is _

3048 *Mr. Carter. But you are a healthcare professional.

3049 *Dr. Schlosser. I am.

3050 *Mr. Carter. You are not a lawyer.

3051 *Dr. Schlosser. I am.

3052 *Mr. Carter. And I am _ you know, I got to feel like
3053 from a lawyer's perspective, they are going to take a
3054 different approach.

3055 *Dr. Schlosser. Well, but that is why I think it is
3056 important that we understand that as a community, as an
3057 industry that we are not turning over decision making. These
3058 are tools. These are tools in their toolbelt that _ and we
3059 need to view them as such, not as an authoritative decision

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

3060 that, you know, that someone should be held accountable to.

3061 *Mr. Carter. Anyone else quickly?

3062 *Dr. Newman-Toker. I will just say that if we can prove
3063 that AI systems save lives, then people should be using them,
3064 and if we can't, then we should be relying on clinician
3065 judgment. And I think that ultimately _

3066 *Mr. Carter. I don't know that we will ever get away
3067 from relying on clinician judgment, though.

3068 *Dr. Newman-Toker. I agree with you. I think that it
3069 is unlikely, certainly in my lifetime.

3070 *Mr. Carter. Right. Good. Okay, thank you.

3071 And I yield back, Mr. Chairman.

3072 *Mr. Guthrie. The gentleman yields back. The chair
3073 recognizes the gentleman from Indiana, Mr. Pence, for five
3074 minutes.

3075 *Mr. Pence. Thank you, Chair Guthrie and Ranking Member
3076 Eshoo, and thank you to the panel for being here today.

3077 Incorporating AI technologies into healthcare systems
3078 may improve and streamline diagnosis and treatment options in
3079 addition to easing the administration burden at healthcare
3080 facilities. Patients' personal medical data and background

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

3081 information, however, is typically the foundation of AI
3082 delivery in healthcare. The trust and safeguarding of
3083 personal information between patients and their providers is
3084 critical for people receiving the highest quality of care.

3085 In the ecosystem of electronic apps and wearables, there
3086 are areas where healthcare data is not clearly protected. I
3087 had a hospital in my district in Hancock County that was on
3088 60 Minutes a number of years ago. That is why this committee
3089 needs to consider a federal data policy law to set the
3090 foundation of protections on how such data is collected,
3091 used, and shared. We should do that before we can look at
3092 regulating AI in healthcare and find the balance in
3093 simultaneously encouraging private innovation.

3094 Our increasingly digital world leaves Hoosiers and all
3095 Americans in the dark about who has access to their
3096 information. It is alarming to me how little consumers and
3097 patients know about how personal details of their lives are
3098 collected, shared with third parties, and monetized without
3099 their informed consent, monetized no _ with no recompense to
3100 the provider of the information. Patient trust in those
3101 responsible for safeguarding personal data is paramount in

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

3102 the use of emerging technologies in healthcare.

3103 Dr. Schlosser, as we introduce new AI technologies in
3104 healthcare, patients deserve to have control over when their
3105 information is collected, who has access to their data, the
3106 right to remove their data, and where their data might be
3107 shared. Here is the question. Should healthcare
3108 organizations that collect protected medical information be
3109 transparent with patients on how their data is stored, who
3110 has access to their data, and for today's hearing,
3111 identifying that AI is part of the process?

3112 *Dr. Schlosser. Yes. So I would agree with everything
3113 that you just said. I think we fully support the idea that
3114 we should be transparent with our patients, and we currently
3115 are through a rigorous consent process as to how the data is
3116 being used, how it is being protected, and how it may be
3117 stored and shared. And I think as the use of AI expands,
3118 that will become increasingly important so patients can know
3119 where that data is going and how it might be used.

3120 I will just add that AI is entirely dependent on the
3121 data, and so if we want the benefits of AI, we also have to
3122 do this in a way that enables us to use that data to train

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

3123 and finetune algorithms. So there is a really important
3124 balance we need to strike here ensuring that we are
3125 transparent and we keep the patient's data private but we
3126 don't create too many barriers to actually using that data to
3127 train algorithms to achieve all these wonderful outcomes we
3128 have been talking about.

3129 *Mr. Pence. Yeah. And, you know, the _ it comes to
3130 mind back in a previous life of mine, you know, it is garbage
3131 in and garbage out, right?

3132 *Dr. Schlosser. Mm-hmm.

3133 *Mr. Pence. I mean, the wrong algorithm or the wrong
3134 collection point of the data can skew the outcome in a big
3135 way. In finance, we used to say you can pay off the national
3136 debt with the wrong numbers.

3137 Would anyone else like to answer that? Yes, sir.

3138 *Dr. Longhurst. Yeah, I appreciate your question very
3139 much. I think that as Dr. Schlosser has said, your AI
3140 strategy is your data strategy. I would point out that
3141 within the ecosystem of treatment, payment, and operations,
3142 all of us, health systems, providers, insurance companies are
3143 covered by HIPAA laws around data privacy. And where I think

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

3144 the greater risk lies is with these consumer health apps and
3145 others that are accessing data either directly from patients,
3146 from health systems with patient consent via the 21st Century
3147 Cares Act, and other mechanisms.

3148 And I think you are absolutely right, there is a lot of
3149 healthcare data floating around that is not subject to HIPAA
3150 today because of these mechanisms, and so I think it is a
3151 risk and something that should be looked at legislatively.

3152 *Mr. Pence. And your concern is that that would go into
3153 AI computation, is that what you are referring to?

3154 *Dr. Longhurst. I think there is a number of risks to
3155 those datasets being used either to generate algorithms
3156 without transparency or to target for advertising other types
3157 of uses to patients without their awareness.

3158 *Mr. Pence. Yeah. I go to the doctor, and I Googled
3159 all the answers, right? So, yeah. Okay, thank you very
3160 much.

3161 Mr. Chair, I yield back.

3162 *Mr. Guthrie. The gentleman yields. Dr. Joyce is
3163 recognized for five minutes for questions.

3164 *Mr. Joyce. Thank you, Chairman Guthrie and Ranking

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

3165 Member Eshoo, for holding today's hearing, and to the
3166 witnesses being with us today, we appreciate both your time
3167 and your testimony.

3168 Artificial intelligence has made a significant impact on
3169 our day-to-day lives and the benefits that industries and
3170 individuals derive through its use are very, very numerous.
3171 As this technology continues to explode onto the scene, it
3172 has become especially prevalent in healthcare. But like many
3173 industries where AI is seeing a dramatic increase in usage,
3174 there are and there will be certain risks associated with it
3175 that we must contend with as policymakers.

3176 While that should not demean the potential efficacy of
3177 its day-to-day uses, applications, and functions, AI remains
3178 a tool, a tool that utilizes vast amounts of data, and with
3179 its integration into healthcare space, we must be vigilant to
3180 ensure that sensitive patient information is safe, is secure,
3181 and is protected. As we move forward, Congress must have
3182 that unique task of analyzing and further understanding AI's
3183 evolution and applicability when it comes to healthcare.

3184 While President Biden's executive order on artificial
3185 intelligence might lay out the administration's policy

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

3186 initiatives, it is still the responsibility of Congress to
3187 legislate. It is paramount that Congress has a firm grasp
3188 and a clear comprehension on how AI interacts with existing
3189 regulations so that we can ensure AI first does no harm but
3190 instead continues to positively reshape the healthcare
3191 industry.

3192 Dr. Nguyen, patients that live in rural areas, like the
3193 district that I represent in Pennsylvania, often face
3194 barriers that impeded their access to healthcare. Do you
3195 believe that AI has the potential to quash those impediments,
3196 and if so, how can we incentivize further adoption of AI
3197 technologies?

3198 *Dr. Nguyen. Thank you for the question, Congressman.
3199 Absolutely. You know, the distribution of care to rural
3200 areas and the barriers to access are well-known and great.
3201 AI can quash those barriers and really close those gaps in a
3202 few different ways.

3203 First, you know, there is always a supply and demand
3204 problem when you think about distribution of resources across
3205 rural areas. Making clinicians more efficient, right, making
3206 clinicians more available means that there are more

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

3207 clinicians available to see those patients in rural areas.

3208 Two, many of the barriers come also from a lack of
3209 health literacy, a lack of access, right, to the healthcare
3210 system. AI also can help patients in rural areas level the
3211 playing field, right, by assisting them in better
3212 understanding their care, better navigating the care system,
3213 and better understanding how to find the best care for
3214 themselves.

3215 The incentives, right, that Congress can encourage,
3216 right, include the development and education of AI skillsets
3217 across the healthcare system but specifically in the
3218 clinicians who are going to practice in rural areas and the
3219 healthcare leaders who are going to lead systems in rural
3220 areas. That education is very, very important, as I
3221 mentioned in my statement, it doesn't come naturally to many
3222 of our institutions, but it is _

3223 *Mr. Joyce. Thank you.

3224 Dr. Schlosser, welcome to another Johns Hopkins-trained
3225 physician. I took that to Congress; you took that another
3226 direction.

3227 The FDA has been regulating some forms of AI under

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

3228 existing authorities for drugs and biologics as well as
3229 medical devices. Do you think that the current regulatory
3230 structure is sufficient to keep up with the innovation in
3231 AI's uses in healthcare?

3232 *Dr. Schlosser. Yes, and thank you for the question. I
3233 actually have some experience, I was a medical officer for
3234 the FDA a number of years ago, and I would say that the rate
3235 at which AI is changing healthcare is likely going to require
3236 us to think a little bit differently about how we regulate
3237 medical devices. The current approach, which really is based
3238 on laws from 1974, I think never really anticipated the kind
3239 of technology we are talking about. So dealing with models
3240 that can learn over time is something that we are going to
3241 have to work together I think to figure out what that
3242 regulatory pathway looks like.

3243 This is _ there is incredible potential here, but I feel
3244 the movement and the progress of AI is a little bit outpacing
3245 the current regulatory approach.

3246 *Mr. Joyce. Thank you.

3247 And, Chairman Guthrie, briefly before I yield, I ask
3248 unanimous consent to enter into the record a letter of

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

3249 support from the American College of Surgeons.

3250 *Mr. Guthrie. Seeing no objection, so ordered.

3251 [The information follows:]

3252

3253 *****COMMITTEE INSERT*****

3254

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

3255 *Mr. Joyce. Thank you. And again thank you to the
3256 witnesses for being here, and I yield.

3257 *Mr. Guthrie. Thank you. The gentleman yields back.
3258 The chair recognizes the gentlelady from Tennessee, Mrs.
3259 Harshbarger, for five minutes for questions.

3260 *Mrs. Harshbarger. Thank you, Mr. Chairman. Thank you
3261 all for being here. I have heard a couple of you speak
3262 before. This is really interesting stuff.

3263 And I will start with you, Dr. Schlosser, since you are
3264 from Tennessee or HCA. Let's just talk about the
3265 pharmaceutical supply chain, and it can be very difficult and
3266 complex to trace, and as a pharmacist I am responsible for
3267 knowing every step in that process from the _ in the supply
3268 chain from the manufacturer to the dispensing of the drug
3269 because of the pedigree. How can AI be used to help
3270 pharmacists in their role optimizing medication used in
3271 patient health outcomes and improve _ providing patient care,
3272 how can we use that and hopefully we can be reimbursed for
3273 that?

3274 *Dr. Schlosser. Yeah. Well, thank you, Congresswoman,
3275 for the question. And I think there is tremendous

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

3276 opportunity. We actually already use varieties of artificial
3277 intelligence in our pharmacy processes, and we have actually
3278 done this for years. We have heuristic models, which are
3279 basically rules-based models that are constantly surveilling
3280 patient charts looking for opportunities that they can serve
3281 up to the pharmacist, be they drug interactions, or
3282 substitutions, or places where we can be more efficient or
3283 provide more effective treatment. And so I think those
3284 models are only going to improve and get better with the
3285 advent of these more advanced artificial intelligent
3286 algorithms.

3287 I think the same is true for our pharmacy supply chains.
3288 And we have mentioned this already today, but the ability to
3289 get predictive in understanding the demands and needs of our
3290 patients on a hospital or even unit basis and then be able to
3291 go back up upstream and ensure that we have the adequate
3292 supply to meet those demands, and if we don't, can we make
3293 kind of preemptive steps to ensure that we can maintain
3294 adequate supplies is another area that we are already working
3295 on and I think there will be great benefit.

3296 *Mrs. Harshbarger. Very good. You have already told us

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

3297 about how HCA, the hospital system, sees value in the
3298 adoption of AI technologies without even additional payment
3299 in that, and you have talked to us about removing the
3300 administrative burden, and it is reduction of time spent that
3301 does not involve direct patient care. So this is my
3302 question, and this is your chance to tell me what to do.

3303 What recommendations do you have for this committee in
3304 creating payment models in AI for healthcare services,
3305 application, and add-ons?

3306 *Dr. Schlosser. Yeah. And some of my panelists have
3307 had a chance to weigh on this already today. I do think as
3308 this technology advances and it becomes more _ a meaningful
3309 and central part of healthcare delivery that CMS is going to
3310 have to fund an approach to reimburse for this technology.
3311 And in my personal opinion, it is not that different than the
3312 initial approaches they tried to take around chronic disease
3313 management of how do you reimburse for sort of the ongoing
3314 work that in this case an algorithm would do to help prevent
3315 complications, to help reduce costs.

3316 The last comment I want to make here is that I think we
3317 have a great opportunity with AI since we are at the

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

3318 beginning is to take a really a business case minded approach
3319 to how we _

3320 *Mrs. Harshbarger. Yeah.

3321 *Dr. Schlosser. _ deploy this technology and not have
3322 it just be another technology that we deploy that adds more
3323 cost and then we try to add more reimbursement and therefore
3324 drive up the cost of the healthcare system, but instead be
3325 really thoughtful about how can these technologies make us
3326 more efficient and more effective and decrease the overall
3327 cost of the healthcare system as we deploy them.

3328 *Mrs. Harshbarger. Well, we are going to have to. So
3329 you will continue to exist.

3330 Dr. Longhurst, how do you think AI and medical liability
3331 intersect?

3332 *Dr. Longhurst. Fantastic question, thank you.

3333 *Mrs. Harshbarger. Mm-hmm.

3334 *Dr. Longhurst. As was previously mentioned on this, AI
3335 is a tool, whether it is being used for diagnosis, or
3336 treatment options, or others, ultimately the liability for
3337 treatment of the patient rests with the treating physician.

3338 *Mrs. Harshbarger. Yeah.

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

3339 *Dr. Longhurst. And so we have had perhaps not AI tools
3340 for a long time, but we have certainly had clinical decision
3341 support tools for a long time that suggest potential
3342 drug/drug interactions, or dose range errors and other
3343 things, and the liability has always rested with the treating
3344 clinician to see these alerts, manage them, but make the best
3345 decision for the patient. So I think the real question about
3346 liability in AI comes if you take the human out of the loop.

3347 *Mrs. Harshbarger. Right.

3348 *Dr. Longhurst. If there is a step that is taken
3349 towards making diagnoses without clinicians, then it begs all
3350 sorts of other questions about licensing these tools.

3351 *Mrs. Harshbarger. Yeah, exactly. Do you see a
3352 scenario where litigation might increase if doctors don't
3353 utilize AI?

3354 *Dr. Longhurst. That is a fantastic question as well.
3355 In fact, a recent Boston Globe survey of patients asked would
3356 you see a doctor that was not using AI, and the _

3357 *Mrs. Harshbarger. Really?

3358 *Dr. Longhurst. _ predominant answer from patients was
3359 I would be concerned if my doctors was not using the latest

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

3360 tools.

3361 *Mrs. Harshbarger. Okay.

3362 *Dr. Longhurst. So I think as was recently described by
3363 Dr. Newman-Toker, if these tools are shown to be best
3364 practice, if they can decrease mortality, if they can
3365 increase survivorship, then they will become a best practice
3366 that should be used in every case.

3367 *Mrs. Harshbarger. Okay. Thank you, sir.

3368 And I think I am out of time, so I yield back.

3369 *Mr. Guthrie. Thank you. The gentlelady yields back.
3370 The chair recognizes the gentlelady from Iowa, Dr. Miller-
3371 Meeks, for five minutes for questions.

3372 *Mrs. Miller-Meeks. Well, thank you very much, and I
3373 just want to add in my own personal experience with
3374 electronic health records as a doctor, and it is much more
3375 than two hours of my time after seeing 30 to _ 35 to 40
3376 patients in a day. Just as an example, on a global post-op
3377 no charge, after I finish completing my medical record, it
3378 took an additional six clicks to put in no charge. Now it
3379 takes me 10 seconds to write N-C. It took two minutes to six
3380 clicks to no charge, so it certainly does lead to burnout.

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

3381 I would also like to follow-up on something Dr.
3382 Longhurst said and then also Dr. Schlosser. And certainly
3383 the FDA has not kept up with medical devices utilizing
3384 artificial intelligence, not only generative but repetitive
3385 machine learning, and at the University of Iowa, Dr. Michael
3386 Abramoff, MD, PhD, has one of those first medical devices
3387 that is approved by the FDA.

3388 And then I would like to submit for the record an
3389 article on "Effectiveness of Artificial Intelligence
3390 Screening in Preventing Vision Loss from Diabetes, a Policy
3391 Model.'" And then that would lead to reimbursement. And
3392 what is great about this is that it increases access by
3393 having a device that can be put into any person's office,
3394 whether it is an eye care provider or family practitioner.

3395 And then the second letter is a letter of support from
3396 Johnson & Johnson that does talk about privacy, equity, bias,
3397 and transparency in the system since those things have been
3398 brought up.

3399 *Mr. Guthrie. Thank you. We will _ we are going to
3400 accept a documents list at the end. We will make sure those
3401 are included and give the _ my friend here a chance to

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

3402 review. Thanks.

3403 *Mrs. Miller-Meeks. I know I did it first because I am
3404 older, and I forget things.

3405 So, Mr. Shen, we have heard a lot about AI over the past
3406 few years and the potential risks attributed to unregulated
3407 AI integration. However, the FDA has been regulating
3408 software-based medical products since the 1970s and we know
3409 that AI integration into healthcare has already raised the
3410 status quo of care. We have seen it in digital pathology,
3411 drug optimization, integration in patient engagement,
3412 personalized risk prediction. Can you give examples where
3413 gaps exist in current regulation that Congress can address to
3414 ensure continued innovation that will drive better, more
3415 personalized care for patients without burdensome
3416 overregulation?

3417 *Mr. Shen. Yeah. Thank you for the question,
3418 Congresswoman. I think what we are seeing with the FDA, and
3419 we continue to work very closely with the FDA to try to make
3420 sure that they stay current with the rapidly changing
3421 technologies that are there. I think the challenge that we
3422 are seeing is that, and it was acknowledged here on this

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

3423 panel today, is really how artificial intelligence continues
3424 to change, and what becomes an AI algorithm today might be a
3425 different AI algorithm tomorrow or might need to be adjusted
3426 or increased in terms of accuracy or whatnot after it is
3427 being used in the clinical setting.

3428 So I think this is where areas like PCCP that we had
3429 worked on here with this committee previously, these are all
3430 important aspects that the FDA needs to consider and actually
3431 not _ and not water it down in terms of its ability because
3432 that actually then will inhibit us from being able to
3433 continue to develop and innovate in this particular area.

3434 *Mrs. Miller-Meeks. Thank you.

3435 Dr. Schlosser, many hospitals and hospital systems are
3436 facing significant staff shortages. We are seeing AI as a
3437 meaningful tool to help alleviate some of the administrative
3438 burdens that are driving providers away from the medical
3439 profession. A recent report from Goldman Sachs notes that
3440 shifts in workflows triggered by these advances could expose
3441 the equivalent of 300 million full-time jobs to automation.

3442 What steps can Congress take to facilitate better AI
3443 integration to health systems to streamline processes that

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

3444 will allow healthcare professionals to focus more on patients
3445 and less on billing, coding, et cetera?

3446 *Dr. Schlosser. That is a great question,
3447 Congresswoman, thank you. And I think this is incredibly
3448 important that we do streamline our ability to use AI to
3449 tackle this serious workforce problem that we have that is
3450 only going to continue to get bigger. We think the gap
3451 between supply and demand for nurses alone is going to
3452 continue to increase over the next decade.

3453 And so I would say the easy answer is let's not put too
3454 many burdensome regulations between us and our ability to
3455 deploy AI to support our healthcare workforce. We are not
3456 talking about AI directly influencing patients or providing
3457 diagnoses, we are talking about it removing administrative
3458 burden. That is an area with the right responsible AI
3459 platforms, we should be able to move quickly to adopt those
3460 technologies and free up that workforce to handle this
3461 increasing demand.

3462 *Mrs. Miller-Meeks. Well, thank you. And I saw Dr.
3463 Nguyen and Dr. Longhurst shaking their heads, so I think that
3464 you are in agreement. And since I am running out of time, I

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

3465 have got another question I will submit for the record.

3466 And with that, I yield back my time. Thank you so much.

3467 *Mr. Guthrie. Thank you. The gentlelady yields back.

3468 And if you will give us those documents you submitted for the

3469 record so we can review those, I would appreciate it.

3470 The chair now recognizes the gentleman from California,

3471 Mr. Obernolte, for five minutes.

3472 *Mr. Obernolte. Thank you, Mr. Chair. Thank you to our

3473 witnesses. It has been a really interesting hearing.

3474 Mr. Shen, I wanted to ask you about some of your

3475 interactions with the FDA because we are really at a

3476 crossroads when it comes to devising a regulatory framework

3477 for artificial intelligence. We can either follow the lead

3478 of entities like the European Union who believe that AI is

3479 its own kind of unique discipline and that there needs to be

3480 a separate bureaucracy spun up to issue licenses with respect

3481 to the use of AI or we can follow the lead of countries like

3482 the UK who has pointed out that because the risk of AI is so

3483 contextual that the existing sectoral authorities are best

3484 equipped to regulate within their sectoral spaces with a

3485 bunch of technical help and resource.

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

3486 So I was curious, I mean, we are _ we have to choose,
3487 right? That is _ we are at a crossroads. We have _ we can
3488 go one way or the other way, there is really no middle
3489 ground. Which of those two paths do you think we should
3490 follow? Is it easier to teach the FDA what it doesn't know
3491 about AI or is it easier to teach a brand new agency
3492 everything the FDA already knows about ensuring patient
3493 safety?

3494 *Mr. Shen. Yeah. Very good question, Congressman. I
3495 think certainly this is a tricky topic, but I think what we
3496 have to remember is that at least in our industry from a
3497 vendor perspective, we have been working closely with the FDA
3498 for many, many years here, and we work _ at Siemens
3499 Healthineers, we have direct dialogues with them around this
3500 topic on a weekly basis.

3501 I think the other thing that is important to remind
3502 ourselves here, especially in the context of artificial
3503 intelligence is that AI is not _ can't not just be considered
3504 as a separate type of technology, but this technology is also
3505 being embedded into the medical devices themselves as well.
3506 So, for instance, you know, CT scanners or MRI scanners, they

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

3507 have AI that is built in there into that system that allows
3508 for better image quality or faster exams for the patients.
3509 So a lot of benefits to the patient are happening already
3510 with the AI technology built into the medical devices
3511 themselves.

3512 So we have to consider that, especially when we consider
3513 how we want to move forward with the FDA.

3514 *Mr. Obernolte. Right. I think that is a good point.
3515 I also am heartened by your comment that you feel the
3516 existing regulatory relationship with the FDA is doing a good
3517 job at both ensuring patient safety and catalyzing innovation
3518 and so, I mean, I think that is a pretty powerful argument,
3519 you know, for maintaining that relationship and empowering
3520 the FDA to regulate in that space.

3521 Dr. Newman-Toker, thank you very much for your
3522 testimony. You said something that I found incredibly
3523 interesting. You said that the best that we can expect from
3524 AI is that it repeat the existing human biases that exist in
3525 the data it was trained with. And I found that a fascinating
3526 statement.

3527 I mean, I don't like the use of the word bias because it

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

3528 is a very human word and when you apply it to a machine
3529 learning algorithm, and there is no such thing as bias, they
3530 are all biased. I mean, machine learning is all about bias
3531 because you are training it to generalize, you know, and we
3532 call that bias when we talk about kind of maintaining our
3533 social standards, you know, when we say, for example, it
3534 would be wrong to consider someone's race when making a
3535 hiring decision. We can all agree that that is true, but
3536 that also means scrubbing the data that we use to train AI
3537 that makes those recommendation for things that can be used
3538 as proxies for race, and that is the difficulty that we have
3539 had so far.

3540 So you were talking about how important it is in the
3541 medical context of maintaining high quality datasets to avoid
3542 those kinds of biases. How do we ethically navigate this
3543 space of patient consent? You know, if you have a chest x-
3544 ray, and I think it was Dr. Longhurst that was talking about
3545 detecting COVID pneumonia from a chest x-ray, you know, if
3546 you were a patient, you come in, you get a chest x-ray, you
3547 have not consented for the use of that x-ray to be used to
3548 train a machine learning algorithm.

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

3549 You know, do you do have the rate to say, no, I don't
3550 want my data used? And if you do, I mean, the problem is
3551 that is introducing bias into the algorithm because, you
3552 know, from a statistical sense, you are biasing the outcome
3553 of the algorithm because who knows what else the group of
3554 people who would withhold consent have in common, right? So
3555 a statistician would say that is a serious problem, so how do
3556 we navigate that space, how do we protect the patient data
3557 and at the same time avoid biasing these algorithms?

3558 *Dr. Newman-Toker. Thank you, Congressman, that is a
3559 great question. So, you know, I come from the world of
3560 clinical research where there is always the opportunity to
3561 refuse to participate, and I am generally of the mind that
3562 that should always be the case, that if patients wish to opt
3563 out, they do. It does create a certain bias, there is a
3564 volunteer bias, of those who want to participate, but I think
3565 that is a bias we can accept.

3566 As far as the issue of the replicating the sort of human
3567 biases, as I mentioned in my testimony, I believe that we
3568 have _ they exist at two different levels, but the most
3569 important piece is where our biases are causing us to behave

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

3570 differently as clinicians. So if I don't order the same test
3571 in a black patient that I order in a white patient for the
3572 same circumstance and the same condition and the same
3573 appropriateness, that is the kind of bias that I don't want
3574 to replicate in my AI systems, and I think that is why well-
3575 curated gold standard datasets are so critical.

3576 *Mr. Obernolte. Yeah. Well, I would agree. And I am
3577 an AI optimist, so I would actually argue against your
3578 statement, you know, that the best we can expect is the
3579 replication of existing biases. I think it is a golden
3580 opportunity to remove the biases.

3581 Well, I see I am out of time, but thank you very much
3582 for your testimony.

3583 *Mr. Guthrie. Thank you.

3584 *Mr. Obernolte. I yield back, Mr. Chairman.

3585 *Mr. Guthrie. Thank you. The gentleman yields back.
3586 We now have a vote on the floor, but we only have one member
3587 left to ask questions, so we are going to hopefully be able
3588 to complete this now. But _ now _ so we will get started on
3589 that.

3590 The next member to speak is the gentleman from Texas,

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

3591 Mr. Crenshaw, for five minutes.

3592 *Mr. Crenshaw. Thank you, Mr. Chairman. I am glad we
3593 are doing this hearing. I think we need a lot more hearings
3594 on AI on multiple subjects, I think, and healthcare _ the
3595 utilization of AI in healthcare might be the least of our
3596 worries.

3597 I also worry that we are not always talking about this
3598 in a accurate way. We are not properly differentiating
3599 between advanced algorithms and AI. We are just saying AI.
3600 And that is not from our witnesses, that is just for every _
3601 that is for Congress, that is for America. If we are going
3602 to properly regulate it, and I am going to ask you what you
3603 guys mean by that, a few of you have said we need to properly
3604 regulate it, I am genuinely curious how and what we do.

3605 But we have to talk about it accurately first. We mean
3606 machine learning. And we mean machine learning that you
3607 can't actually look under the hood and change. That is where
3608 it gets scary. If we are talking about advanced algorithms,
3609 look, people call _ Facebook and Instagram listen and watch
3610 my actions and they make predictive analysis based on that.
3611 I have heard that used in _ like today and called it AI. It

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

3612 is not AI.

3613 You can change that algorithm. You can change how that
3614 works. Programmers can go in there and change it. AI you
3615 cannot change. You cannot look under the hood. And so I
3616 think we just need to be really accurate about what we mean
3617 by AI.

3618 AI is meant to mimic a person, and that can be really
3619 amazing, especially for healthcare. And so I think things we
3620 have to talk about is well what data inputs go into that
3621 machine learning. Is it everything? That is how you get
3622 ChatGPT. And what kind of person is it mimicking, a good
3623 person or a bad person? This stuff gets really scary really
3624 fast.

3625 When we are talking about healthcare, it seems kind of
3626 obvious that you are going to limit the data inputs. Does
3627 that need to be a law? Is that one of the regulations that
3628 you all are talking about?

3629 So actually I am going to stop there and ask you, a
3630 couple of you said that we need to regulate it, but I am
3631 curious what you mean by that. Dr. Newman-Toker, maybe you
3632 can start because I know you said that.

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

3633 *Dr. Newman-Toker. Sure. Thanks very much. I think
3634 your question is very pertinent, Congressman. In terms of
3635 regulatory oversight, I do think that there are certain gaps
3636 with respect in particular to diagnosis in this AI space. So
3637 I believe that, for example, if we think about direct to
3638 patient symptom checkers for diagnosis where there is a legal
3639 disclaimer at the bottom that says this is not medical
3640 advice, but patients are taking it as medical advice, that it
3641 is really incumbent upon us to pay more attention to that
3642 consumer health space, as has been brought up previously.

3643 *Mr. Crenshaw. So kind of like a digital watermark
3644 almost? Like I have talked about that before with respect to
3645 AI, like it should be known that whatever this output is is
3646 from AI and not a person.

3647 *Dr. Newman-Toker. Right. Not just that, but when
3648 people are making decisions about how to _ how and when to
3649 access the healthcare system, and it is based upon some kind
3650 of algorithmic decision making that is behind the scenes,
3651 there should be an accountability if _ in that framework, and
3652 right now there isn't any accountability to everything that
3653 exists outside the proper confines of say the hospital

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

3654 setting or a clinic. Before you get to the healthcare
3655 system, there is a lot going on that is _ that we need to
3656 regulate better.

3657 *Mr. Crenshaw. Can you give me an example of what you
3658 mean by that?

3659 *Dr. Newman-Toker. Yeah. So let's say that somebody
3660 types into their symptom checker that they are dizzy, and the
3661 symptom checker says, don't worry, it is nothing, it is
3662 little rock crystals in your ear and _

3663 *Mr. Crenshaw. Okay.

3664 *Dr. Newman-Toker. _ you can stay home.

3665 *Mr. Crenshaw. This is hypothetical, by the way, or is
3666 it not hypothetical? Is there something _

3667 *Dr. Newman-Toker. No, it is not hypothetical actually.

3668 *Mr. Crenshaw. Okay.

3669 *Dr. Newman-Toker. There are a lot of symptom checkers
3670 that are out there, they have been studied _

3671 *Mr. Crenshaw. Got it, okay.

3672 *Dr. Newman-Toker. _ pretty significantly, and they
3673 have been looked at, and their accuracy is often quite low.

3674 *Mr. Crenshaw. And these are just websites I can go to?

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

3675 *Dr. Newman-Toker. Yes.

3676 *Mr. Crenshaw. They are not FDA regulated?

3677 *Dr. Newman-Toker. Correct.

3678 *Mr. Crenshaw. Okay.

3679 *Dr. Newman-Toker. And what essential happens is that

3680 at the bottom there is a legal disclaimer that essentially

3681 says _

3682 *Mr. Crenshaw. Yeah.

3683 *Dr. Newman-Toker. _ this is just a toy.

3684 *Mr. Crenshaw. Yeah.

3685 *Dr. Newman-Toker. If you want real medical advice, ask

3686 your medical professional. But that is not how patients are

3687 dealing with that. And I do think that some of those

3688 decision making, you may have a stroke that is causing your

3689 dizziness, and if you need to be sent to the emergency

3690 department but this system, this AI system that is out there

3691 unregulated, is saying to you, don't worry, just say home,

3692 that is a real risk to the public health.

3693 *Mr. Crenshaw. I think there is broad agreement here

3694 that we would never want AI to operate independently _ maybe

3695 not never, right, we might be in Star Trek mode at some point

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

3696 but like for _ definitely for foreseeable future that you
3697 would always have a doctor's blessing, even _ because there
3698 is amazing things that can happen. We are seeing this
3699 technology coming out of China, unfortunately, and this gets
3700 to a competition problem, too, if we are going to over-
3701 regulate things, but it is apparently diagnosing pancreatic
3702 cancer at 99 percent success rates. Like, whoa, that is
3703 amazing.

3704 Now a doctor should still look at that after the fact
3705 and be like, yeah, that is pancreatic cancer, but there are
3706 just amazing things that we can do with this technology.
3707 There is also amazing risks that can happen, especially when
3708 we are talking about that more generalized, you know,
3709 generative AI, which is basically mimicking a person.

3710 And again, the question we _ Congress has to ask itself,
3711 whether it is healthcare or any other conversation about AI,
3712 is what kind of person is it mimicking. We don't know the
3713 answers to that, and we have not talked about it enough in
3714 this Congress, so I am glad we are doing this hearing. And I
3715 yield back.

3716 *Mr. Guthrie. Thank you. The gentleman yields back.

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

3717 And that concludes all members present for questions, and we
3718 thank our witnesses for being here.

3719 But before we gavel out, I want _ we have a _ the
3720 documents for the record that some members have asked for and
3721 some others that have been submitted. And I ask unanimous
3722 consent to insert in the record the documents included on the
3723 staff hearing documents list.

3724 *Ms. Eshoo. No objection.

3725 *Mr. Guthrie. Without objection, that will be an order.

3726 [The information follows:]

3727

3728 *****COMMITTEE INSERT*****

3729

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

3730 *Mr. Guthrie. And I will remind members that some said
3731 they were going to submit questions to you. They have 10
3732 business days to submit questions for the record, and we ask
3733 that the witnesses respond to the questions promptly. And
3734 members should submit their question by the close of business
3735 on December the 13th.

3736 And again, we appreciate every one of you being here and
3737 your time. This is something we are still _ as you _ very
3738 curious and a lot _ very engaged members and want to
3739 understand it and working to understand it so we can act
3740 appropriately without _ to protect but without impinging the
3741 great things that could come from this. So that is what we
3742 are focused on, and again I appreciate it.

3743 And without objection, the subcommittee is adjourned.

3744 [Whereupon, at 1:36 p.m., the subcommittee was
3745 adjourned.]