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3 HEARING ON ``THE BATTLE AGAINST DIABETES: PROGRESS MADE;

4 CHALLENGES UNMET''

5 THURSDAY, JULY 1, 2010

6 House of Representatives,

7 Subcommittee on Health

8 Committee on Energy and Commerce

9 Washington, D.C.

10 The subcommittee met, pursuant to call, at 10:05 a.m.,
11 in Room 2123 of the Rayburn House Office Building, Hon. Frank
12 Pallone, Jr. [Chairman of the Subcommittee] presiding.

13 Members present: Representatives Pallone, Dingell,
14 Engel, Green, DeGette, Capps, Schakowsky, Baldwin, Barrow,
15 Christensen, Castor, Space, Sutton, Waxman (ex officio),
16 Shimkus, Whitfield, Burgess, Blackburn and Gingrey.

17 Staff present: Karen Nelson, Deputy Committee Staff
18 Director for Health; Sarah Despres, Counsel; Purvee Kempf,

19 Counsel; Emily Gibbons, Professional Staff Member; Katie
20 Campbell, Professional Staff Member; Stephen Cha,
21 Professional Staff Member; Virgil Miller, Professional Staff
22 Member; Anne Morris, Professional Staff Member; Alvin Banks,
23 Special Assistant; Allison Corr, Special Assistant; Karen
24 Lightfoot, Communications Director, Senior Policy Advisor;
25 Lindsay Vidal, Special Assistant; Clay Alspach, Minority
26 Counsel, Health; and Ryan Long, Minority Chief Counsel,
27 Health.

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28 Mr. {Pallone.} The meeting of the Health Subcommittee
29 is called to order.

30 Today we are having a hearing on our collective battle
31 against diabetes, the progress we have made so and the
32 challenges that remain. Over 30 years ago, Congress passed
33 the National Diabetes Research and Education Act, the first
34 significant legislation directed at coordinating and
35 expanding the government's research and prevention efforts
36 related to diabetes. While we have made tremendous progress
37 in understanding and treating diabetes, it remains a
38 significant public health epidemic. It is staggering to
39 realize that over 23 million Americans have some form of
40 diabetes today, and the number is growing. Even more
41 troubling is that 57 million Americans are at serious risk
42 for developing type 2 diabetes including women with
43 gestational diabetes.

44 Until recently, kids were rarely diagnosed with anything
45 but Type 1 diabetes, and the increasing rate of childhood
46 obesity is changing the face of diabetes though, and
47 certainly not for the better. And as we will hear today from
48 our esteemed panels, diabetes is a leading cause of heart
49 disease, stroke, blindness and kidney failure.

50 As is often the case, diabetes disproportionately

51 affects racial and ethnic minorities. American Indians have
52 the highest prevalence of diabetes, nearly four times those
53 of white Americans, with Hispanics and African-Americans
54 close behind.

55 Moreover, there is a clear economic cost. It has been
56 estimated that over \$220 billion in medical expenses in 2007
57 can be attributed to diabetes.

58 These are serious problems which need aggressive and
59 innovative action. Today we are going to hear from two of
60 our government witnesses from the National Institute of
61 Diabetes and Digestive and Kidney Diseases, located at NIH,
62 and the Centers for Disease Control. Both will speak to
63 their agencies' roles in doing landmark research and
64 surveillance work related to diabetes, and how this
65 information has been translated into more effective
66 prevention and treatment strategies, including the
67 development of key therapies and technologies. I should add
68 that NIDDK has recently celebrated its 60th anniversary
69 conducting and supporting biomedical research to improve
70 health care across the nation. NIDDK leads the Nation's
71 federal commitment in research, education and health
72 information dissemination with respect to diabetes, and
73 supports investigators who continue to make strides in
74 research toward understanding, preventing and treating type 1

75 diabetes, type 2 diabetes and gestational diabetes. It is
76 for these reasons that the ranking member, Congressman
77 Shimkus, and I recently introduced a resolution honoring the
78 NIDDK for its outstanding work.

79 Now, on our second panel, comprised of leaders from the
80 American Diabetes Association, the Juvenile Diabetes Research
81 Foundation and National Indian Health Board, will also be
82 able to shed light on the partnerships they have with
83 government and in the community to maximize technology,
84 translating to improved health outcomes. Lessons learned
85 from innovative research such as that funded by the Special
86 Diabetes Program, have informed our efforts to address the
87 epidemic today and will continue to do in the future. I have
88 to mention my home State and say that innovative, exciting
89 and collaborative work on diabetes research is taking place
90 across the country in public-private partnerships, and I am
91 proud that New Jersey's life sciences industry continues to
92 play a strong role in contributing to our ability to address
93 the epidemic today and will do so in the future.

94 Before I turn it over to Mr. Shimkus--she is here. I
95 wanted to mention that there were many members who asked for
96 this hearing but the most persistent one was certainly the
97 gentlewoman from Colorado, Ms. DeGette, but I know that many
98 members have asked that we have this hearing today. Also, my

99 Native American friends have been asking that we have this
100 for some time because of the high incidence of diabetes in
101 American Indian populations.

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

103 ***** COMMITTEE INSERT *****

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104 Mr. {Pallone.} So with that, I will turn it over to Mr.
105 Shimkus.

106 Mr. {Shimkus.} Thank you, Mr. Chairman. I do want to
107 recognize Dianna DeGette, also, Ed Whitfield and Freddy Upton
108 and Zach Space, and Dianna is a rabid supporter and well
109 known for her hard and diligent work, so there is a story we
110 tell only to ourselves about our first term when we sat
111 together way up front and they moved us, so--they moved me.

112 Let me just welcome folks here, and as a member of the
113 very large Diabetes Caucus and the work from all the whole
114 community to help educate us, to educate, really, children
115 and parents and that whole plethora, it is a success story.
116 Obviously we would like to have the final success which would
117 be, you know, cure and that is the research and that is the
118 disease management and that is what we should be focusing on.

119 We will continue to express concerns about spending and
120 the debt because budgetarily it will affect our ability to
121 get money for research and development. If we continue to
122 spend more and more money on interest on the debt, then the
123 discretionary money and the accounts that we have to do NIH,
124 do CDC, to do all the things that we need to do gets limited.
125 In fact, USA Today in their article the federal debt will
126 represent 62 percent of the Nation's economy by the end of

127 this year, the highest percentage since just after World War
128 II, and that is according to the CBO.

129 So when we raise issues about the new health care law,
130 when we raise issues about spending and dollars, we are
131 putting ourselves in a bad position to really focus on the
132 things we want to do and set priorities interest payments
133 will start consuming that. So as we make those cases, we do
134 that with the best intention.

135 This hearing is a result of a letter that was sent by
136 Dianna and her colleagues. We have sent other letters on the
137 law that we hope will be well received too, whether it is the
138 CMS actuary or of concern now are high-risk pools which were
139 promised in the new health care law which some States can't
140 fully fund and operate or the States that have turned it over
141 to the federal government because they are not going to
142 manage it themselves, we have no idea what we are going to
143 do, and those are promises we made as a Nation with the
144 passage of the law and the signing by the President. So we
145 have to figure out how we can keep our promises.

146 So I have a lot more I would want to say but I know time
147 is short, and I will yield back my time and thank the
148 chairman for letting me use his big chair.

149 [The prepared statement of Mr. Shimkus follows:]

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151 Mr. {Pallone.} Thank you, Mr. Shimkus.

152 Next is the gentlewoman from Colorado, Ms. DeGette.

153 Ms. {DeGette.} Thank you so much, Mr. Chairman, and
154 thanks to Mr. Shimkus for his I think allegedly kind words.

155 I really want to thank Mr. Space and Mr. Whitfield and
156 Mr. Upton for requesting this hearing with me, and I also
157 want to thank Mr. Green and all the rest of the members of
158 this committee because we all share a collective commitment
159 to addressing the issues of diabetes. The 250-member
160 Congressional Diabetes Caucus is the largest caucus in
161 Congress, and we strive hard to keep it that way. The reason
162 is because diabetes is the fastest growing epidemic in this
163 country and it affects everybody, young and old. Twenty-four
164 million people have diabetes in this country. Fifty-seven
165 million people, which is a quarter of all American adults,
166 have pre-diabetes. So one of our tasks as well as giving
167 quality care and management to the people who already have
168 one of the various forms of diabetes is to try to get these
169 other people back from the brink, and this is something that
170 is difficult because most of those people don't even know
171 that they are pre-diabetic.

172 Have we made progress? Yes, we have made some. We know
173 that effective patient self-management of an individual's own

174 diabetes is arguably the most crucial part of an overall care
175 regimen and there is now a substantial body of evidence that
176 diabetes self-management training is effective but only if
177 the patient has access to it. We also know that medical
178 nutrition therapy can have a significant impact on preventing
179 pre-diabetes from becoming full-blown diabetes.

180 One issue that I have been increasingly concerned about
181 and I have talked to a lot of folks about this is access to
182 technology because as the mother of a 16-year-old with type 1
183 diabetes, I see the wonderful care advances that she has
184 access to but these advances are very, very expensive. She
185 now has a continuous glucose monitor, and the sensors that
186 she puts in once or twice a week each cost \$80 before
187 insurance. So I say to myself and the members of the
188 Diabetes Caucus, how can we make those wonderful advances in
189 care and technology available to every diabetic, not just
190 those who are fortunate enough to have parents with good
191 health care coverage. We also know that disparities in
192 minority populations are too prevalent but we haven't done
193 enough research to figure out how to mitigate the disparities
194 in prevention, access and treatment for these populations.

195 So we have made progress but when the incidence of
196 diabetes in the United States continues to rise unabated, it
197 is clear that diabetes has become as described in this week's

198 Lancet a public health humiliation for our Nation. The
199 Diabetes Caucus is unwaveringly committed to tackle these
200 challenges that are still unmet and to remove this
201 humiliation. We will continue to press forward on all of the
202 priorities including making our hard-fought efforts to
203 include certified diabetes educators as Medicare providers,
204 to classify podiatrists as physicians under Medicaid, and
205 many, many other priorities. The caucus is going to host a
206 briefing on July 12th to address the growing epidemic of pre-
207 diabetes so we can start thinking about ways to pull those 57
208 million people back from the brink.

209 For pre-diabetes, type 1 diabetes to type 2, to
210 gestational diabetes and even malnutrition diabetes, this
211 condition comes at us in different forms but the urgency
212 mandates that we continue to work tirelessly to tackle the
213 issue, and Mr. Shimkus is right. It is a health issue and
214 also a cost issue because if we don't start putting the
215 research into this issue now, it is going to overwhelm our
216 health care system, as my two young girls become adults.

217 So I want to thank the witnesses on both panels for
218 coming today. This testimony really helps us set our course
219 as we move forward the rest of this year and into the next
220 year to set our policy as a caucus but also as a Health
221 Subcommittee, and with that, I yield back.

222 [The prepared statement of Ms. DeGette follows:]

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224 Mr. {Pallone.} Thank you.

225 Ms. Blackburn.

226 Mrs. {Blackburn.} Mr. Chairman, I do thank you for
227 calling the hearing, and I want to welcome Mr. Buford Rolin,
228 who is chairman of the Poarch Band of Creek Indians and the
229 national area representative for the National Indian Health
230 Board and say a special welcome to him for coming in today
231 and to all of our witnesses. We thank you for coming in
232 today and to all of our witnesses, we thank you for
233 attending, we thank you for the preparation that you put into
234 the hearings as you come to us.

235 Diabetes presents serious financial burdens and cost
236 patients in Tennessee more than \$3 billion in 2007. I had
237 the pleasure of meeting the Gould family from Middle,
238 Tennessee, last year during the JDRF fly-in. Four of eight
239 children in their family suffer from type 1 diabetes. It is
240 impossible to imagine the financial and emotional toll that
241 this disease takes on each and every day for that family.
242 With the sixth highest rate of diabetes in the Nation, this
243 is a very important issue to our State of Tennessee.

244 According to the JDRF, over 10 percent of Tennessee's
245 population is diabetic. In an annual obesity report released
246 Monday by the Robert Wood Johnson Foundation, Tennessee was

247 ranked the second most obese State in the country. A direct
248 link between diabetes and obesity exists. We all are aware
249 of that, and it appears that Tennessee is on their way to a
250 diabetes epidemic. Due to the prevalence of this disease,
251 the research, treatment and prevention efforts are a
252 significant focus for our Tennessee medical researchers. In
253 fiscal year 2009, NIH--and we thank you--granted over \$17
254 million for research in Tennessee. The American Diabetes
255 Association has eight active research grants in the State.
256 Most are focused on type 2 diabetes. Vanderbilt University
257 Medical Center's Eskin Diabetes Clinic is in the midst of 10
258 clinical trials to develop treatments and learn more about
259 the disease. And finally in my district, we have two
260 wonderful JDRF chapters. They are working actively to
261 support those with type 1 diabetes and the organization who
262 has given more than, get this, \$55 million to Tennessee
263 researchers. They are doing great work.

264 So for all of our agencies that are in the room, we
265 thank you for the working that you are putting in, and these
266 volunteers with associations are doing an incredible job in
267 our State. So I join my colleagues in saying this is an area
268 we want to heighten awareness. We want to be more proficient
269 in our education efforts and we hope that we provide the
270 proper support for the researchers who are trying to find a

271 cure, a treatment and disease management programs for this
272 disease.

273 I thank you, and I yield back.

274 [The prepared statement of Mrs. Blackburn follows:]

275 ***** COMMITTEE INSERT *****

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276 Mr. {Pallone.} Thank you, Ms. Blackburn. I am told we
277 are okay now with the mics, so we will see.

278 Next is our chairman, Mr. Waxman.

279 The {Chairman.} Thank you, Chairman Pallone, for
280 convening today's hearing.

281 The term ``diabetes'' describes a host of related health
282 conditions that are familiar to us, and the facts are
283 staggering. More than 20 million Americans have diabetes,
284 almost 60 million more at risk for diabetes, the leading
285 cause of blindness and kidney failure. People with diabetes
286 are at least twice as likely to die of heart disease or have
287 a stroke, and diabetes is the seventh leading cause of death.
288 It affects all age groups, both sexes and every race and
289 ethnicity. However, older Americans and certain racial and
290 ethnic groups are several times more likely to have diabetes
291 than others. That is why I am glad that we are taking the
292 opportunity to learn about landmark research accomplishments,
293 ongoing efforts to translate what we know works into practice
294 and research questions we have yet to answer.

295 Research has shown genetic causes, effective prevention
296 for type 2 diabetes and ways to delay and prevent
297 complications. NIDDK, CDC and other agencies within the
298 Department are working to ensure that our government has a

299 coordinated effort to advance diabetes research and improve
300 the health of those affected by this condition.

301 Still, there is work to be done. We must continue our
302 efforts to prevent women with gestational diabetes from
303 developing type 2 diabetes later in life. We are not yet
304 able to prevent type 2 diabetes nor have we perfected the
305 link between the continuous monitoring of blood glucose and
306 the administration of insulin, the so-called artificial
307 pancreas. And just this week, two new studies on the drug
308 Avandia underscore the need to better understand and better
309 treat type 2 diabetes.

310 Underpinning all of this is the importance of a broad
311 public health approach to this disease. We need sustained
312 investments in research. We need people who have information
313 to be emphasizing the point that diabetes is 24 hours, 7 days
314 a week. That is why we support what health providers,
315 families, and what is going on workplaces to maximize each
316 person's health and well-being.

317 I want to thank the witnesses for appearing before us
318 today and I look forward to hearing their testimony. With
319 that, Mr. Chairman, I yield back my time.

320 [The prepared statement of Mr. Waxman follows:]

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322 Mr. {Pallone.} Thank you, Chairman Waxman.

323 Next is the gentleman from Georgia, Mr. Gingrey.

324 Dr. {Gingrey.} Thank you, Mr. Chairman.

325 The World Health Organization has found that more than
326 150 million people suffer from diabetes and it is estimated
327 that this number will actually double by the year 2025. For
328 at least the last 20 years, diabetes rates in North America
329 have been increasing substantially with about 18.2 million
330 Americans living with the disease in 2002. Of those, roughly
331 90 percent have type 2 diabetes, which costs the United
332 States as much as \$132 billion a year. These statistics are
333 a stark reminder of the impact the disease has on our Nation
334 but also reminds us that the onset of diabetes for some
335 Americans can be prevented.

336 A majority of the patients with type 2 diabetes are
337 obese, the connection being that chronic obesity leads to
338 increased insulin resistance that can then develop into
339 diabetes. Obesity in many forms is a gateway from which
340 diabetes, heart disease and other chronic conditions can
341 strike American patients. Therefore, as we look at the
342 federal response to diabetes, I would suggest that we also
343 consider the root cause of obesity, reassessing the food
344 stamp program so that healthy foods are encouraged, ensuring

345 access to local parks and recreational programs and promoting
346 employer wellness programs, all the things that the federal
347 government can and should do to encourage healthy lifestyles.

348 We should also ensure that Americans with chronic
349 diseases have access to quality health care. Unfortunately,
350 President Obama's health care reform bill will make it hard
351 for many Americans with chronic diseases to find care when in
352 need. As many of you know, the preexisting condition
353 insurance plan passed as part of President Obama's health
354 care bill, Patient Protection Affordable Care Act of 2010,
355 will begin accepting applications in many States today.
356 However, according to an AP article that ran just yesterday,
357 and I quote, ``Premiums will be a stretch for many and the \$5
358 billion that Congress allocated to the program through 2013
359 could run out well before that.'' The Congressional Budget
360 Office in a report released last week supported this finding
361 when stating that the program's funding will not be
362 sufficient to cover the cost of all applicants.

363 Mr. Chairman, Ranking Member Shimkus has repeatedly
364 called for hearings on the new health care law because it is
365 deeply flawed and certainly can and I think will hurt our
366 country. Since the day the bill was enacted, we have been
367 reminded how this bill fails everyday Americans, companies
368 filing billion-lawsuits with the SEC, the Department of Labor

369 reporting that half of all workers will actually lose the
370 health plan that they have today, and many Americans with
371 chronic illnesses will be offered health insurance that they
372 just simply cannot afford. Mr. Chairman, I would urge this
373 committee to act and hold hearings on the problems in the
374 bill, President Obama's health care law.

375 That being said, however, Mr. Chairman, I really do want
376 to single out and commend Congresswoman DeGette for her
377 efforts in addressing the incidence of diabetes in this
378 country. She represents and is I think chairperson of the
379 largest caucus in Congress today with over 250 members. Her
380 leadership in this area is laudable and worthy of recognition
381 by this committee and by myself, a practicing physician
382 before I got this job.

383 And with that, Mr. Chairman, I yield back.

384 [The prepared statement of Dr. Gingrey follows:]

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386 Mr. {Pallone.} Thank you, Mr. Gingrey.

387 Next is our chairman emeritus, Mr. Dingell.

388 Mr. {Dingell.} Mr. Chairman, I thank you for your
389 courtesy and I commend you for this hearing.

390 First, I wish to recognize the many members of this
391 committee who have continued to beat the drum on this
392 disease, and I thank them for their leadership.

393 It is safe to say that we have a diabetes epidemic on
394 our hands. More than 24 million Americans are afflicted with
395 the disease. That is more than twice the number of people
396 with diabetes in 1997. In my home State of Michigan, more
397 than 680,000 thousand people, 8.6 percent of our population,
398 struggle with the disease daily. In addition to the major
399 health complications caused by diabetes, the economic toll of
400 the disease is considerable. Diabetes costs the U.S. economy
401 \$174 billion every year. One-third of every Medicare dollar
402 is spent on people with diseases and already stretched State
403 Medicaid programs are confronted with the growing costs of
404 diabetes care.

405 Since the passage of the National Diabetes Research and
406 Education Act in 1974, the federal government has worked to
407 coordinate diabetes activities amongst the various
408 responsible agencies. Most notably, the work of the Centers

409 for Disease Control and Prevention and the National
410 Institutes of Health have tossed a tremendous amount on the
411 causes of this disease and ways to control and prevent it.
412 Because of our surveillance, education and treatment
413 activities, individuals today with diabetes live longer and
414 healthier lives than people were diagnosed with the condition
415 in prior decades. However, the rate of new cases of diabetes
416 continues to increase. As a result, the gains in control and
417 treatment are being overtaken and submerged by the increase
418 in the number of people acquiring the condition.

419 The recently enacted health reform law will address the
420 many abuses employed by insurance companies to discriminate
421 against those with diabetes, and I am extremely proud of that
422 fact. Additionally, the new law provides access to the
423 necessary tools to manage and prevent diabetes and its
424 complications including the creation of a National Diabetes
425 Prevention Program, a national report card on diabetes to be
426 updated every 2 years, and State grants to provide healthy
427 lifestyle incentives for Medicare beneficiaries. Now, these
428 steps will go a long way in our fight against diabetes but
429 more can and should be done. We must ensure our approach is
430 consistent with current science and with understanding the
431 disease. Our approach needs to be comprehensive and it must
432 ensure that all we do and that we do all we can to prevent

433 the onset of the disease to ensure the diagnosis of the
434 disease is conducted in the most efficient and accurate
435 manner, and to ensure that our people have the best methods
436 available to control the disease and ensure that diabetics
437 have the best treatment and medications available to prevent
438 complications. These efforts we make in defeating diabetes
439 will have an enormous impact on the health of our Nation.

440 Thank you again, Mr. Chairman. I yield back the balance
441 of my time.

442 [The prepared statement of Mr. Dingell follows:]

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444 Mr. {Pallone.} Thank you, Chairman Dingell.

445 Let me now--they just called three suspension votes but
446 I would like to take one more speaker and then we will recess
447 and come back, which should be about half an hour or so. And
448 next on my list is the gentleman from Kentucky, Mr.
449 Whitfield.

450 Mr. {Whitfield.} Thank you very much, and I certainly
451 want to thank the witnesses for being here today. We
452 appreciate very much the commitment that you have made to
453 help us find a cure for this disease and to reduce the number
454 of people that unfortunately have it, and I also hope that
455 those in the audience are not disillusioned that Republicans
456 and Democrats are so joined together on this issue.

457 I do want to thank Dianna DeGette and Henry Waxman and
458 Frank Pallone as well as John Shimkus, Joe Barton, Fred
459 Upton, Zach Space and all of those who are involved and
460 interested in this issue.

461 Two months ago, I was down in my district and I met with
462 the parents and six teenagers who all had diabetes, and we
463 frequently, those of us who are layman, think that what you
464 eat and your weight is the determining factor of whether or
465 not you have diabetes but when you talk to these young
466 teenagers, all of whom are very thin, very energetic, all of

467 them have diabetes, and then you realize what they go through
468 every single day with the testing that they do, with the
469 monitoring that they do, watching the foods that they eat,
470 the emergency runs to the hospital they make and the impact
471 it is going to have on their entire life, it does bring home
472 very clearly the impact that this disease has. Other
473 speakers have talked about the statistics and the costs and
474 the impact on the number of people in our country, and so I
475 think this hearing is very important. I certainly want to
476 thank Dianna DeGette for sort of leading the charge. I know
477 that all of our physicians on this panel, Dr. Gingrey and our
478 friend from Texas, Dr. Burgess, have particular interest as
479 well.

480 So we look forward to your testimony to help guide us as
481 we move forward, and I also want to point out that while the
482 federal government is spending a lot of money on research, we
483 also have some private companies that are spending a lot of
484 money on research, and one that I would like to particularly
485 mention is Novo Nordisk, which happens to be a company in
486 Denmark but they have 4,000 employees in the United States,
487 and the U.S. federal government is the only entity that is
488 spending more money on research on diabetes than is Novo
489 Nordisk, so I want to thank them and their leadership team
490 for their commitment to this disease as well

491 Thank you, Mr. Chairman.

492 [The prepared statement of Mr. Whitfield follows:]

493 ***** COMMITTEE INSERT *****

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494 Mr. {Pallone.} Thank you, Mr. Whitfield.

495 We have time for one more before we break, so I am going
496 to ask our vice chair, Ms. Capps, to do an opening statement.

497 Mrs. {Capps.} Thank you, Chairman Pallone, for holding
498 this hearing, and it gives me an opportunity to thank my
499 suitemate here, my colleague, Dianna DeGette, as well, for
500 bringing us all together around this issue, and on behalf of
501 the entire diabetes community because as I was just
502 mentioning to her, this is a very well-organized group with
503 juvenile diabetes and make visits to their Members of
504 Congress regularly, and I want to applaud them for doing
505 that.

506 It really has an impact on us. I look forward to an
507 update today from our esteemed witnesses on the progress of
508 diabetes research. After all, despite all the promising
509 discoveries over the past several decades, there still is no
510 cure, no surefire way to prevent the development of diabetes,
511 especially type 1. As many of my colleagues know, I was a
512 school nurse for many years, and if there is one disease that
513 is sure to make a student a frequent visitor into the nurse's
514 office at school is diabetes, so I certainly became very
515 familiar with the maintenance of type 1 diabetes and I have
516 been hopeful that by now we would have something in place but

517 there are many promising things on the horizon which is
518 exciting to know about or what we are going to learn today.

519 The sad truth, however, as my colleagues have indicated,
520 is that children don't suffer today just from type 1
521 diabetes. There is such an increase now in the incidence of
522 type 2 diabetes. I know there are definite steps to prevent
523 the onset of type 2 we can take in our communities such as
524 increased physical activity and better nutrition but we need
525 also to be creative in how we get the message out to at-risk
526 populations, especially minority ones, and design programs
527 targeted for those populations. I think particularly of
528 programs in my district such as St. John's Latino Health
529 Diabetes League, an initiative in Oxnard, California, which
530 is tailored educational programming to at-risk communities.
531 But they can only do this with the right type of evidence-
532 based research being conducted at the institutions
533 represented here today.

534 So I am especially curious today to learn more about how
535 you are working to equip our local communities with the tools
536 that they need to address diabetes prevention and management.
537 I look forward to hearing from our witnesses about the
538 exciting work you are doing now and how Congress can better
539 work with you and help you achieve our shared goal of finding
540 a cure.

541 I yield back.

542 [The prepared statement of Mrs. Capps follows:]

543 ***** COMMITTEE INSERT *****

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544 Mr. {Pallone.} Thank you, Ms. Capps.

545 So we will now take a recess for the three votes. The
546 committee stands in recess.

547 [Recess.]

548 Mr. {Pallone.} The committee hearing will reconvene,
549 and we will begin with the gentleman from Texas, Mr. Burgess.

550 Dr. {Burgess.} Well, I thank the chairman for yielding.

551 The hearing this morning focuses on an important public
552 health issue, obviously a significant impact on our Nation
553 and a crippling effect on our budgets, and we have already
554 heard statistics from a number of members this morning so I
555 won't repeat those, only to mention that in my home State of
556 Texas over 1-1/2 million people over the age of 18 have
557 diabetes, and in our State, it is the sixth leading cause of
558 death.

559 Two bills which I would like this committee to consider
560 to move expeditiously and mark up, of course, we have already
561 heard about H.R. 3668, Representative DeGette, would
562 reauthorize the special diabetes programs for type 1
563 diabetes. This program was started back in the 1990s under
564 the guidance of then-Speaker Newt Gingrich, and he continues,
565 as do I, to support the innovative work of this program. In
566 fact, there have been some rather dramatic things that have

567 come out of this program including auto transplantation of
568 beta cells from people who have had a dramatic disruption of
569 the pancreas.

570 Now, I also have a bill with Elliot Engel, the
571 Gestational Diabetes Act of 2009. Having practiced as an
572 OB/GYN for over 25 years, I am clearly well aware of the
573 problems of untreated gestational diabetes affecting over
574 200,000 pregnancies a year, over 7 percent of the pregnancies
575 in this country, and they can have significant impact on both
576 the mother and child because they are at significant risk of
577 developing type 2 diabetes, and mothers are almost three
578 times more likely to have a recurrence of gestational
579 diabetes in future pregnancies. As with other diabetes
580 trends, the rates of gestational diabetes are higher among
581 women of African American, Hispanic, Asian and Native
582 American descent. H.R. 5354 creates a research advisory
583 committee headed by the CDC to expand monitoring including
584 coordinating efforts to help mothers avoid contracting type 2
585 diabetes.

586 So I would urge members of the committee to cosponsor
587 this legislation. It does just so happen that I have a
588 signup sheet for anyone interested in cosponsoring this bill,
589 and I Mr. Engel and I would be happy to take that to the
590 Floor to save you the trouble.

591 While we hear about the increase of obesity in the
592 United States that has raised the prevalence of diabetes
593 generally, we also need to hear about the impact of genetics,
594 ethnicity and maternal age, particularly in the case of
595 gestational diabetes, and focus our research on how diabetes
596 cost can be reduced through better lifestyle choices. With
597 the correlation between obesity and lower income levels and
598 diabetes, this committee really needs to stress being
599 involved in encouraging proper nutritional choices for our
600 populations that we serve under Medicare, which is under our
601 jurisdiction.

602 So I thank you, Mr. Chairman. I will unbelievably yield
603 back the balance of my time.

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

605 ***** COMMITTEE INSERT *****

|
606 Mr. {Pallone.} I am supposed to take notice, I guess,
607 right? All right. Thank you.

608 Next is the gentlewoman from the Virgin Islands, Ms.
609 Christensen.

610 Dr. {Christensen.} Thank you, Mr. Chairman, and Ranking
611 Member Stupak for holding this hearing today to discuss the
612 yet unmet challenges facing us regarding diabetes, and thank
613 you also to Dianna DeGette for her leadership on this issue.

614 I would like to welcome our witnesses today on both
615 panels and recognize in addition the 60th anniversary of the
616 National Institute of Diabetes and Digestive and Kidney
617 Disease and wish you many more years of leadership and
618 conducting and supporting biomedical research.

619 I too also want to thank Novo Nordisk for their work on
620 diabetes both in the lab and in communities like mine, which
621 has a prevalence of diabetes that is far higher than the
622 national average.

623 Diabetes is a disease that strikes at every age level
624 and every racial and ethnic group in America, and while it
625 does still disproportionately affect the elderly, the fact
626 remains that its prevalence is growing among all groups. In
627 addition to the nearly 24 million people currently living
628 with diabetes, there are 57 million estimated to have pre-

629 diabetes, putting them at increased risk for developing
630 diabetes and complications therefrom. Particularly
631 disturbing to me is the increase in type 2 diabetes in
632 children and the racial and ethnic differences in prevalence
633 of diagnosed diabetes. When nearly 12 percent of non-
634 Hispanic blacks, more than 10 percent of Hispanics and an
635 unacceptable 16.5 percent of Native Americans and Alaska
636 Natives have been diagnosed with diabetes compared to 6.6
637 percent in non-Hispanic whites and 7.5 percent in Asian
638 Americans, it is undeniable that aggressive action must be
639 taken to address these disparities. It is also alarming that
640 the prevalence of a disease which 100 years ago was unknown
641 to them affects now Native Americans and Alaska Natives at a
642 rate that is more than twice that of their white
643 counterparts.

644 It is because of these disturbing facts that I am
645 especially pleased to see that Mr. Buford Rolin is present
646 from the National Indian Health Board. Although the
647 diversity that exists among Native Americans, Alaska Native
648 populations must be recognized. Your presence here is
649 certainly a step in the right direction, and giving these
650 populations a voice on this issue and ensuring that the
651 diversity that exists on every American health issue is not
652 overlooked or forgotten.

653 It has been over 35 years since the Interagency
654 Committee to Coordinate Diabetes was set up at HHS, and while
655 advances have been made, in that time diabetes has exploded,
656 especially in the South, and racial and ethnic minorities and
657 type 2 in children, so I look forward to exploring today what
658 is going to change forward so we can reverse this really
659 terrible trend that we are seeing in our country.

660 Dr. {Gingrey.} Will the gentlelady yield to me before
661 she yields back just for a friendly purpose?

662 Dr. {Christensen.} Certainly.

663 Dr. {Gingrey.} I thank the gentlewoman.

664 Earlier a member on our side of the aisle recognized a
665 couple of physicians on the committee and on the
666 subcommittee, and he failed to mention Dr. Christensen, who
667 has come to this Congress from the Virgin Islands, having
668 practiced family medicine there for many years, and she knows
669 of what she speaks, so I just wanted to recognize that fact.

670 Dr. {Christensen.} Thank you for that. I yield back.
671 Thanks.

672 [The prepared statement of Dr. Christensen follows:]

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

|

674 Mr. {Pallone.} I thank the gentlewoman.

675 Next is the gentleman from Ohio, Mr. Space.

676 Mr. {Space.} Mr. Chairman, I will enter my opening
677 statement into the record on the condition that I will be
678 allotted time for my questioning.

679 Mr. {Pallone.} Absolutely. That is how we work.

680 Mr. {Space.} I would like to thank you, however, for
681 calling this very important hearing, and my gratitude should
682 also go out to Dianna DeGette for her leadership and to Ed
683 Whitfield and Fred Upton for joining me in the request for
684 this hearing.

685 [The prepared statement of Mr. Space follows:]

686 ***** COMMITTEE INSERT *****

|
687 Mr. {Pallone.} Okay. Next is the gentlewoman from
688 Ohio, Ms. Sutton.

689 Ms. {Sutton.} Thank you, Mr. Chairman, and I too
690 appreciate you holding this hearing today. This is an
691 incredibly important to have. I, like so many members of the
692 subcommittee, care deeply about diabetes and I am a member of
693 Ms. DeGette's Congressional Diabetes Caucus, and I thank her
694 very much for her tremendous leadership.

695 Yesterday a young woman from northeast Ohio, Selena
696 Williams, came into my office. Selena is a 15-year-old and
697 was diagnosed 2 years ago with type 2 diabetes. As you can
698 imagine, and as some of you in this room have experienced
699 personally, this was an incredibly scary time for Selena and
700 her parents. She was very lucky to be able to participate in
701 a treatment program at Rainbow Babies and Children's
702 Hospital, which is home to a center for excellent for
703 childhood diabetes, activity and nutrition, and through
704 Rainbow Babies Selena and her family joined a program called
705 the TODAY program, which stands for Treatment Options for
706 Type 2 Diabetes in Adolescents and Youth. The TODAY
707 program's goal is to study the best ways to treat type 2
708 diabetes in children, and in the TODAY program Selena and her
709 family learned the basic skills that she would need as a

710 diabetic--how to test her blood on a home meter, give insulin
711 shots and manage high and low blood sugars. And she also
712 learned through home visits with a certified diabetes nurse
713 how to make lifestyle changes to help her and her entire
714 family be healthier such as how to read food labels, manage
715 portions and stay active. And through the TODAY program,
716 Selena has improved her health and she recently did something
717 that she said she never thought she would do. She tried out
718 for the freshman basketball team, and I am proud to report
719 that she made it. Sadly, there are millions of children like
720 Selena but not all children have the same treatment
721 opportunities or educational programs that Selena has had but
722 all of those children have great potential, and the fact that
723 they don't have that opportunity is heartbreaking.

724 So I look forward to hearing about the progress that has
725 been made in the battle against diabetes and about the work
726 that still needs to be done and what we can do to help.

727 Thank you, and I yield back.

728 [The prepared statement of Ms. Sutton follows:]

729 ***** COMMITTEE INSERT *****

|
730 Mr. {Pallone.} Thank you.

731 Next is the gentlewoman from Illinois, Ms. Schakowsky.

732 Ms. {Schakowsky.} Thank you, Mr. Chairman.

733 You know, if for no other reason, we should as
734 policymakers and as taxpayers pay very close attention to
735 diabetes. According to a Mathematica report by Drs. Marsha
736 Gold and Ronette Briefel, diabetes costs the government, just
737 the government cost, \$80 billion a year in medical costs.
738 That is Medicare and Medicaid, and I am sure veterans health
739 care, etc. The CDC's testimony reports that national costs
740 for 2007 exceeded \$218 billion. That includes private
741 insurance. So if we were to really target diabetes in terms
742 of research, in terms of the kinds of public education
743 programs that Congresswoman Sutton talked about in
744 controlling this disease, we would also be able to save
745 billions of dollars and change lives forever.

746 Diabetes is really a very cruel disease that affects
747 23.6 million Americans. It is cruel to young children who
748 have to draw blood every day, monitor their sugar and their
749 diet, which is a good thing for all children but in the ways
750 that diabetic children have to do, it is really difficult,
751 and to millions of adults who develop diabetes later in life
752 particularly for type 2 where there really are lifestyle

753 kinds of changes that can be made. We need to invest in
754 public health programs, and for all the rest of diabetes type
755 1 and also type 2, we need to invest in research.

756 So I want to thank Congresswoman DeGette, who has been a
757 champion throughout her career here and even earlier on
758 addressing this important disease, important in so many ways,
759 and a disease that we can in so many ways effectively
760 address. So let us do it. I yield back.

761 [The prepared statement of Ms. Schakowsky follows:]

762 ***** COMMITTEE INSERT *****

|
763 Mr. {Pallone.} Thank you.

764 And next is the gentlewoman from Wisconsin, Ms. Baldwin.

765 Ms. {Baldwin.} Thank you, Mr. Chairman and Ranking
766 Member Shimkus for calling this hearing today, and I too want
767 to echo my colleagues' comments of gratitude for the
768 leadership of my friend Dianna DeGette on this issue.

769 I also want to welcome all the witnesses that we have
770 today. We are very much looking forward to hearing your
771 testimony.

772 Diabetes clearly has a sweeping impact on our society,
773 and in that vein I would like to share the story today of a
774 very brave family making a tremendous difference in my
775 district and across the State of Wisconsin. The Wickmans are
776 just like many other American families. They love the
777 outdoors, they love to take road trips on weekends, and they
778 would do anything for their children. Yet this family has
779 really been ravaged by diabetes. Grandpa Rick has type 2
780 diabetes and just had to have his foot amputated recently.
781 Their daughter, Stella, just 4 years old, has type 1 diabetes
782 and has to have her finger pricked dozens of times each day
783 to make sure that her blood sugar level is at a safe level.
784 This disease infiltrates every waking moment of their lives.
785 You know, the Wickmans discovered that Stella was sick on a

786 family trip to the upper peninsula of Michigan after a
787 midnight ambulance ride and an admission to a pediatric ICU.
788 Since that day they really could have sat back and bemoaned
789 their fate but instead they have really thrown themselves
790 into helping Stella and the many children like her across the
791 country by championing the Juvenile Diabetes Research
792 Foundation of Western Wisconsin. They also carry the torch
793 of another Wisconsin hero, Jesse Alswager. Jesse traveled
794 extensively in his young life educating others about
795 diabetes. He even testified before a panel here in Congress
796 in support of stem cell research. Jesse died due to
797 complications of juvenile diabetes in February of this year
798 at age 13 but his legacy clearly lives on.

799 In my hometown at the University of Wisconsin, the
800 progress towards better treatment is real. An FDA-approved
801 clinical trial is currently underway for the use of adult
802 stem cells in the treatment of type 1 diabetes. This study
803 is cosponsored jointly by Osiris Therapeutics and the
804 Juvenile Diabetes Research Foundation. Researchers are
805 specifically targeting newly diagnosed type 1 diabetes
806 patients who still have some functioning beta cells left. An
807 infusion of targeted stem cell therapy could stop the immune
808 destruction and preserve individuals' remaining ability to
809 make insulin.

810 Perhaps the most exciting news for both the Wickmans and
811 researchers in the district that I represent is the passage
812 of the comprehensive health care reform legislation earlier
813 this year. This year, the bill bans insurers from citing
814 preexisting conditions as a reason to refuse to insure
815 children in America and to ensure that a child like Stella
816 will never be without health care coverage, and this year
817 that piece of legislation invests \$126 million through the
818 new prevention and public health fund to help create the
819 necessary infrastructure to prevent, detect and manage
820 chronic diseases like diabetes. Clearly, much work remains
821 to be done.

822 So as we work to implement this legislation, we must
823 remember the toll that diabetes takes on our families and on
824 our health care system but we must also work to improve and
825 expand existing federal programs that are making a difference
826 today, and I am glad that our witnesses are here to help
827 inform that process.

828 Thank you, Mr. Chairman, and thank you again to our
829 witnesses.

830 [The prepared statement of Ms. Baldwin follows:]

831 ***** COMMITTEE INSERT *****

|

832 Mr. {Pallone.} Thank you, and I think that concludes
833 our members' opening statements. We will now move to our
834 witnesses. Let me introduce, well, first welcome you both
835 and introduce the two of you. On my left is Dr. Judith
836 Fradkin, who is director of the Division of Diabetes,
837 Endocrinology and Metabolic Diseases at the National
838 Institute of Diabetes and Digestive and Kidney Diseases at
839 the National Institutes of Health. Fradkin--did I pronounce
840 that properly? Okay. And then is Ann Albright, who is
841 director of the Division of Diabetes Translation of the
842 Centers for Disease Control and Prevention, and thank you
843 both for being here. I think you know the drill, 5-minute
844 speeches, and then if you want to submit additional written
845 comments, you can, and I will start with Dr. Albright.

|

846 ^STATEMENTS OF ANN ALBRIGHT, PH.D., R.D., DIRECTOR, DIVISION
847 OF DIABETES TRANSLATION, CENTERS FOR DISEASE CONTROL AND
848 PREVENTION; AND JUDITH FRADKIN, M.D., DIRECTOR, DIVISION OF
849 DIABETES, ENDOCRINOLOGY AND METABOLIC DISEASES, NATIONAL
850 INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES,
851 NATIONAL INSTITUTES OF HEALTH

|

852 ^STATEMENT OF ANN ALBRIGHT

853 } Ms. {Albright.} Mr. Chairman, Mr. Shimkus and
854 distinguished members of the subcommittee, thank you for the
855 opportunity to participate in the hearing. I am Dr. Ann
856 Albright. I am the director of the diabetes division at CDC.
857 I am trained as an exercise scientist and nutritionist but I
858 also live with type 1 diabetes for 42 years.

859 The diabetes division at CDC translates the science of
860 diabetes into practical strategies to control and prevent
861 diabetes in the U.S. population and I will be describing some
862 of our work in surveillance to define and monitor diabetes,
863 the reduction of the risk factors, the prevention of type 2
864 diabetes, and management of this disease.

865 The ability to identify the magnitude of a problem
866 through ongoing surveillance is a foundation of CDC's work.

867 CDC developed and maintains the National Diabetes
868 Surveillance System. It is the world's first system for
869 monitoring diabetes. It relies on national and State-based
870 household telephone and hospital-based surveys, vital
871 statistics to monitor trends in diabetes. In the last 2
872 years, CDC has developed a methodology to estimate levels of
873 diabetes and obesity at the county level, providing
874 policymakers and communities with new information to guide
875 programming and resource allocation.

876 CDC in collaboration with NIH has also initiated the
877 largest major surveillance system to quantify and track type
878 1 and type 2 diabetes in those under 20 years of age called
879 Search for Diabetes in Youth. Among other things, Search
880 allows us to clarify the degree to which type 2 diabetes is
881 affecting youth of different racial and ethnic backgrounds.

882 Findings from our national surveillance system document
883 several increases or successes in the public health response
884 to diabetes over the past decade but have also revealed areas
885 of major concern and continuing threats to the public's
886 health. Rates of blood glucose being out of control,
887 amputations and end-stage renal disease among adults have
888 declined. However, considerable variation and disparities in
889 diabetes care and outcomes remain.

890 CDC does work to impact and improve outcomes for women

891 with and at risk for gestational diabetes. In collaboration
892 with the National Association of Chronic Disease Directors
893 and the Agency for Health Care Research and Quality, we have
894 established a five-State collaboration to identify, catalog
895 and validate routinely collected data about gestational
896 diabetes, identify gaps and documenting prevalence and
897 determine implications for care.

898 Our greatest concern, though, is the continued increase
899 in the rate of new cases of diabetes. This is evident in
900 virtually all segments of society. This continued increase
901 in the rate of development of new cases is unfortunately
902 negating many of the successes that clinical and public
903 health efforts have achieved in reducing the rates of
904 complications. The continued increase in diabetes incidence
905 calls for a comprehensive implementation of a diabetes
906 prevention strategy.

907 So CDC is engaged in risk-reduction efforts on multiple
908 levels including focus on obesity for the general population
909 but the diabetes division focuses on those at highest risk
910 for diabetes, so there are very complementary efforts, and in
911 fact we have focused much of our work in the Native American
912 community, helping many members achieve vouchers for
913 nutritious foods, particularly fruits and vegetables, and the
914 use of those vouchers have been in excess of 50 percent, so a

915 very tangible, concrete example of a way to reduce those risk
916 factors.

917 Based on the findings of the NIH-led diabetes prevention
918 program clinical trial, CDC is now actually translating those
919 findings into practice. We are able to do this with our
920 partners. At the top of the leading role is the YMCA of USA
921 and United Health Group, and we are able to offer this for
922 about \$250 to \$300 a person. This is the first time ever
923 that a private health insurer has joined forces with a
924 national community-based organization not deliver this work,
925 and we are focusing on training the workforce, on recognizing
926 those programs for quality assurance, for actually investing
927 in delivery of the programs, and for health marketing so
928 people know where to go and how to get those programs.

929 We are also preventing complications of diabetes, and we
930 have research trials that we have been doing, the Triad
931 study. We are taking those findings and we are working with
932 our State-based diabetes prevention and control programs to
933 actually put those into practice and change what health care
934 systems are actually delivering as a result of that study.

935 I want to just close with two new projects that we have
936 going on that are exciting, and one is the national program
937 to eliminate diabetes-related disparities in vulnerable
938 populations. We will now be funding six organizations that

939 will focus on reducing the mortality and premature mortality
940 and morbidity, and we will be helping this by helping these
941 communities to organize, plan and implement effective
942 strategies. And finally, we will also be initiating a new
943 platform of research studies to examine the impact of
944 population-targeted policies emanating from health systems,
945 business and community organizations and the government.

946 So several steps have been taken to stem the diabetes
947 epidemic. Work in risk factor reduction must continue so
948 fewer people develop pre-diabetes. The programs and policies
949 for obesity prevention and control are critical. There is a
950 critical need for effective programs that prevent people with
951 pre-diabetes from developing a disease and the first steps
952 have been taken in the form of the National Diabetes
953 Prevention Program. The complications of diabetes have a
954 very high cost in terms of dollars and human suffering, and
955 while improvements have been made, much work remains to be
956 done, especially in those vulnerable populations. Thank you.

957 [The prepared statement of Ms. Albright follows:]

958 ***** INSERTS 1, 2 *****

|

959 Mr. {Pallone.} Thank you, Dr. Albright.

960 Dr. Fradkin.

|

961 ^STATEMENT OF JUDITH FRADKIN

962 } Dr. {Fradkin.} Thank you, Mr. Chairman and members of
963 the subcommittee, and I also want to thank you for your
964 congratulations on our 60th anniversary and particularly to
965 thank Congresswoman DeGette and Mr. Space and Mr. Green, who
966 actually participated in our celebratory breakfast, and Ms.
967 DeGette in particular made some remarkably inspiring remarks
968 at that event, and I want to thank her. I am also very
969 pleased to testify with Dr. Albright, because our two
970 agencies work so effectively together on multiple efforts to
971 combat diabetes including our National Diabetes Education
972 Program which is co-led by the two agencies.

973 On behalf of NIDDK and the NIH, I am pleased to report
974 that we are vigorously pursuing research on diabetes and its
975 complications and today I would like to tell you about some
976 of NIH-supported research including research supported by the
977 special statutory program for type 1 diabetes research, which
978 is administered by NIDDK and has resulted in many scientific
979 advances that are improving the health and quality of life of
980 people with diabetes. A parallel funding stream for a
981 special diabetes program for Indians is administered by the
982 Indian Health Service and has led to substantial improvements

983 in diabetes care in American Indians.

984 Mr. Chairman, the need to pursue research on prevention,
985 treatment and cure of diabetes is greater than ever because
986 the rates of several types of diabetes are rising. The good
987 news is that we have made tremendous progress in recent years
988 which has led to improvements in survival and quality of life
989 for people with diabetes. For example, now thanks to
990 continuous glucose monitoring technology, some parents of
991 young children with type 1 diabetes can sleep through the
992 night without having to rise repeatedly to check their
993 child's blood glucose level. The device measures glucose
994 every several minutes and sounds an alarm if the levels are
995 too high or too low, a technological piece of mind allowing
996 parents to sleep more soundly.

997 Because genetic and antibody tests can predict with
998 great accuracy which children will develop type 1 diabetes,
999 we can now test prevention strategies and are doing so. To
1000 find new approaches to prevention, we launched the TEDDY
1001 study. TEDDY researchers screened over 400,000 newborns to
1002 find 8,000 who had genes that put them for particularly high
1003 risk of type 1 diabetes. Those children are now enrolled in
1004 the study and are being followed until age 15 with a goal of
1005 identifying environmental triggers of type 1 diabetes. For
1006 example, if we could find an infectious trigger, we must

1007 develop a vaccine to prevent the disease. To date, the
1008 number of children who have developed autoimmunity in type 1
1009 diabetes are exactly as predicted in the study, showcasing
1010 the tremendous power of these predictive tests.

1011 We can prevent or delay the development of type 1
1012 diabetes in people at high risk for the disease as
1013 demonstrated by the NIDDK-led landmark diabetes prevention
1014 program clinical trial that Dr. Albright mentioned. A modest
1015 amount of weight loss through diet changes and moderate
1016 exercise substantially reduced the occurrence of type 2
1017 diabetes at 3 years and now in the most recent report at 10
1018 years after enrollment in the trial. This intervention
1019 worked in all the ethnic and racial groups studied in both
1020 men and women and in women with a history of gestational
1021 diabetes.

1022 Building on this success, NIDDK supports research to
1023 translate these results to people who can benefit from them.
1024 For example, just this week NIDDK-supported scientists
1025 announced exciting results from research in which community
1026 health workers effectively delivered a group-based lifestyle
1027 intervention to people at high risk for type 2 diabetes. At
1028 1 year, the participants lost as much weight as was observed
1029 in the diabetes prevention program, suggesting that this
1030 approach may be a low-cost way to reach Americans.

1031 Another NIDDK-supported pilot study is already having a
1032 far-reaching impact. Researchers successfully utilized local
1033 YMCAs to deliver a lower-cost group-based DPP lifestyle
1034 intervention, and Dr. Albright has provided information about
1035 how the CDC is building on the results of this NIDDK-
1036 supported research to improve the public health by
1037 implementing a National Diabetes Prevention Program.

1038 Diabetes during pregnancy brings risks to mother and
1039 child. Because of the NIH-supported hyperglycemia and
1040 adverse pregnancy outcome study, we now have precise
1041 information on what blood glucose levels should be during
1042 pregnancy to avoid complications near birth.

1043 These are just a few examples of how far we have come in
1044 recent years through vigorous supported research toward
1045 increasing knowledge about diabetes and improving the health
1046 of people with diabetes. However, much work remains to be
1047 done to curb the diabetes epidemic. For example, it is
1048 critical to move beyond continuous glucose monitoring
1049 technology and link glucose monitoring to insulin delivery to
1050 create the so-called artificial pancreas. This technology
1051 could help patients achieve blood glucose control that has
1052 been shown to reduce complications and also alleviate the
1053 burden of self-care. Now that we have thousands of samples
1054 collected through the TEDDY study, it is vital to use new and

1055 emerging technology to analyze those samples and identify an
1056 environmental trigger of type 1 diabetes. Building on the
1057 success of the many new available therapies for type 2
1058 diabetes, comparative effectiveness research can help inform
1059 doctors' decisions about what medications to prescribe for
1060 their patients and when.

1061 Loss of the insulin-producing beta cells underlies both
1062 type 1 and type 2 diabetes. Research through NIDDK's beta
1063 cell biology consortium may develop new approaches to
1064 treatment by providing insights on how to reprogram cells to
1065 become insulin-producing cells, stimulate beta cell
1066 replication or replace lost beta cell function with cells
1067 derived from stem cells. Complementing these efforts,
1068 clinical research can provide information on how best to
1069 preserve beta cell function in people newly diagnosed with
1070 type 1 or type 2 diabetes.

1071 Perhaps most important to combating the diabetes
1072 epidemic is reversing the trend of both type 1 and type 2
1073 diabetes occurring at younger ages because earlier disease
1074 onset means earlier development of complications and
1075 premature mortality. For women, earlier development of
1076 diabetes also endangers her offspring. The intrauterine
1077 environment plays an important role not only in problems at
1078 the time of birth but also in the future development of

1079 diabetes and obesity, a finding observed among the Pima
1080 Indians in Arizona. Thus, it is critical to pursue research
1081 to break the vicious cycle of ever-growing rates of diabetes
1082 by preventing or mitigating the effects of diabetes and
1083 obesity during the childbearing years and pregnancy.

1084 Implementing research findings into clinical practice
1085 has led to reductions in rates of heart disease, kidney
1086 failure and blindness in people with diabetes. By building
1087 on recent advances in diabetes research, we are poised to
1088 realize even greater improvements in health and quality of
1089 life for people with diabetes. We have come far but we must
1090 go farther.

1091 Thank you, Mr. Chairman, for your leadership in calling
1092 this hearing to focus attention on the problem and for your
1093 continued support of NIH research.

1094 [The prepared statement of Dr. Fradkin follows:]

1095 ***** INSERT 3 *****

|
1096 Mr. {Pallone.} Thank you, Dr. Fradkin.

1097 Now we are going to have questions now from the members
1098 of the subcommittee, and I will start with myself for 5
1099 minutes.

1100 As you both know, the Diabetes Mellitus Interagency
1101 Coordinating Committee is in the midst of finalizing a
1102 diabetes research strategic plan. It is the first
1103 comprehensive research plan to be released in several years.
1104 I understand it is going to describe the future direction for
1105 10 major diabetes research areas, and Dr. Fradkin, if I could
1106 start with you, can you briefly summarize the major focus
1107 areas of this report, and then I was going to ask Dr.
1108 Albright, she identifies the increasing rate of new diabetes
1109 cases as an area of great concern for CDC, so how do you
1110 think that plan will help stem the diabetes epidemic? I will
1111 start with Dr. Fradkin.

1112 Dr. {Fradkin.} Thank you. So NIDDK is pleased to chair
1113 the DMICC, which includes participation from CDC and multiple
1114 agencies across HHS and throughout the government and really
1115 serves as a very effective organization to bring us together
1116 to share information and develop plans. So we have developed
1117 with the help of over 100 external researchers chapters
1118 focusing on each of 11 critical opportunities, and these

1119 range from very basic areas such as autoimmunity and the beta
1120 cell function that I was telling you about to needs with
1121 regard to comparative effectiveness research and
1122 translational research to build translation from clinical
1123 research into translational research, and we have identified
1124 a number of opportunities for important clinical trials that
1125 we would like to undertaken if funds are available as well as
1126 some key opportunities utilizing new genomics, proteomics
1127 technologies to try to elucidate the basis of diabetes so
1128 that we can develop new strategies for prevention and cure.

1129 Mr. {Pallone.} All right. Thanks.

1130 Dr. Albright, as I mentioned, how is this new plan going
1131 to stem the diabetes epidemic looking at the rate of new
1132 diabetes cases?

1133 Ms. {Albright.} There certainly is continued research
1134 that needs to be done in developing ways to reduce the onset
1135 of diabetes in those that have pre-diabetes and reducing the
1136 risk factors so people don't even into the world of pre-
1137 diabetes. So particularly the trend. There will be
1138 certainly chapters in this plan that will help with those
1139 more basic biologic mechanistic work, which is critical, but
1140 importantly, this plan also includes a chapter on
1141 translational research and that is an area that CDC and NIH
1142 and others share. We both have a role to play in the

1143 translation of the basic science into practice. So there
1144 will be questions and guidance in that chapter for how to
1145 identify those areas that are real world in which you take
1146 what we learn in a laboratory or in a contained setting and
1147 now you have got to take it out to the real world. So it
1148 important that we have studies that allow us to make those
1149 transitions, and then certainly from CDC's perspective, we
1150 then take that information and try to scale it and sustain it
1151 and be sure that there is a much broader research. Otherwise
1152 the discoveries that we made end up with a very limited
1153 reach, and that is not effective for the investment in
1154 research. We need to be sure that we get it out to as many
1155 people as we possibly can.

1156 Mr. {Pallone.} All right. Dr. Albright, let me ask you
1157 this. You talked about, you know, trying to promote fresh
1158 vegetables, fresh fruit, that type of thing. I actually am
1159 still the vice chair of the Native American Caucus and I have
1160 taken an interest in diabetes as it pertains to Native
1161 Americans in particular, and also in urban areas, and I have
1162 always felt that the biggest problem is not having access to
1163 fresh fruits and vegetables. I remember when I went to the
1164 Tahona Odem reservation years ago, they were a desert people
1165 that relied on just, you know, nuts and fruits and things
1166 they gathered in the desert, and all of a sudden they are

1167 eating processed cheese and tacos and all this kind of stuff,
1168 and I know that they have made an effort there to try to go
1169 back to some of the subsistence agriculture, but it is often
1170 difficult for people. Like I take my kids to McDonald's.
1171 One day I was at McDonald's, and McDonald's is now starting
1172 to offer salads and fruits and different things that are
1173 better, but if you stand there for a half an hour, nobody
1174 orders any of that. They still order the burgers and
1175 everything. So how do you promote this effectively? And
1176 also, are there alternatives? Like some people have
1177 suggested that maybe use dietary supplements, vitamins,
1178 because if people aren't going to eat the fresh fruits and
1179 vegetables, there is some other way to supplement their diet
1180 through vitamins or whatever, I don't know. It just seems
1181 like even though there are a lot of people out there trying
1182 to promote the fresh fruits and everything that we continue
1183 to lose the battle, not just amongst Native Americans but
1184 just in general. I mean, it is sort of a comment, but if you
1185 could just--how do we get there and are there alternatives
1186 like supplements that could be used instead?

1187 Ms. {Albright.} I think that some of the things that we
1188 are trying that have an evidence basis behind them, and that
1189 is first important, that what we do try has an evidence basis
1190 behind it. I think part of the challenge is that we haven't

1191 been able to implement these on a large enough scale to have
1192 the kind of impact. We do have to change the culture and
1193 change the environment so that the healthier choice is the
1194 easier choice for people, and that can have to do with
1195 pricing strategies and other kinds of things that make it
1196 easier, so it is availability both from a geographic--you
1197 don't have to hike 10 miles to get an orange and you can
1198 reach right next to you and get a 52-ounce soda. So we have
1199 really got to make access to those things easier. That can
1200 be supported by policies and by pricing, other sorts of
1201 things that may help with that. So it is going to require a
1202 culture change.

1203 As far as supplements, they may have a role to play if
1204 people are not getting adequate nutrition but really our
1205 major challenge is that people are overconsuming calories.
1206 So we do have to consider ways to reduce caloric consumption
1207 and that is what is resulting in the obesity epidemic and
1208 increase the physical activity opportunities which again is
1209 another situation where people need to have safer places to
1210 be physically active and know what they can do to improve
1211 their health. So while there certainly may be a role for
1212 supplements and vitamins and minerals, as a dietician I often
1213 recommend that people are taking those but they are not a
1214 replacement or an answer for reducing caloric intake and

1215 increasing physical activity.

1216 Mr. {Pallone.} Thank you very much.

1217 Mr. Shimkus.

1218 Mr. {Shimkus.} Thank you, Mr. Chairman. I have to
1219 continue my role as the burr underneath the saddle of the
1220 majority and the loyal opposition sometimes, but I need to
1221 stand up for McDonald's and understand the market. If they
1222 are not making any profit off those salads, they just
1223 wouldn't be selling them.

1224 Mr. {Pallone.} But they don't sell that many.

1225 Mr. {Shimkus.} They must be selling enough to keep it
1226 on the menu board. My son used to get the apples over the
1227 fries but now he is older, he is moving to the fries now.
1228 But that is a real issue. They wouldn't--they are marketing
1229 and they are selling, and if they weren't--you know, they are
1230 doing it for the bottom line, but it is an educational
1231 aspect, so when parents are taking their kids in, you know,
1232 the parents can also choose healthy. They can set the
1233 example for the kids. But I just wanted to put that aside
1234 there.

1235 And I also want to put down, the first of the health
1236 law's \$569 million in tax increases starts today with the
1237 \$2.7 billion tax on tanning services, so I just got a little
1238 blurb on that and wanted to put that on the record. We can

1239 celebrate.

1240 Now, this is more in line with your visit here, and I do
1241 appreciate it, and it is a little technical so I have got to
1242 read some of this. You all, CDC and NIH through this section
1243 shows the positive benefits of lifestyle intervention, diet
1244 and physical exercise to individuals with type 2 diabetes,
1245 plus it has been known that diet plays a major role in
1246 treatment and management of type 1 diabetes, and we were
1247 talking about that. In fact, insulin's effectiveness
1248 requires diet interventions to manage diabetes and slow the
1249 progression of diabetes comorbidities, primarily
1250 cardiovascular, kidney and eye complications, again something
1251 that you were just referring to, Mr. Chairman. So this is a
1252 question directing about the registered dietitians who
1253 provide medical nutrition therapy which for a decade since
1254 the Benefits Improvement Protection Act, BIPA, as a lot of us
1255 like to say, passed has been a Medicare Part B-covered
1256 intervention for diabetes chronic kidney disease. Under the
1257 health care law, the Affordable Care Act, states that
1258 copayment and deductible fees are waived for prevention and
1259 interventions recommended by the U.S. Preventive Services
1260 Task Force with a grade A or B. CMS recently released
1261 proposed rules for section 4104 of the medical nutrition
1262 therapy, was given a grade B. So the U.S. preventive

1263 Services Task Force recommends intensive behavioral diet
1264 counseling for cardiovascular and other diet-related chronic
1265 diseases. Does CDC believe diet interventions for
1266 cardiovascular risk factors such as high blood pressure and
1267 high cholesterol for pre-diabetes and other diet-related
1268 chronic diseases should be included with diabetes and chronic
1269 kidney disease in Medicare Part B medical nutrition therapy?
1270 I know it is a lot. I had to read it. And if this is too
1271 big and voluminous, you know, if you could respond in writing
1272 or get back to us, unless you know the answer.

1273 Ms. {Albright.} Sir, I can't speak to the specific
1274 official position of our agency. What I would offer, though,
1275 is to think about those services that you are describing
1276 which are education and counseling. Those are important
1277 services. They will have limited impact if they are not
1278 undergirded and supported by other interventions that focus
1279 on making the opportunities for people easier to get to so
1280 the advice they get from their dietician, and I advise
1281 patients as a dietician, they have to go home to their
1282 settings, and if those do not support easier opportunities to
1283 get those healthy foods and to participate in physical
1284 activity, it makes it more difficult to implement the advice
1285 that they are being given by their registered dietician
1286 whether it is for hypertension or for diabetes. So there are

1287 other opportunities to help support that education and
1288 counseling so it can actually have the best impact it could
1289 possibly have. But it does need to be supported by these
1290 other options and other sorts of things that allow people to
1291 make that choice, the healthy choice, much easier for them to
1292 make.

1293 Mr. {Shimkus.} And if I may, has the Common Fund, which
1294 was established in the NIH reauthorization law, been used to
1295 coordinate diabetes research across NIH? Dr. Fradkin, do you
1296 know?

1297 Dr. {Fradkin.} So the Common Fund is actually focused
1298 on things that are of broad interest and are not disease
1299 specific with the idea that it is, for example, developing
1300 new technologies that will be applied to diabetes. But over
1301 half of the institutes, in fact, a great majority of the
1302 institutes and centers at NIH do participate in the Diabetes
1303 Mellitus Interagency Coordinating Committee which is the
1304 major coordinating function. Could I just speak to your
1305 previous question briefly also?

1306 Mr. {Shimkus.} Oh, yes, if the chairman will allow.

1307 Dr. {Fradkin.} The study that I just mentioned that was
1308 just reported actually 2 days ago on a more cost-effective
1309 way to deliver the diabetes prevention program intervention,
1310 it provided people with three sessions with a dietician and

1311 then all the rest of the sessions were with low-cost
1312 community caseworkers, and they found a very dramatic
1313 reduction in weight. So that is an example of the kind of
1314 study that we support, you know, which does provide evidence
1315 for the value of dieticians. And if I could just make one
1316 additional comment? When the U.S. Preventive Services Task
1317 Force gives something a relatively low grade, that could be
1318 because it doesn't work, but often it is because it simply
1319 hasn't been studied.

1320 Mr. {Shimkus.} Thank you, Mr. Chairman.

1321 Mr. {Pallone.} Thank you, Mr. Shimkus.

1322 Next is the gentlewoman from Colorado, Ms. DeGette.

1323 Ms. {DeGette.} Thank you.

1324 Dr. Fradkin, my first questions nicely piggyback on Mr.
1325 Shimkus's question because one of the big concerns of the
1326 Diabetes Caucus for a long time has been the disparities
1327 between minority populations like African Americans, Latinos
1328 and American Indians and Alaska Natives and Anglos, and we
1329 are not really sure why those disparities exist other than a
1330 combination of factors of health access, community,
1331 environment, genetics, so I am wondering if you can talk a
1332 little bit more about any ongoing research by NIH to address
1333 the cause of the disparities because until we find out the
1334 cause, we can't really address how to deal with it.

1335 Dr. {Fradkin.} So first of all, we make a big effort to
1336 include minorities in all of our clinical research and in
1337 fact to over-represent minorities because they are
1338 disproportionately affected by diabetes, and in a study such
1339 as the diabetes prevention program, the interventions worked
1340 just as well in minority participants as in non-minority
1341 participants, but we do see some differences. So, for
1342 example, there has been research recently, for example,
1343 suggested that African Americans may have higher hemoglobin
1344 A1C values at the same level of glucose values.

1345 Ms. {DeGette.} Right.

1346 Dr. {Fradkin.} We need more research to look at that,
1347 but if that is the case, what it means is that they aren't
1348 necessarily getting worse glucose control but it is the
1349 measure of the glucose control that could potentially--

1350 Ms. {DeGette.} Right, which means you are going to have
1351 different therapies for those groups. And then we have some
1352 groups like the Pima Indians we were talking about earlier
1353 where they have a huge percentage of their populations with
1354 type 2 diabetes and it could be that not necessarily those
1355 groups, dietary habits or exercise habits are that much worse
1356 than a comparable other population but that there is some
1357 kind of genetic propensity or something else that we could
1358 use. Is that right?

1359 Dr. {Fradkin.} Absolutely, and so most of the studies
1360 that have up to now been done in terms of genetics of type 2
1361 diabetes have looked at Caucasian largely European
1362 populations and the NIDDK just established a very major
1363 genetics consortium to look specifically at genes for type 2
1364 diabetes in high-risk minorities.

1365 Ms. {DeGette.} And just for the commercial portion of
1366 my questioning, we have this minority disparities legislation
1367 which has attempted to deal with this exact issue, and Dr.
1368 Christensen has been a huge help and some of the other
1369 caucuses, Mr. Chairman, so we should really look at that bill
1370 too as we move along.

1371 I want to ask you, Dr. Albright, very briefly about this
1372 new report that came out from the Robert Wood Johnson
1373 Foundation this week. Unfortunately, it is called F is for
1374 Fat and it says that the intensity, the rate of obesity
1375 continues to increase in 2010, particularly in the Hispanic
1376 and African American subpopulations, and this is despite all
1377 of CDC'S public health campaigns to improve diet choices and
1378 activities and everything else. I am wondering what CDC's
1379 strategy is to try to reverse this trend. I know CDC has
1380 been working assiduously on it but it just seems every time
1381 we get one of these reports, it is worse and worse. My State
1382 of Colorado is almost always the vast State but that doesn't

1383 mean it is good because it just means that the rate of
1384 obesity is lower than other places. It doesn't mean people
1385 aren't obese. I am wondering if you can talk about how we
1386 can ramp up our efforts to reverse these trends.

1387 Ms. {Albright.} It is certainly a significant issue and
1388 one that is going to require a multi-pronged approach. I
1389 think that is one of the things we all have to remember is
1390 that there isn't a simple single answer for this, it is
1391 multifactorial. Other divisions within CDC and other
1392 agencies in the federal government are certainly tackling and
1393 taking on obesity, particularly working on childhood obesity
1394 so starting early in life and trying to change those habits
1395 early in life. They are also working on things related to
1396 adult obesity prevention and treatment issues. Much of the
1397 focus is turning toward policies and changing the built
1398 environment that will help with that. There will need to be
1399 some time in order to determine the impact of those broader
1400 changes in policy that should have a much bigger impact on a
1401 larger segment of the population.

1402 Ms. {DeGette.} Thank you. One last question for you,
1403 Dr. Fradkin. Going back to the special diabetes funding that
1404 we are trying to get reauthorized, what benefits, if any,
1405 does the multiyear funding stream in that program provide to
1406 the ability to fund the most promising research in the field

1407 and how important is that multiyear funding aspect of the
1408 special diabetes program?

1409 Dr. {Fradkin.} Let me give you an example of one thing
1410 that we did with the special funding that absolutely required
1411 multiyear funding. We created a program for career
1412 development, research career development for researchers
1413 studying childhood diabetes so we gave funds to the
1414 institutions that had very, very strong programs in pediatric
1415 diabetes research which enabled them to recruit in promising
1416 new investigators with the promise of 5 years of career
1417 support, and I can tell you that some of the people supported
1418 through that program have already made tremendous
1419 contributions so, for example, at Yale one of the
1420 investigators who was supported through that program has
1421 already got NIH funding and is working on trying to close the
1422 loop, and in fact three out of four of the people supported
1423 at Yale are now junior faculty there. We had to stop that
1424 program because we don't have 5 years of funding remaining
1425 and so as a result we couldn't offer people 5 years of career
1426 development support. That is just a specific kind of an
1427 example but I think it kind of gives the flavor of why it is
1428 important, and many of things that we are doing like TEDDY
1429 where we have to follow kids until they are 15 just clearly
1430 require a sustained stream of funding.

1431 Ms. {DeGette.} Thank you very much.

1432 Thank you, Mr. Chairman.

1433 Mr. {Pallone.} Thank you.

1434 The gentleman from Georgia, Mr. Gingrey.

1435 Dr. {Gingrey.} Thank you, Mr. Chairman.

1436 Dr. Fradkin, you responded to one of my colleagues just
1437 a few minutes ago, and this is not an exact quote but you
1438 essentially said when the United States Preventative Services
1439 Task Force gives something a low grade, it often means that
1440 it hasn't been well studied. I would like to ask your
1441 opinion in regard to the low grade that they, the U.S.
1442 Preventive Services Task Force, gave regarding screening
1443 mammography for women in their 40s to either prevent or early
1444 detection of breast cancer. Do you have any thought on that?

1445 Dr. {Fradkin.} I really have not followed screening
1446 mammography closely. That is not in my area.

1447 Dr. {Gingrey.} But you are a medical doctor.

1448 Dr. {Fradkin.} So, you know, I think probably the grade
1449 that concerns us in particular relates to their grade on
1450 screening for identifying people with diabetes and with pre-
1451 diabetes where the quality of evidence that it would require
1452 for them to recommend supporting that would require many,
1453 many years because simply identifying people with diabetes or
1454 pre-diabetes doesn't rise to the status that they require to

1455 find something effective. You have to actually--

1456 Dr. {Gingrey.} Well, let me pull back just for a second
1457 and then I will let you continue, because the reason I ask
1458 you that, I do have some real serious concerns, because you
1459 know that in the Patient Protection and Affordable Care Act
1460 of 2010, sometimes referred to as Obamacare, that this task
1461 force will begin pretty darn soon to not just recommend but
1462 to mandate, and I think it is really important that we take a
1463 very, very close at that. But let me go ahead and shift to
1464 the area in which you are now involved of course.

1465 With some 57 million Americans estimated today to have
1466 pre-diabetes, strategies to prevent or delay the progression
1467 to type 2 diabetes are critical to stemming the burden of
1468 diabetes on patients and our health care system. Do you
1469 think the existing guidelines sufficiently address the needs
1470 of patients with pre-diabetes or is it more important or more
1471 attention needed to ensure these patients have access to the
1472 most appropriate treatment options? My concern being that,
1473 you know, we know a lot of people have pre-diabetes. You
1474 gave a figure, an astoundingly large figure, but are we doing
1475 enough to really prevent them from progressing to full-blown
1476 type 2 diabetes?

1477 Dr. {Fradkin.} So I think this is where the kind of
1478 joint effort that Dr. Albright and I have been talking about

1479 is particularly important. We at NIH are doing research to
1480 try to figure out how to most cost-effectively prevent
1481 diabetes in those patients. We have a very strong program
1482 looking at multiple different ways to achieve prevention and
1483 specifically looking at culturally sensitive approaches,
1484 looking at what works best in particular populations and then
1485 CDC and actually it is wonderful to see even private payers,
1486 you know, building on the results of our research to try then
1487 to create public health programs that give people access to
1488 the things that the research has shown was effective. But
1489 clearly our research shows that about 90 percent of people
1490 with pre-diabetes don't even know that they have pre-diabetes
1491 and most of them are not taking effective steps to try to
1492 reduce their risk.

1493 Dr. {Gingrey.} Thank you, Dr. Fradkin.

1494 Dr. Albright, again, regarding that, and you mentioned
1495 the vast majority of cases in the United States today are
1496 preventable and certainly these many people with pre-
1497 diabetes. What are the top things that can be done to
1498 prevent these cases from progressing?

1499 Ms. {Albright.} At this point the evidence that we have
1500 suggests really scaling up and making this National Diabetes
1501 Prevention Program widely available to people. We are now
1502 offering it. CDC is providing funding to 11 sites. United

1503 Health Group is providing it to six. They have agreed to
1504 take over coverage of their beneficiaries so it is a very
1505 good public-private model. We will get the ball rolling in
1506 some of these locations and the private insurer can take over
1507 and continue to reimburse as time goes on, and so that is a
1508 nice combination. But we do need to get to more places and
1509 get to more locations, particularly harder to reach places.
1510 We need more entities that can deliver this in addition to
1511 the YMCA USA, who is outstanding, and other additional third-
1512 party payers. So we have got the beginning infrastructure
1513 there and it is time now for us to expand that infrastructure
1514 and allow it to reach across the country.

1515 Dr. {Gingrey.} Thank you, Dr. Albright, Dr. Fradkin,
1516 and I will yield back. Thank you both.

1517 Mr. {Pallone.} Thank you, Mr. Gingrey.

1518 Next is the gentlewoman from the Virgin Islands, Ms.
1519 Christensen.

1520 Dr. {Christensen.} Thank you, Mr. Chairman, and I want
1521 to thank you both for your testimony and your answers thus
1522 far.

1523 Dr. Albright, you mentioned working with five States and
1524 six organizations. Do they have a good mix of the
1525 population, a good population mix?

1526 Ms. {Albright.} Yes, they--

1527 Dr. {Christensen.} I don't know if you had mentioned
1528 what States they are or--

1529 Ms. {Albright.} Yes. We can't publicly announce them
1530 yet because the reviews have just been done, but we work to
1531 pay special attention to that. We first look for the best
1532 applicants. Certainly that is number one. But we are
1533 working and always seek to assure a wide representation of
1534 States and more territories and Pacific jurisdictions as
1535 well. We do provide funding to all of the U.S.-affiliated
1536 territories, so we are eager to have them involved as well.

1537 Dr. {Christensen.} I just wanted to make sure that
1538 there was diversity represented in those States and
1539 organizations.

1540 Ms. {Albright.} Yes.

1541 Dr. {Christensen.} Both of you have talked about the
1542 importance of the social and economic determinants of health,
1543 and certainly that is some of the reason why we haven't been
1544 able to make the impact in the African American, Native
1545 American, Hispanic communities. I have been supporting
1546 having an executive order similar to the one that President
1547 Clinton had issued back in 1998, I guess, around
1548 environmental justice requiring that all agencies of
1549 government, all departments do health impact assessments on
1550 their policies and programs and actually go beyond that to

1551 try to address some of the social and economic environmental
1552 issues through their policies. Is that something that you
1553 could support? Because it seems as though we are not going
1554 to make any progress as long as people live in food deserts,
1555 have, you know, all of the social and economic and
1556 environmental barriers to improving their health.

1557 Ms. {Albright.} I can certainly say that CDC's focus is
1558 growing in that area under the leadership of our agency
1559 director, Dr. Tom Frieden. We certainly are focused on
1560 policies and environmental changes that will support that,
1561 and really one of the themes that CDC is really seeking help
1562 in all policies. It is going to take--because it is so
1563 multifactorial of a problem, we do have to consider and
1564 evaluate the kinds of things that we are doing to try to make
1565 inroads in these very broad areas in our society but it is
1566 critical that we do investigate them and find solutions
1567 within these multiple areas.

1568 Dr. {Fradkin.} Maybe I could just speak to one specific
1569 investigation that we have done in this regard that we
1570 actually just reported the results on this past week, and
1571 that was a huge study in which we looked at the environment
1572 in 42 middle schools focusing on the schools that
1573 predominantly serve minority and low-income students. Fifty
1574 percent were Hispanic, over 20 percent were African American.

1575 Most of them were on free or reduced lunch. And we looked in
1576 those schools at changing the food services, increasing
1577 physical activity, and also promoting behavioral change, and
1578 we got some positive results. We didn't get everywhere we
1579 wanted to be but we saw reductions in obesity in the kids who
1580 started overweight or obese, which was half the kids in these
1581 schools were overweight or obese, and those children had
1582 reduced obesity as a result of this intervention, decreased
1583 waist circumference, decreased levels of insulin. So some
1584 positive impacts on risk factors for type 2 diabetes, and
1585 this is the kind of societal intervention that I think, you
1586 know, NIH likes to do research to test and then when we see
1587 results from studies like this, you know, then the public
1588 health agencies move to try to translate that.

1589 Dr. {Christensen.} Thank you. I yield back, Mr.
1590 Chairman.

1591 Mr. {Pallone.} Thank you.

1592 Mr. Space for 8 minutes.

1593 Mr. {Space.} Thank you, Mr. Chairman, and thank you
1594 again for exhibiting your commitment to such an important
1595 issue by convening this hearing.

1596 Where to begin? Dr. Albright, your testimony, and
1597 actually both of your testimonies, I think, underline the
1598 increase that we are seeing all types of diabetes and your

1599 testimony briefly alludes to, and I think some of my
1600 colleagues have referenced it very specifically, the cost
1601 that this is visiting upon our country, and just doing a
1602 little bit of quick math, assuming that we are somewhere
1603 north of \$200 billion a year now, which I know is probably
1604 true. I know the ADA's study from a couple years ago, 2007,
1605 was at \$174 billion. That computes to over a half a billion
1606 dollars a day that this disease is costing our society, and
1607 as Ms. Schakowsky pointed out, much of that is a direct
1608 governmental expenditure, and to put it in perspective, in
1609 2009 we spent \$148 billion on two wars in this country, and
1610 now we are spending upwards of \$200 billion a year dealing
1611 with the effects of this one disease that has taken several
1612 different forms. Is it a safe assumption that with the
1613 increase in incidence of diabetes that these costs will
1614 continue to escalate?

1615 Ms. {Albright.} Yes. That would be the short answer.

1616 Mr. {Space.} And much of the costs associated with
1617 diabetes consist of treating the complications of diabetes,
1618 correct?

1619 Ms. {Albright.} They certainly are associated with the
1620 costs of treatment. Fortunately, as we have said, there are
1621 ways for us now to prevent, and we have been trying to work
1622 to get those to be delivered as cost-effectively as possible.

1623 Mr. {Space.} Right. So with the delivery of those
1624 preventive mechanisms and maintenance mechanisms, in the end
1625 you will mitigate the total cost associated with treating the
1626 complications that you can prevent or reduce through
1627 effective maintenance and treatment, and in the end, dollars
1628 spent today will result in a significant decrease in dollars
1629 spent tomorrow. Is that a safe statement?

1630 Ms. {Albright.} I think there are some little
1631 parameters you have to put around there when you are looking
1632 at cost-effectiveness. You are very right, that you have to
1633 look at the time horizon and you have to look at the
1634 assumptions, but there certainly are opportunities for us to
1635 drive the costs down in treatment and prevention so that we
1636 can indeed have more productive citizens who can be
1637 contributing to the economy in successful ways, so there is
1638 certainly benefit to doing that.

1639 Mr. {Space.} If we were to develop a cure for diabetes,
1640 and I want to on subsequent panels maybe talk a little bit
1641 about we might better do that, but just hypothetically if we
1642 were to develop a cure for diabetes, and that cure can take
1643 many different forms, it could be an artificial cure like the
1644 closed loop system that you have referenced or it could be a
1645 more natural cure, perhaps some day some embryonic stem cell
1646 research, if you have got a young person that develops

1647 diabetes at the age of 6 or 7 years old was diagnosed with
1648 type 1, the complications that that child is likely to
1649 experience as a result of the disease are not likely to
1650 manifest themselves for decades, correct?

1651 Ms. {Albright.} That is right.

1652 Mr. {Space.} So by the that child is 40 or 50 years
1653 old, his risk for heart disease, blindness, stroke, kidney
1654 disease, amputation is much, much higher than it would be for
1655 someone who is not diabetic at that age.

1656 Ms. {Albright.} Absolutely.

1657 Mr. {Space.} What I am trying to drive at here is the
1658 future costs of this disease, as debilitating as they are
1659 today, you know, society in a country that can't afford the
1660 luxury of \$200 billion a year in one disease, as debilitating
1661 as these costs are today, can you give us some projection as
1662 to where may be in 20 years or 30 years given the rather
1663 rapid increase in incidence of both type 1 and type 2
1664 diabetes in the event that we do not see a cure and we do not
1665 see the implementation on a wide scale of some of the
1666 measures that you are testifying about today with
1667 maintenance? What will be the implications economically to
1668 the society in 20 years if we continue to go the way we are
1669 going now without massive intervention and maintenance and/or
1670 cure?

1671 Dr. {Fradkin.} Well, I think obviously the CDC is
1672 predicting that one in there children born today and one in
1673 two minority children born today will develop type 2 diabetes
1674 if we don't intervene and change things, but I would like to
1675 point out that things actually--there are some very real
1676 improvements in terms of the prognosis for people with
1677 diabetes that have effects on health care costs, so because
1678 rates of diabetes are increasing so fast, if it weren't for
1679 some of the effective things that we are doing to bring down
1680 the complications of diabetes, we would be seeing even
1681 greater costs than we are seeing today. So, for example,
1682 even though rates of end-stage kidney disease, which is a
1683 huge expense for Medicare, are going up, the actual
1684 proportion of people with diabetes who develop end-stage
1685 renal disease is falling. So if we weren't doing those
1686 effective interventions as diabetes is increasing, we would
1687 be seeing even greater increase in the cost than we are
1688 seeing.

1689 Ms. {Albright.} And I think this is definitely a
1690 combination of we are--this is--where we are seeing a greater
1691 number of people with diabetes, and that is because as people
1692 live longer, as we diagnose them earlier, as we catch them,
1693 people have undiagnosed diabetes, we are going to have a
1694 bigger total prevalence or total population. We want to

1695 drive that number down by reducing the new cases so that what
1696 resources we have can be delivered to effectively manage
1697 those people that have the disease and then hopefully over
1698 time not have a future of one in three and the devastating
1699 complications so we have got to make headway in preventing
1700 all forms of diabetes and better treating diabetes because it
1701 also is where we will spend the cost. Yes, it does cost to
1702 take care of people with the disease, it does cost to
1703 prevent, but the opportunity to not have people suffer the
1704 ravages of this disease and continue to be productive members
1705 of society is a critical piece to be sure we keep in the
1706 discussion about the economics of diabetes.

1707 Mr. {Space.} Thank you, Doctor. Thank you, Doctor.

1708 I regret that I have no additional time.

1709 Mr. {Pallone.} No, that is all right. I mean, I am
1710 glad you don't because we are going to have a vote. We have
1711 three votes. I am going to try to get in our other two
1712 people here.

1713 Ms. {DeGette.} Mr. Chairman, before you recognize, can
1714 I just ask unanimous consent to submit a folder of different
1715 statements by different groups about their activities for the
1716 record? And this has been cleared with the minority.

1717 Mr. {Pallone.} We will take a look at it first.

1718 Ms. {DeGette.} They have seen it.

1719 Mr. {Pallone.} You have?

1720 Ms. {DeGette.} Yes.

1721 [The information follows:]

1722 ***** COMMITTEE INSERT *****

|

1723 Mr. {Pallone.} Without objection, so ordered, and I am
1724 going to try to get in Ms. Schakowsky and Mr. Engel and then
1725 we will let you go and we will come back after the votes for
1726 the second panel. I recognize the gentlewoman from Illinois.

1727 Ms. {Schakowsky.} I really--I think this is a quick
1728 question. There has been a lot of recent news about Avandia,
1729 the drug that is used to treat type 2 diabetes by increasing
1730 the body's sensitivity to insulin. Two new studies released
1731 earlier this week add to the body of evidence about the risk
1732 of heart attack, stroke and heart failure among people who
1733 take these drugs and those are of course the very things we
1734 are trying to prevent by treating diabetes. The FDA is
1735 holding an advisory committee meeting in July where the
1736 safety of Avandia will be under review, and I think this is
1737 an appropriate action at this time. While the FDA
1738 deliberates on the safety and effectiveness of this drug, I
1739 wanted to ask about the underlying research and public health
1740 implications. Dr. Fradkin, in your professional opinion,
1741 what are the implications of the recent studies? And Dr.
1742 Albright, if you have anything else to add.

1743 Dr. {Fradkin.} Well, let me just say that there are now
1744 multiple different classes of drugs that are available to
1745 treat type 2 diabetes as a result of research, and

1746 rosiglitazone, Avandia and pioglitazone are members of one of
1747 those classes of drugs. Most of the drugs have been approved
1748 based on relatively short-term studies that show that they
1749 are effective in reducing glucose but I think what we really
1750 need and what the strategic plan that the chairman referred
1751 to that the DMICC is developing is what we really need to
1752 head-to-head comparisons of the various drugs that are
1753 available for treating type 2 diabetes with longer-term time
1754 frames looking not simply at glucose lowering but looking at
1755 what they do over the course of diabetes in terms of heart
1756 disease, in terms of weight gain, in terms of quality of life
1757 for people, and we don't have those head-to-head comparisons
1758 and so most of the data like these current studies that you
1759 are referring to are basically analyses of observational
1760 studies. They aren't the ideal rigorous kind of research
1761 that you need to answer the question, and the rigorous
1762 research is something that we need.

1763 Ms. {Schakowsky.} So let me ask you, Dr. Albright, then
1764 what advice would you have for people who are taking Avandia
1765 right now? Because it appears that not only do we have to
1766 reduce the blood sugar but how we do it is very important,
1767 and obviously more and more research and studies
1768 scientifically based studies have to be done. But in the
1769 meantime, what do we tell them?

1770 Ms. {Albright.} Well, our response when we are asked,
1771 and we are asked these questions, is that it is critical that
1772 people have the discussion with their health care
1773 professional because as Dr. Fradkin referenced, there are
1774 other treatments. Their particular risks can be very
1775 carefully examined and determined. So it is important that
1776 people have a conversation with their health care provider
1777 because diabetes is a disease where you have to make lots of
1778 decisions and it is imperative that you have a good
1779 discussion with your health care provider to make those
1780 decisions for you as an individual.

1781 Ms. {Schakowsky.} Well, all of this really is a
1782 humbling reminder that we still have a lot to learn about
1783 diabetes and that we need to do that, so thank you very much.

1784 I yield back.

1785 Mr. {Pallone.} Thank you.

1786 Mr. Engel.

1787 Mr. {Engel.} Thank you, Mr. Chairman. I will try to
1788 speak very fast.

1789 A hundred and thirty-five thousand women are diagnosed
1790 with gestational diabetes each year as well. I know that Dr.
1791 Burgess spoke about it. He and I have introduced the
1792 Gestational Diabetes Act, H.R. 5354, and we have gotten many
1793 cosponsors and I hope people on this subcommittee will all

1794 cosponsor it in a bipartisan way. And what our Act aims to
1795 do is lower the incidence of gestational diabetes and prevent
1796 women afflicted with this condition and their children from
1797 developing type 2 diabetes, and the legislation creates a
1798 research advisory committee headed by CDC to develop multi-
1799 site gestational diabetes research projects to enhance
1800 surveillance, provides demonstration grants to focus on
1801 reducing the incidence of gestational diabetes and expands
1802 basic clinical and public health research investigating
1803 gestational diabetes and current treatments and therapies,
1804 and I ask unanimous consent for my opening statement to
1805 appear in the record.

1806 [The prepared statement of Mr. Engel follows:]

1807 ***** COMMITTEE INSERT *****

|
1808 Mr. {Pallone.} Without objection, so ordered.

1809 Mr. {Engel.} Thank you, Mr. Chairman.

1810 Let me ask first Dr. Fradkin, and I will ask each of you
1811 one question. First of all, Doctor, congratulations on the
1812 NIH National Institute of Diabetes and Digestive Kidney
1813 Diseases 60th anniversary.

1814 Dr. {Fradkin.} Thank you.

1815 Mr. {Engel.} It is because of the tremendous support of
1816 the National Institute's research toward understanding,
1817 preventing and treating diabetes that we are closer than ever
1818 to better fighting and curing the disease, so
1819 congratulations.

1820 Could you tell me more, please, about the results of the
1821 hyperglycemia and adverse pregnancy outcome study? I guess
1822 it is the HAPO study. And do you find that expansion of
1823 basic clinical and public health research investigating
1824 gestational diabetes and obesity during pregnancy such as our
1825 Act would be useful to further develop the insights gained
1826 from the hyperglycemia and adverse pregnancy outcome study?

1827 Dr. {Fradkin.} I can't speak specifically to the Act
1828 but I can tell you that I think gestational diabetes is one
1829 of the most important problems confronting us in the area of
1830 diabetes because not only does it cause problems at the time

1831 of birth for both the mother and the child, increasing rates
1832 of cesarean section and injury to the child but also it puts
1833 the mother at increased risk for subsequent diabetes but also
1834 we have data suggesting that the intrauterine environment
1835 puts the offspring at increased risk for diabetes and
1836 obesity. So you can imagine the vicious cycle that can occur
1837 as type 2 diabetes occurs at younger and younger ages moving
1838 toward people developing gestational diabetes or even type 2
1839 diabetes during their childbearing years, then the offspring
1840 of that pregnancy not only has the genetic risk that it gets
1841 from the parent but also has the increased risk conferred by
1842 this adverse metabolic environment that also then increases
1843 the risk, so you can imagine sort of a vicious cycle where
1844 rates of diabetes will increase at expanding rates. So this
1845 is a cycle that we really need to break and I think the HAPO
1846 study has given us some extremely important information
1847 showing that adverse effects of hyperglycemia in pregnancy
1848 occur at much lower levels of glucose than we previously
1849 appreciated.

1850 Mr. {Engel.} Thank you. Very well said.

1851 Dr. Albright, you mentioned in your testimony that women
1852 with type 2 diabetes are at increased risk for having babies
1853 with birth defects and women with a history of gestational
1854 diabetes should receive targeted intervention strategies to

1855 prevent type 2 diabetes before they become pregnant, during
1856 pregnancy, postpartum and between. Can you please describe
1857 some of the intervention and educational outreach strategies
1858 the CDC is undertaking to increase awareness of gestational
1859 diabetes and the risks associated with it?

1860 Ms. {Albright.} Yes. Briefly, we are making special
1861 effort in the National Diabetes Prevention Program that we
1862 mentioned earlier to really put recruitments efforts and
1863 raising the awareness of women of childbearing years and
1864 their risk if they have had for GDM for developing type 2
1865 diabetes and special efforts will be made to really try to
1866 seek to get them involved in this program. They are a
1867 terrific candidate for the National Diabetes Prevention
1868 Program. We also as part of the National Diabetes Education
1869 Program that Dr. Fradkin and I have the honor of working on
1870 together, we are working on some more gestational diabetes
1871 education efforts. We have received some funding from HHS
1872 and NIH will be taking the lead in doing some comparative
1873 effectiveness work with our NDEP materials. So we are
1874 continuing to work together in that area.

1875 Mr. {Engel.} Thank you. And before I yield back, I
1876 just want to throw a little accolades to our counsel here to
1877 my left, Emily Gibbons. I am going to thoroughly embarrass
1878 her, but she was my long-term legislative director and health

1879 person, and Mr. Pallone stole her from me.

1880 Mr. {Pallone.} With permission.

1881 Mr. {Engel.} With permission, and she does marvelous
1882 work and has done the work for both of us on gestational
1883 diabetes. So now that I have thoroughly embarrassed you, I
1884 yield back the balance of my time.

1885 Mr. {Pallone.} I will second that.

1886 Thank you, Mr. Engel, and thank you both of you. This
1887 was very helpful. We really appreciate it, and obviously
1888 something that we have to deal with long term, but we
1889 appreciate your testimony.

1890 And what we are going to do is take--we are voting now.
1891 We have three votes. It should take us to approximately
1892 1:30. So if anybody wants to have lunch, we will reconvene
1893 at 1:30 and we will have our second panel. Thank you.

1894 The committee stands in recess.

1895 [Recess.]

1896 Mr. {Pallone.} The subcommittee will reconvene, and as
1897 I promised, we will begin with our second panel. Let me
1898 introduce each of you. First is Chairman Buford Rolin, who
1899 is vice chairman and national area representative for the
1900 National Indian Health Board and also chairman of the Poarch
1901 Band of Creek Indians. Thank you for being here. Then we
1902 have Dr. Robert Goldstein, who is senior vice president for

1903 Scientific Affairs of the Juvenile Diabetes Research
1904 Foundation, and Dr. Robert R. Henry, who is president-elect,
1905 Medicine and Science for the American Diabetes Association,
1906 professor of medicine at the University of California,
1907 Department of Medicine, and chief of the section of
1908 endocrinology, metabolism and diabetes at the VA Medical
1909 Center in San Diego.

1910 I need to mention to the panel that Chairman Rolin is
1911 going to testify and then leave because he has to catch a
1912 plane and pervious commitments, but he will take written
1913 questions, and the way we work, as I think you know, we have
1914 5 minutes' opening from each of you and then we take
1915 questions, but you can submit additional written statements
1916 if you like and then members may also follow up with some
1917 written questions as well.

1918 So we will start with Chairman Rolin. Nice to see you
1919 again.

|

1920 ^STATEMENTS OF BUFORD ROLIN, VICE CHAIRMAN AND NASHVILLE AREA
 1921 REPRESENTATIVE, NATIONAL INDIAN HEALTH BOARD, AND CHAIRMAN,
 1922 POARCH BAND OF CREEK INDIANS; ROBERT A. GOLDSTEIN, M.D.,
 1923 PH.D., SENIOR VICE PRESIDENT, SCIENTIFIC AFFAIRS, JUVENILE
 1924 DIABETES RESEARCH FOUNDATION; AND ROBERT R. HENRY, M.D.,
 1925 PRESIDENT-ELECT, MEDICINE AND SCIENCE, AMERICAN DIABETES
 1926 ASSOCIATION, PROFESSOR OF MEDICINE, UNIVERSITY OF CALIFORNIA
 1927 DEPARTMENT OF MEDICINE, AND CHIEF, SECTION OF ENDOCRINOLOGY,
 1928 METABOLISM AND DIABETES, VA MEDICAL CENTER IN SAN DIEGO

|

1929 ^STATEMENT OF BUFORD ROLIN

1930 } Mr. {Rolin.} Thank you, Mr. Chairman and members of the
 1931 subcommittee. I am Buford Rolin, chairman of the Poarch Band
 1932 of Creek Indians and vice chairman of the National Indian
 1933 Health Board. I also serve as the co-chair of the Tribal
 1934 Leaders Diabetes Committee and--

1935 Mr. {Pallone.} I am not sure, Chairman, that your mic
 1936 is on. Is it green?

1937 Mr. {Rolin.} It is green.

1938 Mr. {Pallone.} Then you have to bring it a little
 1939 closer.

1940 Mr. {Rolin.} Can you hear me?

1941 Mr. {Pallone.} That is better. Thanks.

1942 Mr. {Rolin.} I will just begin again.

1943 Good afternoon, Mr. Chairman and members of the
1944 subcommittee. I am Buford Rolin, chairman of the Poarch Band
1945 of Creek Indians and vice chairman of the National Indian
1946 Health Board. I also serve as the co-chair of the Tribal
1947 Leaders Diabetes Committee, and on a personal note, I have
1948 lived with diabetes for the last 6 years. Thank you for
1949 inviting NIHB to participate in this important hearing. I
1950 apologize, but I must leave early to catch a flight.

1951 Today, American Indians and Alaska Natives suffer
1952 disproportionately from diabetes. Indian adults are two
1953 times more likely to have diabetes compared with the non-
1954 Hispanic whites. In some tribal communities, more than half
1955 of the adults have been diagnosed with diabetes. Sadly, the
1956 highest rate of diabetes diagnosis has appeared among our
1957 young children and young adults. From 1990 to 2009, young
1958 native people ages 25 to 34 years experienced a 161 percent
1959 increase in diagnosis of type 2 diabetes. In addition,
1960 diagnosis of diabetes rose 110 percent in our teenagers 15 to
1961 19 years old during the same period.

1962 Despite these alarming statistics, progress is being
1963 made. This progress would not have been possible without the
1964 Special Diabetes Program for Indians. Congress created the

1965 SDPI in 1997 in the wake of increasing public concern about
1966 the burden of diabetes in native communities. In 1998, the
1967 Indian Health Service established the Tribal Leaders Diabetes
1968 Committee to provide guidance on SDPI, diabetes and related
1969 chronic diseases. Today, through SDPI, IHS provides funding
1970 in support for diabetes prevention and treatment programs,
1971 services and activities to over 450 IHS tribal and urban
1972 Indian SDPI programs, and it is working. Diabetes-related
1973 health outcomes have improved significantly in native
1974 communities since the launch of SDPI. For example, there is
1975 11 percent decrease in the blood sugar level A1C in Indian
1976 people who have been diagnosed with diabetes. This decrease
1977 translates to a 40 percent reduction in diabetes-related
1978 complications such as blindness, kidney failure, nerve
1979 disease and amputations, 16 percent in total cholesterol
1980 level and a decrease of 20 percent in bad cholesterol.
1981 Research has shown that lowering cholesterol levels reduces
1982 the risk of developing complications associated with diabetes
1983 such as heart attacks, stroke or heart failure, 32 percent
1984 decrease in the prevalence of protein in urine and a risk of
1985 kidney disease. New cases of diabetes-related dialysis in
1986 Indian people decreased 31 percent between 1999 and 2007
1987 while remaining relatively unchanged in other races.
1988 Preventing kidney failure is critical to help people with

1989 diabetes, avoid needing dialysis or kidney transplants. In
1990 addition, SDPI has enabled the IHS tribal and urban Indian
1991 programs to provide expanded screening, prevention and
1992 diabetes treatment services as well as to build a desperately
1993 needed infrastructure.

1994 The committee should also know that the outcomes of the
1995 SDPI and knowledge gained through these scientific-based
1996 programs have helped to inform and advance other IHS diabetes
1997 programs such as the model diabetes program established under
1998 the Indian Health Care Improvement Act. The 19 model
1999 diabetes programs in the Indian health system have made
2000 significant contributions including state-of-the-art
2001 comprehensive clinical diabetes care through a
2002 multidisciplinary preventive and treatment approach. The
2003 Special Diabetes Program for Indians has been lifesaving to
2004 people who have diabetes, life-changing to those who have
2005 avoided diabetes because of early detection and prevention
2006 efforts, and perhaps most importantly, it is helping to
2007 ensure a diabetes-free future for our children and future
2008 generations. Making real progress in this area and ensuring
2009 that future generations will be free of the burden of this
2010 disease requires federal and tribal government collaboration.
2011 We have shown it can work. Now we need to recommit ourselves
2012 and this hearing is a good first step.

2013 On behalf of the National Indian Health Board, thank you
2014 for this opportunity to address the subcommittee regarding
2015 this important issue. Thank you.

2016 [The prepared statement of Mr. Rolin follows:]

2017 ***** INSERT 4 *****

|

2018 Mr. {Pallone.} Thank you, Chairman, and thank you. I
2019 know that you have to leave but I do appreciate your
2020 testimony, and I want you to know that I speak for myself but
2021 I think I can speak for everyone in saying that you were
2022 particularly conscious of the impact of diabetes on the
2023 Native American community and want to help in any way we can
2024 to deal with this epidemic. I appreciate your comments.
2025 Dr. Goldstein.

|

2026 ^STATEMENT OF ROBERT A. GOLDSTEIN

2027 } Dr. {Goldstein.} Chairman Pallone, Ranking Member
2028 Shimkus and members of the subcommittee, thank you for the
2029 opportunity to testify before you today. I am Robert
2030 Goldstein, senior vice president of Scientific Affairs for
2031 the Juvenile Diabetes Research Foundation. I am honored to
2032 be here today before this distinguished committee with my
2033 colleagues from the diabetes ct.

2034 JDRF is the largest charitable funder and advocate of
2035 diabetes research worldwide. Since our founding 40 years ago
2036 by parents of children with type 1 diabetes, JDRF has awarded
2037 more than \$1.4 billion to diabetes research.

2038 Type 1 diabetes, also known as juvenile diabetes, is an
2039 autoimmune disease for which there is no cure, at least not
2040 yet. It is the second most common chronic disease affecting
2041 children. It is growing rapidly, particularly in our
2042 youngest children. Diabetes overall costs our Nation more
2043 than \$174 billion a year and one in three Medicare dollars is
2044 spent on people with the disease. But the good news is that
2045 we are moving faster toward a cure for type 1 diabetes than
2046 ever before, thanks to a strong federal commitment to
2047 diabetes research funding as well as JDRF's private

2048 investment.

2049 A key component of the federal investment is the Special
2050 Diabetes Program, which provides a critical 35 percent of NIH
2051 funding for type 1 diabetes research and supports the
2052 multicenter human clinical trials that are contributing to
2053 discovering better treatment. Let me highlight some of the
2054 key advances which benefit not only those with type 1
2055 diabetes but those with type 2 diseases and other autoimmune
2056 diseases.

2057 Researchers have discovered ways to slow the autoimmune
2058 attack that causes type 1 diabetes. Charlotte Cunningham, a
2059 15-year-old from Maryland, was able to produce her own
2060 insulin for 3 years after receiving a drug treatment called
2061 anti-CD3, and today is better able to control her blood
2062 glucose levels. Great strides have been made in
2063 investigating therapies to regenerate and replace insulin-
2064 producing cells. Thanks to this research, Anne Sidell
2065 Demarek of Texas and now California, who received an islet
2066 transplantation, no longer suffers from frequent low blood
2067 sugar episodes which impacted her ability to care for her
2068 young son who unfortunately also has type 1 diabetes.
2069 Researchers have paired continuous glucose monitors with
2070 insulin pumps to develop an artificial pancreas to help those
2071 with type 1 more easily and accurately control their blood

2072 glucose levels. A study recently published in the Lancet
2073 found an early artificial pancreas system lowered the risk of
2074 low blood sugar emergencies in children and teenagers while
2075 they were asleep. Researchers have recently found a way to
2076 reverse diabetic eye disease, the leading cause of adult-
2077 onset blindness. Sally Cartwright, a 66-year-old type 2
2078 patient, can now drive thanks to a treatment combining a drug
2079 and laser treatment.

2080 As this progress shows, diabetes research is one of the
2081 world's most effective public-private partnerships focused on
2082 curing a particular disease, yet despite tremendous advances,
2083 there is still much work to be done. On behalf of JDRF and
2084 the millions of families affected by diabetes, I thank the
2085 committee for its leadership and strong support for the
2086 Special Diabetes Program, which is a key element of our
2087 continued success. We deeply appreciate your commitment and
2088 look forward to continuing to work with you to cure this
2089 devastating and costly disease.

2090 Thank you again for holding the hearing. I will be
2091 happy to answer questions.

2092 [The prepared statement of Dr. Goldstein follows:]

2093 ***** INSERT 5 *****

|

2094 Mr. {Pallone.} Thank you, Dr. Goldstein.
2095 Dr. Henry.

|

2096 ^STATEMENT OF ROBERT R. HENRY

2097 } Dr. {Henry.} Well, thank you for the opportunity to
2098 testify today and to Chairman Pallone and Ranking Member
2099 Shimkus for holding this hearing. I am pleased to be here on
2100 behalf of the American Diabetes Association. My full written
2101 testimony has been submitted for the record, and in the 5
2102 minutes I have, I will summarize it.

2103 I have just come from the American Diabetes
2104 Association's 70th scientific sessions conference in Orlando,
2105 Florida, the world's largest diabetes research meeting, where
2106 over 14,000 diabetes researchers, providers and educators
2107 gathered to hear and discuss the latest in diabetes research.
2108 The CDC has identified diabetes as a disabling, deadly
2109 epidemic that is on the rise. Between 1980 and 2007, the
2110 prevalence of diabetes has increased by 300 percent. Its
2111 total cost is over \$218 billion a year.

2112 The Association is grateful to the committee for
2113 supporting vital HHS diabetes programs including the NIDDK,
2114 CDC'S DDT and the Indian Health Service. Because of this
2115 investment, our knowledge of the disease has been expanded
2116 and the critical work towards ending this epidemic can
2117 continue.

2118 Our efforts have significantly changed the way diabetes
2119 is addressed in both the clinical and community settings.
2120 Since 1952, more than 4,000 research projects on type 1, type
2121 2 diabetes and gestational diabetes has been funded by the
2122 American Diabetes Association. In 2009, the Association
2123 awarded \$33.55 million in new research support. We strive
2124 particularly to bring research from bench to the bedside and
2125 swiftly into the hands of patients and care providers. We
2126 fund cutting-edge research. Association-funded work
2127 developed the first handheld blood glucose meters, a key tool
2128 to achieving diabetes control. Currently, our research has
2129 found a potential new treatment for diabetic retinopathy, a
2130 complication that makes diabetes the number one cause of
2131 adult-onset blindness.

2132 We value our partnerships with key health organizations,
2133 and I am pleased to point to our continued work with JDRF in
2134 the development of an artificial pancreas that holds the
2135 promise of revolutionizing diabetes management for type 1
2136 diabetes. We are committed to developing the pipeline of
2137 diabetes researchers including funding younger researchers
2138 and more minority investigators to ensure the vitality of
2139 future research. We have made great progress but more has to
2140 be done.

2141 With this in mind, I want to outline several key next

2142 steps in the battle to stop diabetes. More attention must be
2143 paid to the pressing needs of special populations
2144 particularly affected by the diabetes epidemic including
2145 minority populations. We remain steadfast in our effort to
2146 support research that addresses these disparities. H.R.
2147 3668, sponsored by Representatives Dianna DeGette and Mike
2148 Castle, helps address this issue by renewing the Special
2149 Diabetes Program. SDP programs in American Indians and
2150 American Native communities and SDP-funded type 1 are highly
2151 successful. The program expires in 2011, and I urge Congress
2152 to pass this legislation soon so this work can continue.

2153 H.R. 1995, the Eliminating Disparities and Diabetes
2154 Prevention Access and Care Act, also seeks to address racial
2155 and ethnic health disparities related to diabetes. We thank
2156 Representative DeGette again for introducing this bill and
2157 Representative Donna Christensen for including it in the tri
2158 caucuses health disparities legislation.

2159 We also must increase efforts to prevent and treat
2160 gestational diabetes. Representatives Elliot Engel and
2161 Michael Burgess have sponsored H.R. 5354, the Gestational
2162 Diabetes Act, which aims to lower the incidence of
2163 gestational diabetes in order to protect mother and baby and
2164 prevent future cases of type 2 diabetes.

2165 Our collective fight to stop diabetes must be continued.

2166 Your leadership in combating this growing epidemic is
2167 absolutely essential. Thank you for your commitment to the
2168 diabetes community and it will be my pleasure to answer any
2169 questions you might have on these important issues. Thank
2170 you again.

2171 [The prepared statement of Dr. Henry follows:]

2172 ***** INSERT 6 *****

|
2173 Mr. {Pallone.} Thank you, Dr. Henry.

2174 We are going to have questions from the panel, and I
2175 will start with myself.

2176 Dr. Goldstein, can you explain how the promising
2177 research you are doing with the NIH and the private sector on
2178 initiatives like the continuous glucose monitor, artificial
2179 pancreas was mentioned several times, how these are going to
2180 be better control diabetes and the disease's associated costs
2181 and complications? Because we know the costs are
2182 unbelievable. One out of three Medicare dollars is spent on
2183 diabetes.

2184 Dr. {Goldstein.} Mr. Chairman--

2185 Mr. {Pallone.} And I ask Dr. Henry to comment as well.

2186 Dr. {Goldstein.} The NIH-supported DCCT study in 1993
2187 for the first time demonstrated that high-quality tight
2188 control of the blood sugar variations resulted in
2189 improvements. Over time, those patients have now been
2190 studied for 20 years and the complication rates have just
2191 dropped from very large numbers to 15 and 20 percent numbers
2192 so that the reduction in complication rate from just exerting
2193 tight control has been enormous. With the continuous glucose
2194 monitors, we have upped the ante because patients can now
2195 achieve high-quality tight control with lower risk for

2196 getting blood sugars that are too low and with just an
2197 improvement in the overall quality of life because they don't
2198 have to concern themselves so much with measuring blood
2199 sugars six, seven, eight times a day. So the JDRF supported
2200 a study that was published a couple of years ago that showed
2201 you could drive the hemoglobin A1C down which is directly
2202 correlated to reduction in complication rates, and we are in
2203 the phase now where we are working with everybody we can
2204 find, industry, other organizations, to implement high-
2205 quality tight control in as many patient populations as
2206 possible ranging from children, adolescents, pregnancy--we
2207 are just beginning to start there--and the idea is, while we
2208 are waiting for a cure, we want people to implement very
2209 high-quality control of their diabetes so that they will be
2210 in good enough health when the cure does appear.

2211 Mr. {Pallone.} Dr. Henry, you can answer that. Also, I
2212 wanted to ask you a question too separately about the
2213 Association's role as a government partner and how you strike
2214 a balance in addressing the needs of the different types of
2215 diabetes, you know, type 1, type 2, gestational. So if you
2216 want to follow up on him and then get into that.

2217 Dr. {Henry.} Well, I would say I agree with everything
2218 that Dr. Goldstein has stated, and clearly the goal for an
2219 artificial pancreas is to make it easier to be able to

2220 regulate the blood sugar within the normal limits and as you
2221 heard, complications are minimized by good glycemic control,
2222 particularly low blood sugars, hypoglycemia, which can have
2223 devastating consequences, as well as persistent high blood
2224 sugars, which leads to complications. So these can be
2225 minimized by feedback between understanding the blood glucose
2226 levels and injections of insulin.

2227 The other thing that we found that the DCT research, the
2228 long term funded by the NIDDK data showed is that there was a
2229 legacy effect so that controlling diabetic patients today
2230 with type 1 diabetes had effects on cardiovascular disease,
2231 beneficial effects on cardiovascular disease 10 years later
2232 so that there was this short-term--the study lasted for
2233 several years but even 10 years later there were significant
2234 benefits. So I think that it emphasizes that good control
2235 now will not only reduce the long-term consequences but they
2236 will have sustained benefits for many, many years.

2237 In terms of the second question, can I ask you to repeat
2238 that?

2239 Mr. {Pallone.} I may forego that because I did want to
2240 ask something else. I am so interested in the issue as it
2241 affects the Native Americans, and Chairman Rolin left, but I
2242 just wanted to ask, he gave me the impression that we really
2243 were getting a handle on diabetes amongst American Indians.

2244 Is that--I mean, obviously there is some success but my
2245 recollection just talking to different tribes is that the
2246 incidence of diabetes is still on the increase and
2247 particularly amongst younger people. How do I reconcile that
2248 with what he said? I mean, he is not here so it is difficult
2249 but--

2250 Dr. {Henry.} Sure. I would be happy to. I think you
2251 are correct that the prevalence continues to rise in the
2252 Indian and the Native Alaskan population. However, we are
2253 doing a better job of taking control of those people so they
2254 are living longer but we are doing a better job of preventing
2255 the complications.

2256 Mr. {Pallone.} So more people are still contracting
2257 diabetes but you are able to control it and make them live
2258 longer?

2259 Dr. {Henry.} And many of the complications of the
2260 nerves and of the kidneys and the eyes, we have made
2261 substantial progress in reducing those so while there has
2262 been significant progress, as he states, the prevalence of
2263 the disease does continue to rise, though.

2264 Mr. {Pallone.} Thank you very much.

2265 Mr. Shimkus.

2266 Mr. {Shimkus.} Thank you, Mr. Chairman.

2267 Dr. Goldstein, and Dr. Henry, you can chime in too, you

2268 talked about the islet technology and use, and I know in the
2269 early part of the decade there was widespread media reports
2270 on the promise of this, especially those with type 1
2271 diabetes, and the hope was that they would be able to live
2272 without daily injections of insulin. You briefly mentioned
2273 one case. What is the promise of the islet use?

2274 Dr. {Goldstein.} So the pancreatic islet
2275 transplantation study you are referring to, which was
2276 reported from Canada in the year 2000, was widely heralded
2277 and adopted and NIH studied it and the initial promise
2278 probably exceeded what could be delivered, but the long-term
2279 promise is quite interesting. So if we prepare islets from a
2280 donor, a cadaveric donor pancreas, and transplant that into
2281 somebody who has got relatively severe disease, typically
2282 with what is called hypoglycemia unawareness where they don't
2283 know that they are getting low blood sugars and could be
2284 prone to seizures and that sort of thing. The islet
2285 transplant actually reverses the hypoglycemia unawareness,
2286 even if you still have to take insulin, and for those
2287 patients who have had to continue to take insulin, the
2288 quality of their treatment has improved so much and two
2289 complications have begun to reverse, one in the eyes and one
2290 in the nerves. So it has had an important conceptual effect
2291 which we would call a proof of therapy that cell therapy or

2292 replacement therapy can actually work. That kind of
2293 replacement therapy requiring lifelong immunosuppression to
2294 prevent graft rejection is not exactly what we would like to
2295 give to our children, so we made improvements on that and
2296 hopefully this will lead the way towards the next generation
2297 of productivity.

2298 Mr. {Shimkus.} Great.

2299 Dr. Henry, do you want to add anything to that?

2300 Dr. {Henry.} Well, I would only say that there was a
2301 large number of symposia at this recent ADA meeting in
2302 Orlando which addressed islet cell rejection and techniques
2303 to prevent rejection, techniques to stimulate other cells to
2304 become islet cells and so I think that this is a very sort of
2305 stimulating area of research that is currently ongoing.

2306 Mr. {Shimkus.} Dr. Goldstein, you mentioned also in
2307 your statement, not the written but when you were talking,
2308 anti-CD3. Can you elaborate on that?

2309 Dr. {Goldstein.} Can I divert your attention for 30
2310 seconds?

2311 Mr. {Shimkus.} It happens all the time.

2312 Dr. {Goldstein.} Dr. Burgess talked about a soldier who
2313 was injured by a blast injury and was losing his pancreas
2314 surgically to save his life in other ways. That pancreas
2315 went to one of the islet transplantation programs in Miami.

2316 They recovered the islets from this soldier's damaged
2317 pancreas, sent them to Walter Reed. They were transplanted
2318 back, and he now has function and doesn't have diabetes
2319 because of that traumatic event. That couldn't have happened
2320 if there weren't a facility that understood how to prepare
2321 those islets.

2322 Let me tell you about anti-CD3 in a moment, please. So
2323 type 1 diabetes is an autoimmune disease where the immune
2324 system reacts in an abnormal way. If we could stop that
2325 autoimmune response, we presumably can stop the attack on the
2326 insulin-producing cells. Anti-CD3 is a monoclonal antibody
2327 which blocks the autoantibody response. If you give it to
2328 Charlotte Cunningham within 4 or 5 weeks of the time she got
2329 the disease and blocked that autoimmune response, her body
2330 stops destroying insulin-secreting cells and she keeps them
2331 functional now almost up to 4 years.

2332 Mr. {Shimkus.} Great. That is good news on hopefully
2333 future uses. And I will just end with this.

2334 Dr. Goldstein, I know that the charity, JDRF, has a good
2335 ratio of money spent out versus overhead costs, and I was
2336 going to ask questions but I will just place that in the
2337 record because we do know that you are good stewards of the
2338 donations and I put on the record a family who especially
2339 since I got elected to the Congress has just been all over

2340 me, and they have two--their youngest boy is Kevin
2341 Covarubius. He has been up here for the Congress years ago.
2342 And what was challenging is that he as a young, young body
2343 was identified. Then his brother, who is older, only was
2344 identified in his late teens, like 18 or 19 years old, which
2345 I guess had Ryan appreciate what Kevin went through for all
2346 those years. So my hats off to the Covrarubius family for
2347 doing the work in the field, and I yield back, Mr. Chairman.
2348 Thank you.

2349 Mr. {Pallone.} Thank you.

2350 Ms. DeGette.

2351 Ms. {DeGette.} Thank you, Mr. Chairman, and I want to
2352 thank both of you for coming and for all of the work of your
2353 organizations. I was getting a lot of thanks up here but
2354 really it is you and your partners at the federal agencies
2355 that are doing all the work and all of the families too.
2356 Whenever Mr. Space and Mrs. Capps and the chairman and I and
2357 everybody will tell you that--even Mr. Shimkus will tell you
2358 that when these families come up to the Hill to testify and
2359 to talk to members, it is the most powerful evidence that we
2360 get up here. So thank you for that.

2361 I want to follow up on a couple of questions. Both of
2362 you were talking about the islet cell transplantation work
2363 that has been done, and I just think it is worth noting as

2364 well as the anti-rejection issues, the other issue that we
2365 have right now with using the islet cells from cadavers is
2366 that the supply is--even if you could figure out the
2367 rejection issues, you would have such a low supply of
2368 existing islet cells that you couldn't possibly treat the
2369 existing populations. I am wondering if either of you or
2370 both of you would like to comment on that.

2371 Dr. {Henry.} Well, my comment would be that is likely
2372 to be true. The options of stem cells I think is really a
2373 true one, and while we still have to get around the rejection
2374 issue, because that has been sort of the thorn in the side of
2375 getting a cure, I think that stem cells still hold
2376 significant promise.

2377 Ms. {DeGette.} And that is because with the stem cells
2378 you can actually make new cells versus the existing research
2379 where you have to just collect--

2380 Dr. {Henry.} Right, and hopefully immune tolerant so
2381 that they don't get rejected.

2382 Ms. {DeGette.} Right. Let me ask you along those
2383 lines, the NIH recent work of trying to improve new cell
2384 lines, is that sufficient to be doing the research that is
2385 out there right now on the stem cell research and what about
2386 this issue of having cell lines that might have the genetic
2387 predisposition towards diabetes? What is the status from

2388 your perspective as private organizations?

2389 Dr. {Goldstein.} There are now many approved lines for
2390 NIH funding. We think that is terrific. There are
2391 alternative sources for new lines from induced pluripotent
2392 stem cells, which are excellent resources, and disease-
2393 specific lines are being produced, for example, at the
2394 Harvard Stem Cell Institute with the technique of induced
2395 pluripotent stem cells and they are making the cells
2396 available for study by researchers. They include rare
2397 genetic disorders as well as things like type 1 diabetes. So
2398 I would say the rate-limiting event today is funding for
2399 research to take advantage of the available material more
2400 than we need to make even more material this week.

2401 Ms. {DeGette.} Yes, because not only did we have
2402 President Obama's expansion of the embryonic stem cell
2403 research but just in the last few years we had discovery of
2404 the IPS cells and so now we need the funding to capitalize on
2405 that.

2406 I just have one more question for both of you, which is,
2407 a lot of your testimony and the previous panel's testimony
2408 was around this concept of an artificial pancreas, and of
2409 course, as the parent of a diabetic, I follow these research
2410 developments with interest, and I think the closed loop
2411 system will be the next big step. How far away are we,

2412 though, from really developing, to being able to get clinical
2413 trials of the closed loop system and then to actually have it
2414 be widely available for folks?

2415 Dr. {Henry.} Well, there have been some clinical trials
2416 that are already being conducted and have shown efficacy in
2417 small numbers of patients. I think the difficulty right now
2418 is having sufficient funds to be able to do in larger
2419 populations of patients, and of course to research to make it
2420 more user friendly. Right now the artificial pancreases that
2421 have been studied are still bulky and large and they are very
2422 effective but not particularly adaptable to everyday life,
2423 and that is what we have to strive to do. But I think we are
2424 certainly heading in the right direction, moving quickly but
2425 perhaps not quickly enough.

2426 Ms. {DeGette.} Dr. Goldstein?

2427 Dr. {Goldstein.} The technology is a bit cumbersome at
2428 the moment. Not every teenager likes to wear it. And if we
2429 can package that and shrink it and make it more user friendly
2430 and get more widespread use, we will be able to take
2431 advantage of current technology. We need improvements. We
2432 are funding work that is going ahead full blazes in terms of
2433 understanding how to set an algorithm to describe exercise
2434 situation or sleeping at night situation with the infinite
2435 variety of details that a person might go through. But our

2436 notion is that to whatever extent we can automate the
2437 technology, we will get those tough-to-treat patient
2438 populations like adolescents and teenagers to use the
2439 technology, and that will make it better for everybody.

2440 Ms. {DeGette.} Thank you.

2441 Mr. {Pallone.} I am going to try to finish, guys. You
2442 have 5 minutes each, which is fine. Because we have not only
2443 a series of votes but also a motion to recommit, so it will
2444 probably be at least an hour, so we are going to try to
2445 finish. So we will go to Ms. Capps next.

2446 Mrs. {Capps.} Thank you very much for your testimony
2447 and also for your patience getting through this very long
2448 day. Two questions for each of you, and they can be brief and
2449 we can go to Mr. Space.

2450 A couple for Dr. Goldstein. In your testimony, you
2451 state that type 1 diabetes typically strikes in childhood,
2452 adolescence or young adulthood, then you note that the
2453 incidence has increased particularly among children under 4.
2454 I wonder if you could briefly give us a couple of reasons for
2455 that if they are known.

2456 Dr. {Goldstein.} I wish I could give you a couple.

2457 Mrs. {Capps.} Or some kind of--

2458 Dr. {Goldstein.} I should say two things quickly.

2459 About half the cases come in people 20 years old and older,

2460 so type 1 diabetes is not strictly speaking only a disease of
2461 children.

2462 Mrs. {Capps.} Right.

2463 Dr. {Goldstein.} What has happened from the
2464 epidemiologic studies in the past 5 years from both Europe
2465 and the United States is unfortunately we are seeing it in
2466 younger and younger children in a more aggressive version,
2467 and since nothing much has changed in the genetic structure
2468 of people, the assumption is that it is related to something
2469 in the environment, so studies are focusing on identifying a
2470 theoretical virus that could do that, some antigen within
2471 your body that--

2472 Mrs. {Capps.} So there is no clear path or--and
2473 therefore we need a lot more research in this area.

2474 Dr. {Goldstein.} We do.

2475 Mrs. {Capps.} Let me move on, because you described
2476 also the disproportionate burden of type 2 and gestational
2477 diabetes on certain groups. I wonder if this also holds true
2478 for type 1 and can you tell us whether there are certain age
2479 groups beyond children under 4 that are particularly affected
2480 by type 1 diabetes, you know, with ethnic, racial, whatever
2481 kind of groups that you--

2482 Dr. {Goldstein.} Well, type 1 diabetes appears to be an
2483 equal opportunity disease, and the numbers are fairly similar

2484 across ethnic groups. Where it is extremely important, for
2485 example, as in, let us say, Los Angeles, if we would like to
2486 get the technology into certain areas of Los Angeles to treat
2487 ethnic groups with type 1, that is a tour de force because
2488 that is not easily done without an army of educators and
2489 third-party pay, etc. So we have some of our artificial
2490 pancreas researchers working there on that. That is the hope
2491 for the future.

2492 Mrs. {Capps.} I see. So it is going to depend on some
2493 other things. Maybe that will segue into questions that I
2494 have for you, Dr. Henry. These could have been interchanged
2495 with each of you.

2496 Earlier today, Dr. Albright was talking about in
2497 testimony that CDC is actively working with the First Lady
2498 and Let's Move, that campaign to provide expertise in healthy
2499 eating and physical activity as a way to deal with diabetes,
2500 and they are also sponsoring the diabetes--CDC is--the
2501 diabetes prevention program Master Training Curriculum. I am
2502 particularly interested in types of prevention research and
2503 activities that will really work and that ties into areas
2504 like that they would work with particular community groups,
2505 and Dr. Henry, maybe you can tell us more about some efforts
2506 that your organization is getting behind and the advocacy
2507 community is working on in terms of outreach, specifically,

2508 how they are being tailored to meet the needs of individual
2509 communities.

2510 Dr. {Henry.} I think one of the major ways is in the
2511 application of the diabetes prevention program information
2512 which was highly effective, as you know, a 58 percent
2513 reduction in the development of diabetes in individuals who
2514 are able to lead a healthy lifestyle, so clearly one can make
2515 big inroads in that. The task has now been to take it to the
2516 community level, and that has been done. The translational
2517 part of that program has been initiated and we are obviously
2518 very supportive of that and has been done for a reasonable
2519 amount of money, as you heard, in the range of \$250 to \$300
2520 per year per person, which is, I think, a reasonable amount
2521 of an expenditure. So I think that that is right now where
2522 our major efforts are going. But there are also many
2523 preventive efforts that are being directly truly at the
2524 pancreatic beta cell, which not only does it decline and
2525 cease in type 1 diabetes but it declines progressively in
2526 type 2 and is a major contributor to many of the
2527 complications through poor glucose control. So there is
2528 again a great deal of research focusing on preserving the
2529 beta cell, preserving and also treating the insulin
2530 resistance that you heard about because we now know that
2531 efforts directed at treating the insulin resistance, whether

2532 it be through lifestyle modification or through medications,
2533 prolongs the pancreas and gives it a longer period where it
2534 can produce sufficient insulin to maintain glucose control.

2535 Mrs. {Capps.} Thank you very much.

2536 Mr. {Pallone.} Thank you.

2537 Mr. Space.

2538 Mr. {Space.} Thank you, Mr. Chairman.

2539 Thank you both for being here today, and I certainly
2540 want to echo the remarks of my colleague, Mrs. DeGette,
2541 regarding how valuable the work that both your agencies do
2542 is. I have, Dr. Henry, for you first. Your testimony
2543 references special populations as being especially prone to
2544 contracting diabetes, and there has been some talk today
2545 about ethnic minorities and Native Americans, and there
2546 hasn't been much said, however, about geographic and
2547 demographic breakdowns. My district in southeastern Ohio, it
2548 is Appalachian Ohio. It is a very poor, very rural district.
2549 Some of my counties have actually twice the incidence of
2550 diabetes than the national average or even the statewide
2551 average, and I would be interested in your thoughts as to
2552 whether those types of demographics, location or access to
2553 health care facilities or poverty, whether or not they have
2554 negatively influenced the diabetes incidence rate and whether
2555 your studies are accounting for that and what can be done to

2556 offset that.

2557 Dr. {Henry.} I think that it seems unquestionable that
2558 is the case, and access to care is definitely one of the
2559 limiting factors because in many cases there is prodrome, not
2560 only obesity but different forms of obesity, that precede the
2561 development of at least type 2 diabetes and individuals at
2562 risk for gestational diabetes, and certainly those
2563 populations, they need to be effectively treated and have
2564 access to care. Just as well, I think that healthy
2565 lifestyles are difficult when you are poor. It is very
2566 difficult to eat the fruits and vegetables that we have
2567 talked about, and I think that that also increases the
2568 likelihood that individuals with a genetic risk of diabetes
2569 which it clearly has a genetic component are more likely to
2570 develop diabetes. So I think that those are real issues that
2571 have to be addressed, and I think that better access to
2572 preventive technology as well as better treatment of the
2573 comorbidities will translate to a reduction in the
2574 development of diabetes.

2575 Mr. {Space.} Thank you.

2576 And Dr. Goldstein, thank you, by the way, for meeting
2577 with me earlier today and taking time out of your busy
2578 schedule. We have about 2 minutes, and if you could give us
2579 just a very brief account of how the NIH funding works in

2580 conjunction with foundational funding that comes from sources
2581 like ADA and JDRF and how it works in conjunction with
2582 industry sources of funding for research and development from
2583 biotech and pharmaceutical companies.

2584 Dr. {Goldstein.} So here is the 2-minute version. We
2585 work very closely with the NIH to do complementary things so
2586 we are not funding the same things, and I would say that most
2587 important piece of information is that the NIH, which has
2588 made a historically important investment in basic science and
2589 discovers new things, to develop those things, you have to
2590 pass that off as you go along. So initially new discoveries
2591 get in the hands of small companies. NIH has a modest
2592 program. JDRF has a modest program to encourage small
2593 companies to develop things. We like to nourish them along
2594 the pathway to get into proof-of-concept clinical trials,
2595 which is about the first place that large pharma becomes
2596 interested after you have already got some data. And once
2597 you have got the data and a phase III trial, large pharma
2598 becomes very interested. So, for example, the anti-CD3 I
2599 spoke about, two large pharmaceutical companies are both
2600 taking that to market, and it costs lots of money to do that.
2601 We can't afford to do it nor can the ADA probably.

2602 Early on, NIH gets us the discovery, but once you hit
2603 the small company level and the small biotech and the small

2604 investigators, the handful of people who are moving the next
2605 generation of science along, it is really hard to get money
2606 to do that these days. Venture capital has dried up, and the
2607 foundation world has said that is a gap we need to think
2608 about filling, how could we do it wisely, and that is exactly
2609 where we are focusing our more limited resources in a more
2610 strategic way. So we frankly pick and choose. We try to
2611 take something more promising and try to move it along to the
2612 point where it can either move or not, and that is a
2613 partnership that I would argue has served the United States
2614 of America very well in terms of being a model for how to do
2615 things for people, and at some point the big clinical
2616 translation apparatus comes into play and NIH has played an
2617 important role in doing that as well.

2618 Mr. {Space.} Thank you very much.

2619 Mr. {Pallone.} We are going to have to end, otherwise
2620 we are going to miss the votes.

2621 I thank my colleagues and both of you for your
2622 presentations. It was very helpful. The way we work is, we
2623 have about 10 days to submit written questions and
2624 particularly since Chairman Rolin had to leave, I am sure
2625 there will be some, and the clerk will send you those and
2626 then we ask you to get back to us as quickly as possible.
2627 But again, thank you, and I know there is a lot more to be

2628 done on this issue but at least we had a beginning here
2629 today.

2630 And without objection, this meeting of the subcommittee
2631 is adjourned.

2632 [Whereupon, at 2:18 p.m., the Subcommittee was
2633 adjourned.]