

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1 {York Stenographic Services, Inc.}

2 RPTS BURDETTE

3 HIF169.020

4 ``CONTINUING CONCERNS OVER BLOWATCH AND THE SURVEILLANCE OF

5 BIOTERRORISM''

6 TUESDAY, JUNE 18, 2013

7 House of Representatives,

8 Subcommittee on Oversight and Investigation

9 Committee on Energy and Commerce

10 Washington, D.C.

11 The subcommittee met, pursuant to call, at 10 a.m., in  
12 Room 2322 of the Rayburn House Office Building, Hon. Tim  
13 Murphy [Chairman of the Subcommittee] presiding.

14 Present: Representatives Murphy, Burgess, Blackburn,  
15 Scalise, Harper, Olson, Gardner, Johnson, Long, Ellmers,  
16 Bilirakis, DeGette, Butterfield, Tonko, Green and Waxman {ex

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee’s website as soon as it is available.**

17 officio).

18 Staff present: Carl Anderson, Counsel, Oversight; Sean  
19 Bonyun, Communications Director; Karen Christian, Chief  
20 Counsel, Oversight; Andy Duberstein, Deputy Press Secretary;  
21 Brad Grantz, Policy Coordinator, Oversight and  
22 Investigations; Brittany Havens, Legislative Clerk; Sean  
23 Hayes, Counsel, Oversight and Investigations; Alan Slobodin,  
24 Deputy Chief Counsel, Oversight; Phil Barnett, Democratic  
25 Staff Director; Stacia Cardille, Democratic Deputy Chief  
26 Counsel; Kiren Gopal, Democratic Counsel; Hannah Green,  
27 Democratic Staff Assistant; Elizabeth Letter, Democratic  
28 Assistant Press Secretary; Stephen Salsbury, Democratic  
29 Special Assistant; and Roger Sherman, Democratic Chief  
30 Counsel.

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

|  
31           Mr. {Murphy.} Good morning. I convene this hearing of  
32 the Subcommittee on Oversight and Investigations on  
33 Continuing Concerns Over BioWatch and the Surveillance of  
34 Bioterrorism. We will be examining the effectiveness and  
35 efficiency of BioWatch, a Department of Homeland Security  
36 program that relies heavily on the Centers for Disease  
37 Control and Prevention, and the State and local public health  
38 laboratories that are members of the CDC Laboratory Response  
39 Network.

40           BioWatch is an early warning system designed to detect a  
41 large-scale, covert attack that releases anthrax or other  
42 agents of bioterrorism into the air. The program was  
43 launched in January 2003 as this country was preparing for  
44 war against Iraq when many believed that state-actor programs  
45 had stockpiles of anthrax, smallpox and botulinum.

46           BioWatch deploys collectors in 34 of the largest U.S.  
47 metropolitan areas in outdoor locations, with indoor  
48 deployments in three sites, and special event capacity.  
49 These collectors hold filters that gather air samples. Every  
50 24 hours, a government worker goes to these collectors,

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

51 manually retrieves the filters, and takes them to a State or  
52 local laboratory for analysis and testing. If the lab  
53 testing shows a positive result, called a BioWatch Actionable  
54 Result, or BAR for short, government officials review other  
55 evidence and information to decide if it is an actual attack,  
56 or just the detection of a bacteria in the environment that  
57 has similar DNA to the pathogen of concern. Since the  
58 program started, there have been 149 BARs, none of them being  
59 an actual attack. BioWatch costs about \$85 million a year to  
60 operate, with over \$1 billion spent since 2003.

61 For 9 years BioWatch has sought to develop and deploy a  
62 more advanced type of technology that would include air  
63 sampling and analysis of the samples in the same device, a  
64 so-called lab-in-a-box. This technology, known as Generation  
65 3, is estimated by GAO to cost \$5.8 billion over 10 years.  
66 According to a senior CDC official, the cost is ``an  
67 abomination.''

68 Unfortunately, after much hype, versions of lab-in-a-box  
69 technology have failed. One version, BioWatch Generation  
70 2.5, was actually deployed for 2 years and then halted  
71 because it was ineffective. The latest version of

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

72 technologies for Generation 3 failed testing. About \$300  
73 million has already been spent on these failed detection  
74 technologies. Last year, the Senate and House Appropriations  
75 Committees removed the \$40 million requested by the  
76 Administration for Generation 3, and no procurement of this  
77 technology can proceed until after the Secretary of Homeland  
78 Security certifies that the science is proven.

79 Almost a year ago, this committee opened this  
80 investigation after a National Academy of Sciences report in  
81 2011 and an article in the Los Angeles Times in July 2012  
82 noted that the BioWatch system was generating false positives  
83 or indicating the ``the potential occurrence of a terrorist  
84 attack when none has occurred.'' A DHS official responded,  
85 stating that the reports of false positives were incorrect  
86 and unsubstantiated, and that ``there has never been a false  
87 positive result.''

88 However, the committee's investigation found other  
89 serious problems with the BioWatch program besides the BAR  
90 false positives. Most troubling is whether we are better  
91 prepared to respond to bioterrorism than we were 5 years ago.  
92 Unfortunately, the answer would seem to be no.

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

93           The public health workforce has been reduced by 21  
94 percent over the last 5 years, with emergency preparedness  
95 being hardest hit. Several of the bioterrorism threats we  
96 thought we faced in 2003 no longer apply or have been  
97 lessened. According to the DHS experts interviewed by  
98 committee staff, recent threat assessments show that a large-  
99 scale catastrophic attack is less likely. However, the  
100 threat is still dangerous because of certain technological  
101 advances and the greater likelihood of smaller-scale attacks  
102 that would probably not be detected by BioWatch.

103           Yet, if the science of Generation 3 is proven, DHS would  
104 be expected to pursue the multibillion-dollar Generation 3.  
105 We cannot afford another DHS boondoggle. This costly  
106 approach is unbalanced and misdirected. It makes no sense to  
107 expand outdoor monitoring for a less likely large-scale  
108 attack, while not addressing the declining number of public  
109 health responders who are needed in any kind of attack. If  
110 public health authorities lack the capability to respond,  
111 BioWatch will not produce a benefit.

112           The committee's investigation did not find a strategy  
113 reflecting changes in the threat and the reduced resources in

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

114 the public health workforce. Last July, the President put  
115 out a National Strategy for Biosurveillance. He directed  
116 that a strategic implementation plan be completed within 120  
117 days, but there is no strategic implementation plan that has  
118 been publicly released, and the committee staff have been  
119 unable to confirm if this plan even exists.

120       Once the role of BioWatch is appropriately analyzed in  
121 the context of an overarching biodefense strategy, tough  
122 questions need to be examined. After 10 years of operation,  
123 we don't still know if the current BioWatch technology can  
124 detect an aerosolized bioterrorism agent in a real-world  
125 environment. DHS expects to have this data this fall. We  
126 don't know if past management problems have been corrected.  
127 Bipartisan committee staff asked DHS to produce documents  
128 from an internal DHS investigation of a DHS official's  
129 conduct related to BioWatch, but DHS has not done so.

130       There has been bipartisan and non-partisan concern over  
131 BioWatch, including the ranking member of the House Homeland  
132 Security Committee, Bennie Thompson, the GAO, the National  
133 Academies of Science, Congressman David Price, Democrats and  
134 Republicans on the Senate and House Appropriations

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

135 Committees, House Homeland Security Committee Republicans,  
136 Congressman Gus Bilirakis, now a member of the House Energy  
137 and Commerce Committee, and Congressman Dan Lungren. Let us  
138 work together to get the right solution.

139 We want to thank the witnesses for being here today. I  
140 would now like to give the ranking member, my good friend  
141 from Colorado, Ms. DeGette, an opportunity now to give her  
142 opening statement for 5 minutes.

143 [The prepared statement of Mr. Murphy follows:]

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

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

145 Ms. {DeGette.} Thank you, very much, Mr. Chairman.

146 Mr. Chairman, I am so glad we are here talking about  
147 this BioWatch surveillance program. Bioterrorism remains a  
148 threat to our Nation, and BioWatch's detection capabilities  
149 are critical, and I agree with you, that is why we need to  
150 make sure that the program is operating efficiently.

151 After the anthrax mailings of 2001, the federal  
152 government needed to act fast. In September 2001, the New  
153 York Times reported that the government's bioterrorism  
154 planning was so disjointed that the agencies involved could  
155 not even agree on which biological agents posed the biggest  
156 threat. Boy, we have come a long way since then, in large  
157 part because of the BioWatch program.

158 BioWatch has been monitoring the air for potential  
159 bioterror agents like anthrax for the last decade. It is a  
160 valuable tool because it provides us with advanced warning of  
161 a biological attack. If a release of anthrax was detected  
162 before it began to adversely affect people, for example,  
163 public health officials could take action to mitigate its  
164 impact and prevent it from being spread. Local hospitals

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

165 could be told to be on the lookout for certain symptoms and  
166 ensure victims weren't being misdiagnosed. Any time that we  
167 can buy through early detection could mean many lives saved.

168 With this kind of biosurveillance system in place, the  
169 likelihood of a biological attack inflicting mass casualties  
170 and overwhelming our public health system would be greatly  
171 reduced. That is why biosurveillance is an essential  
172 activity and a national priority, and that is BioWatch is a  
173 beneficial program that helps meet our national security  
174 needs. But, Mr. Chairman, there is a big ``if'', and I agree  
175 with you: those facts only hold true if we can be confident  
176 that the BioWatch program works the way it says it should.

177 Experts have in recent years raised a number of  
178 technical and management concerns with the BioWatch program.  
179 Mr. Chairman, you talked about some of those in your opening  
180 statement. This committee's job is to hear about those  
181 concerns so we can make sure that the program is on the right  
182 path forward. Is the federal, State and local collaboration  
183 running smoothly? Are constructive recommendations being  
184 implemented? Is the program now being effectively managed?  
185 Is the current generation of BioWatch technology meeting

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

186 appropriate standards, and is the next generation of BioWatch  
187 technology fiscally and technically feasible.

188 I appreciate both of our witnesses today, and I hope  
189 they can help us answer these questions. We have heard from  
190 officials that General 3 that you discussed, which is the  
191 proposed new BioWatch technology, could provide more timely  
192 threat detection. Before we expend considerable resources on  
193 that, though, I think we can be in agreement, we have got to  
194 be confident that this technology works. If it can be tested  
195 and proven, Generation 3 holds the potential to provide  
196 continuous and autonomous detection and expanded population  
197 coverage. Unfortunately, the acquisition process for  
198 BioWatch Generation 3 has been marred with difficulties, and  
199 serious questions remain about whether Generation 3 is a  
200 viable advance.

201 Last September, GAO reported that decisions were made to  
202 go forward with this automation detection technology without  
203 the proper due diligence and without justifying the mission  
204 need. DHS didn't develop a complete and reliable performance  
205 schedule and cost information before approving the  
206 acquisition, and if there is one thing we have learned since

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

207 September 11th, let us just stop throwing money around willy-  
208 nilly. Let us make sure that we target it to programs that  
209 work.

210 Generation 3 acquisition is currently on hold as DHS  
211 tries to resolve these issues, and that seems like the  
212 prudent course of action to me. The delays and mismanagement  
213 that led us to this point, however, are unacceptable, and DHS  
214 must do better. I am looking forward to hearing from Dr.  
215 Walter about what has been done to rectify these deficiencies  
216 so that we can move forward.

217 The BioWatch program is only a small part of our efforts  
218 to detect and to deter bioterrorism. That is why part of our  
219 discussion about BioWatch must also ask about broader  
220 biosurveillance activities and where this picture fits into  
221 the large picture. We obviously can't protect against every  
222 potential threat but we should be figuring out what the  
223 likeliest threats are, and if our current infrastructure  
224 meets the challenges of today as well as the future, given  
225 the limited resources.

226 I look forward again to hearing from the witnesses about  
227 BioWatch, and I know we will be able to have a constructive

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee’s website as soon as it is available.**

228 discussion about where we go from here, and I yield back, Mr.  
229 Chairman.

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

231 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

|  
232 Mr. {Murphy.} The gentlelady yields back, and now I  
233 turn towards the vice chairman of the committee, Dr. Burgess,  
234 for 5 minutes.

235 Dr. {Burgess.} I thank the chairman for the  
236 recognition.

237 We have already heard this morning the result of the  
238 9/11 attacks, the anthrax letters in 2001 of escalated  
239 bioterrorism from a concept to a reality. In response, the  
240 BioWatch program was launched as an early-detection warning  
241 system for bioterrorist attacks. Unfortunately, in the rush  
242 to launch BioWatch, the government failed to ensure the  
243 proper role for the program in the greater United States  
244 biosurveillance strategy.

245 Public health is best administered at the local and  
246 community level. While BioWatch has the potential to provide  
247 valuable data to federal, State and local officials, the  
248 promise continues to remain one in theory.

249 The Centers for Disease Control requires reliable, high-  
250 quality evidence in order to decide to respond to a  
251 bioterrorism event. The Department of Homeland Security, who

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

252 is in charge of the BioWatch system, has failed to utilize  
253 BioWatch to gather the information necessary to guide the  
254 decisions of public health authorities.

255 We have another problem. Since 2003, BioWatch has  
256 produced 56 false alarms. This unfortunately has the effect  
257 of destroying public confidence that public health officials  
258 may have had in the system. Federal, State and local  
259 agencies already operate and maintain a wide variety of  
260 outdoor air monitoring systems across the United States. The  
261 26th district of Texas, which produces a lot of natural gas  
262 through a process known as fracking, maintains a number of  
263 air quality sensors, both from the Texas Commission for  
264 Environmental Quality as well as the private sector as well.  
265 If private companies have the ability to capture real-time  
266 air quality data through remote sensing, why do we still lack  
267 the ability to detect that that came from a bioterrorism  
268 attack?

269 Terrorist threats have changed since 2001. The enemies  
270 are developing new strategies that will circumvent our  
271 surveillance. Our surveillance and response strategy must  
272 improve at an even faster pace. We should identify and

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

273 address the evidence gaps in our public health surveillance  
274 system, ensuring that all United States surveillance systems  
275 cooperate to achieve our biosurveillance strategy and prevent  
276 those threats before they become a reality.

277         And then lastly, I feel obligated just to mention that  
278 back in the early 1950s, the United States Navy undertook a  
279 series of exercises that were famously declassified in the  
280 mid-1970s that provided evidence that yes, indeed there can  
281 be a problem. The dispersal of what was thought to be a  
282 harmless bacteria along the coastline in the United States  
283 ended up causing illness in a limited number of individuals  
284 but nevertheless illness all the same. So it certainly  
285 underscores the importance of undertaking this work but it is  
286 also important that we get it right.

287         Mr. Chairman, I thank you for the consideration and I  
288 will yield back to you.

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

290         \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

|  
291           Mr. {Murphy.} The gentleman yields back. I would now  
292 recognize the ranking member of the committee, Mr. Waxman,  
293 for his opening statement for 5 minutes.

294           Mr. {Waxman.} Thank you, Mr. Chairman, and my comments  
295 are going to be similar to my colleagues because we all  
296 understand what we are facing today.

297           The history of this is that in 2003 in his State of the  
298 Union address, President Bush announced the deployment of  
299 ``the Nation's first early warning network of sensors to  
300 detect biological attack.'' Just months after this  
301 announcement, the BioWatch program was up and running. We  
302 have since learned that BioWatch, like other post-September  
303 11 programs, was implemented too hastily and without  
304 appropriate long-term planning.

305           But that doesn't mean that the program cannot be  
306 repaired. In fact, progress is already being made. In  
307 recent years, Government Accountability Office and other  
308 analysts have identified legitimate concerns with the  
309 management of the BioWatch program that should be addressed,  
310 particularly with respect to the acquisition of new early-

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

311 detection Generation 3 technology. This new technology is  
312 promising because it could lead to faster detection in the  
313 event of a bioterror attack.

314 According to GAO, however, the Department of Homeland  
315 Security approved the Gen-3 acquisition ``without fully  
316 developing critical knowledge that would help ensure sound  
317 investment, decision making, pursuit of optimal solutions,  
318 and reliable performance, cost, and schedule information.''  
319 To protect taxpayers, DHS officials have now put the  
320 acquisition on hold until all the necessary steps are taken  
321 to ensure we are making a wise investment decision that is  
322 grounded in the facts, and that of course is a prudent  
323 approach.

324 The L.A. Times, however, has brought other issues to  
325 light. In its reporting, the Los Angeles Times exposed a  
326 series of false positives identified by BioWatch sensors. As  
327 the Times documented, BioWatch sensors have repeatedly  
328 indicated the detection of possible bioterror agents that  
329 were later found to be harmless, naturally occurring  
330 organisms. Fortunately, all of these false positives were  
331 identified before the public was needlessly alarmed. When

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

332 the sensors went off, scientists were alerted to determine if  
333 these were legitimate bioterror agents or detections of  
334 benign agents. The Department is now working to lower the  
335 incidence of false positives, and this seems to be improving.  
336 There have been none so far this year.

337 We have also heard about scientific disagreements within  
338 the program. Much of the debate about the program's path  
339 forward and particularly the acquisition of new Generation 3  
340 technology revolves around complex scientific questions.  
341 These types of scientific questions are not surprising in a  
342 highly technical program like this. We can't answer the  
343 questions ourselves, but we can listen to the experts in  
344 biology, epidemiology and detection technology to become  
345 better informed, and I hope today's hearing will help in this  
346 area.

347 While we hear criticism of the BioWatch program,  
348 especially today, we also need to bear in mind its important  
349 public safety objectives. BioWatch's early-detection  
350 capabilities and its role in facilitating communication  
351 between key State and local decision makers can help protect  
352 our communities. We should use this hearing as an

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

353 opportunity to strengthen the program. That is why I am glad  
354 that Dr. Walter is here today to discuss the history of the  
355 BioWatch program and how the Administration is learning from  
356 past mistakes to make the program even more effective in the  
357 future. It shouldn't be all that hard, but if we are going  
358 to keep this program, let us make sure it is effective.

359 Mr. Chairman, I thank you for calling this hearing, and  
360 I thank our witnesses for being with us today to help us  
361 answer these questions about this important Homeland Security  
362 program.

363 I want to apologize to the witnesses in advance. We  
364 have another hearing going on simultaneously, and I am going  
365 to have to be going back and forth, but I will have a chance  
366 to review the record and my staff is here to learn all the  
367 information that will be brought out at this hearing. I  
368 yield back the balance of my time, and thank you calling on  
369 me.

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

371 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

372           |  
              Mr. {Murphy.} The gentleman yields back.

373           I would like to note and state that all those who just  
374 had opening statements agree that this is area we are unified  
375 on in purpose, so now to our witnesses.

376           You are aware--well, first let me introduce the  
377 witnesses so everybody knows who you are. I want to do that.  
378 First, Dr. Michael Walter, welcome here. He is the Detection  
379 Branch Chief and BioWatch Program Manager with the Office of  
380 Health Affairs at the Department of Homeland Security. He  
381 works with labs, public health, law enforcement and emergency  
382 management personnel to assist federal, State and local  
383 governments in developing and testing response measures to  
384 biological attacks. In addition to directing operations of  
385 the current BioWatch system, Dr. Walter also oversees the  
386 testing, acquisition and deployment of the newer technology  
387 referred to as Generation 3. Welcome. Our second witness is  
388 Dr. Toby Merlin. He has been with the Centers for Disease  
389 Control and Prevention since 2003. He is the Director of the  
390 Center for Disease Control and Prevention's Division of  
391 Preparedness and Emerging Infections and has been the CDC's

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

392 main interface with the BioWatch program since 2011. Prior  
393 to his current role, Dr. Merlin served as the Deputy Director  
394 of the Influenza Coordination Unit during the 2009 H1N1  
395 pandemic.

396 I will now swear in the witnesses, and you are that the  
397 committee is holding an investigative hearing, and when doing  
398 so has the practice of taking testimony under oath. Do you  
399 have any objections to testifying under oath?

400 Mr. {Walter.} No.

401 Dr. {Merlin.} No.

402 Mr. {Murphy.} So now the Chair then advises you that  
403 under the rules of the House and the rules of the committee,  
404 you are entitled to be advised by counsel. Do you desire to  
405 be advised by counsel during your testimony today? Both  
406 witnesses indicated no. In that case, if you would please  
407 rise and raise your right hand and I will swear you in?

408 [Witnesses sworn.]

409 Mr. {Murphy.} Both of the witnesses are now under oath  
410 and subject to the penalties set forth in Title XVIII,  
411 Section 1001 of the United States Code. You may now each  
412 give a 5-minute summary of your written statement. Dr.

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

413 Walter, you may begin.

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

|  
414 ^TESTIMONY OF MICHAEL WALTER, PH.D., BIOWATCH PROGRAM  
415 MANAGER, U.S. DEPARTMENT OF HOMELAND SECURITY, OFFICE OF  
416 HEALTH AFFAIRS; AND TOBY L. MERLIN, MD., DIRECTOR, DIVISION  
417 OF PREPAREDNESS AND EMERGING INFECTIONS, NATIONAL CENTER FOR  
418 EMERGING AND ZONOTIC INFECTIOUS DISEASES, CENTERS FOR  
419 DISEASE CONTROL AND PREVENTION

|  
420 ^TESTIMONY OF MICHAEL WALTER  
  
421 } Mr. {Walter.} Chairman Murphy, Ranking Member DeGette  
422 and distinguished members of the subcommittee, thank you for  
423 inviting me to speak with you today. I appreciate the  
424 opportunity to testify on the Office of Health Affairs'  
425 BioWatch program, and I am honored to testify alongside my  
426 distinguished colleague from the Centers for Disease Control  
427 and Prevention, Dr. Toby Merlin. My name is Dr. Michael  
428 Walter. I am the Program Manager for the DHS Office of  
429 Health Affairs' BioWatch program.

430 Bioterrorism remains a continuing threat to the security  
431 of our Nation. A biological attack would impact every sector

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

432 of our society and place enormous burdens on our Nation's  
433 public health with rippling effects on critical  
434 infrastructure. Biological attacks are particularly  
435 challenging because they can be so difficult to detect.  
436 Early detection is critical to the successful treatment of  
437 affected populations and provides public health decision  
438 makers more time and thereby more options in responding to,  
439 mitigating and recovering from a bioterrorism event. If a  
440 bioagent is detected and confirmed to be a threat to the  
441 public health, prophylactic treatment could be started prior  
442 to the widespread onset of symptoms resulting in a more  
443 cohesive response and more lives saved.

444 The BioWatch program is the country's only nationwide  
445 program whose goal is to continuously monitor for aerosolized  
446 environmental agents. The program consists of planning,  
447 preparedness, exercising, training and early-detection  
448 capabilities. Deployed throughout the country, the system is  
449 a collaborative effort of health professionals at all levels  
450 of government. The program is operated by a team comprised  
451 of field operators, laboratory technicians, and public health  
452 officials from city, county, State and federal organizations.

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

453 The current detection capabilities used by the BioWatch  
454 program consist of aerosol collectors whose filters are  
455 manually collected and retrieved for subsequent analysis in  
456 BioWatch laboratories that are located in State or county  
457 public health laboratories that are members of the CDC  
458 laboratory response network.

459 When a detection of a positive signal occurs, a BAR, or  
460 a BioWatch Actionable Result, is declared. A BAR is declared  
461 by the Director of the Public Health Laboratory or their  
462 designee, not by the federal government. To be clear, a BAR  
463 does not mean a terrorist attack has occurred, a viable agent  
464 has been released or that people have been exposed,  
465 additional information is needed to determine if an attack  
466 has occurred and if there is a threat to the public health.  
467 A BAR simply means that DNA of a select organism is present.  
468 Each BioWatch jurisdiction across the country has a BioWatch  
469 Advisory Committee, or BAC, made up of State, local and  
470 federal partners who operate the program and are responsible  
471 for planning and leading response efforts.

472 The BioWatch program has succeeded in bringing together  
473 State and local public health first responders and law

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

474 enforcement personnel along with locally deployed federal  
475 officials, resulting in communities that are better prepared  
476 not only for a biological attack but for an all-hazards  
477 response. The BioWatch program relies heavily on our federal  
478 partners for expertise in public health, law enforcement,  
479 intelligence and technical support to ensure optimum  
480 operations throughout the program.

481 To that end, the BioWatch is supported by federal  
482 partners including the CDC, the Federal Bureau of  
483 Investigations, the Department of Defense and the  
484 Environmental Protection Agency, and I would like to take  
485 this opportunity to thank Dr. Merlin and the CDC for their  
486 continued engagement in support of the program.

487 Consistent with the National Strategy for  
488 Biosurveillance, we have been looking at new technologies  
489 that could shorten the time to detect including autonomous  
490 detection technology. The BioWatch program understands the  
491 importance of providing public health officials the timeliest  
492 information possible to help them make high-consequence  
493 decisions. Automated detection would reduce the time to  
494 detect significantly, handing back precious time to our

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

495 public health officials faced with responding to a potential  
496 bioterrorism event. In addition, it would reduce cost of  
497 operations while providing continuous collection and analysis  
498 capability. The Department is currently conducting an  
499 analysis of alternatives consistent with Government  
500 Accountability Office recommendations prior to moving forward  
501 with a potential acquisition of advanced automated detection  
502 technologies.

503 I appreciate the committee's interest in the BioWatch  
504 program and your continued partnership as we work to improve  
505 our Nation's biopreparedness. The Office of Health Affairs  
506 believes strongly in a comprehensive surveillance approach  
507 that includes environmental and clinical surveillance as well  
508 as point-of-care diagnostics.

509 Thank you for the opportunity to appear today, and I  
510 look forward to your questions.

511 [The prepared statement of Mr. Walter follows:]

512 \*\*\*\*\* INSERT 1 \*\*\*\*\*

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

|

513 Mr. {Murphy.} Thank you.

514 Dr. Merlin, you are recognized for 5 minutes.

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

|  
515 ^TESTIMONY OF TOBY MERLIN

516 } Dr. {Merlin.} Thank you, Mr. Chairman.

517 Chairman Murphy, Ranking Member DeGette and members of  
518 the subcommittee, I want to thank you for the opportunity to  
519 speak to you today about the Department of Homeland  
520 Security's BioWatch program. I am Dr. Toby Merlin, Director  
521 of CDC's Division of Preparedness and Emerging Infections in  
522 the National Center for Emerging and Zoonotic Infectious  
523 Diseases. I am honored to testify alongside my distinguished  
524 colleague from DHS, Dr. Michael Walter, with whom I regularly  
525 work.

526 CDC works 24/7 to save lives and protect Americans from  
527 health threats. Throughout its history, CDC and its local,  
528 national and international partners have worked to detect,  
529 respond to and prevent health security threats. My remarks  
530 today will describe how CDC collaborates with DHS on the  
531 BioWatch program, explain the related role that CDC's  
532 Laboratory Response Network plays in this program, and  
533 discuss CDC's broader role in outbreak detection and

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

534 response. All of these efforts are designed to protect  
535 Americans from infectious public health threats including  
536 threats of bioterrorism.

537 In 2003, DHS initially launched the BioWatch program,  
538 which is a nationwide biosurveillance system designed to  
539 detect the intentional aerosolized release of selected  
540 biologic agents. At that time, CDC helped establish and  
541 staff BioWatch laboratories and develop and validate  
542 laboratory methods for detection of targeted biologic agents.  
543 Since the establishment of the BioWatch program, CDC has  
544 provided technical assistance to DHS by ensuring that  
545 scientific experts are available for consultations with the  
546 BioWatch laboratories and conducting additional laboratory  
547 testing at CDC when requested. CDC provides BioWatch  
548 laboratories with specialized reagents used in the testing  
549 and a system for secure electronic messaging of results.

550 CDC also provides scientific expertise and guidance,  
551 especially as it pertains to laboratory methodology and  
552 analyses to DHS and States and localities that participate in  
553 the BioWatch program. In the event that a biological threat  
554 agent is detected through the BioWatch program and it is

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

555 determined that a response is needed, CDC would coordinate  
556 any needed federal public health response.

557 CDC's Laboratory Response Network, or LRN, has 150  
558 member facilities and provides support to DHS's BioWatch  
559 program. The LRN is a network of local, State and federal  
560 public health and other laboratories that provide the  
561 laboratory infrastructure and capacity to respond to  
562 biological and chemical threats and other public health  
563 emergencies. Participation in the network is voluntary, and  
564 all member laboratories work under a single operational plan  
565 and adhere to strict policies of safety, biocontainment and  
566 security. Laboratories also perform testing using LRN  
567 procedures and reagents provided by CDC, which allows for  
568 rapid testing, reproducible results and standard reporting.  
569 BioWatch laboratories are usually collocated with LRN sites  
570 in the States and they use LRN procedures and reagents in the  
571 second phase of testing of material collected from air  
572 samples. CDC and the LRN provide support to the BioWatch  
573 program by participating in this BioWatch testing and the  
574 review steps which are designed to detect a possible release  
575 of a biological agent into the air.

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

576           Laboratory detection and epidemiological response to  
577 disease are the foundation of CDC's activities. In addition  
578 to managing the LRN and providing support to DHS's BioWatch  
579 program, CDC plays a broader, critical role in the detection  
580 of and response to local, State, national and international  
581 outbreaks of infectious diseases whether naturally occurring  
582 or manmade. CDC is home to the country's leading experts and  
583 gold-standard laboratories in infectious disease prevention  
584 and control. CDC's laboratories serve as an early warning  
585 system to rapidly identify, confirm and characterize new  
586 infectious disease threats. CDC often serves as a resource  
587 for our State and local partners during outbreaks and plays a  
588 critical role in identifying disease patterns and linkages  
589 across State and local lines.

590           In closing, CDC and LRN laboratories are critical and  
591 unique laboratory-based assets to ensure that our Nation is  
592 prepared to detect and respond to biological and chemical  
593 terrorism. CDC and LRN laboratories are essential to  
594 assuring rapid detection of these threat agents and other  
595 infectious diseases that pose a threat to the public. The  
596 BioWatch program is an important component of this national

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee’s website as soon as it is available.**

597 effort at early detection of biological threats. CDC will  
598 continue to work closely with DHS to support the BioWatch  
599 program whenever requested specifically in the areas of  
600 laboratory testing and public health response.

601 Thank you, Mr. Chairman, and I would be pleased to  
602 answer any questions.

603 [The prepared statement of Dr. Merlin follows:]

604 \*\*\*\*\* INSERT 2 \*\*\*\*\*

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

|  
605           Mr. {Murphy.} I thank both the witnesses here. We want  
606 to find out if this BioWatch system actually works, and I  
607 guess this speaks to the old adage, we want to know what time  
608 it is and we are told how a clock is made, so help us. I  
609 respect both of your experience and your intelligence, so  
610 help us walk through this.

611           Dr. Walter, this question is for you. In yesterday's  
612 Los Angeles Times, former Homeland Security Secretary Tom  
613 Ridge, who oversaw the start of BioWatch, stated, ``Everyone  
614 knew it''--that is, the BioWatch program--``was a primitive,  
615 labor-intensive, fairly unsophisticated attempt.'' That same  
616 technology for BioWatch is still out in the field. Do you  
617 agree with former Homeland Security Secretary Ridge that  
618 BioWatch is a primitive, labor-intensive and fairly  
619 unsophisticated tool?

620           Mr. {Walter.} Thank you for that question, sir. With  
621 respect to Mr. Ridge, no, I do not agree with his assessment,  
622 and I think it lacks the insight of where the program has  
623 come from since the beginning of the program's origin.  
624 BioWatch uses the same collector technology that was deployed

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

625 in 2003, that is true, and BioWatch is a labor-intensive  
626 process; that is also true. In the areas of laboratory  
627 analysis, our preparedness, our response and our training,  
628 Mr. Ridge is unaware of those advances to the BioWatch  
629 program and I think they have taken the BioWatch program to  
630 the next level and made it more effective.

631 Mr. {Murphy.} Let me ask you, the BioWatch is designed  
632 to detect a catastrophic, covert bioterrorism attack. Is  
633 that correct?

634 Mr. {Walter.} Yes, sir.

635 Mr. {Murphy.} And for BioWatch to meet its mission, the  
636 DHS is supported especially by the State and public health  
637 laboratories, correct?

638 Mr. {Walter.} That is correct, sir.

639 Mr. {Murphy.} And do you agree that State and local  
640 health departments need to have the capability to respond  
641 with public health or medical measures to minimize illness  
642 and death?

643 Mr. {Walter.} It is essential, sir.

644 Mr. {Murphy.} Okay. Well, the threat that BioWatch is  
645 detecting is a large-scale covert bioterrorism attack, so

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

646 when BioWatch was launched in 2003, the threat assessment was  
647 concerned with large-scale threats posed by state actor  
648 programs or terrorists getting possession of biological  
649 weapons from state actor program. Do you agree that there  
650 was a large-scale threat in 2003?

651 Mr. {Walter.} There was a perceived threat, yes, sir.

652 Mr. {Murphy.} And isn't it correct that the DHS  
653 official who conducts the bioterrorism risk assessment has  
654 found that under the current threat assessment, a large-scale  
655 bioterrorism attack is less likely and small-scale  
656 bioterrorism attacks are more likely?

657 Mr. {Walter.} That is possible, but ``less likely''  
658 doesn't mean impossible, and ``less likely'' means there is  
659 still a threat.

660 Mr. {Murphy.} Let me go on to this. Dr. Merlin, if you  
661 could turn to tab 48 of that booklet, and I will note while  
662 you are looking at that, in a May 23, 2012, email, you wrote,  
663 and I will quote it here, ``The Material Threat Assessment,  
664 or MTA, which DHS is required to perform by statute, these  
665 drive the downstream decisions about medical countermeasure  
666 acquisition, diagnostic test development, BioWatch testing

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

667 and preparedness plans. But the MTAs seem to be developed  
668 without input from people who really understand the agents,  
669 the diseases or practical implications of these decisions.''  
670 Do you still have these concerns about CDC having input in  
671 DHS threat assessment, sir?

672 Dr. {Merlin.} Mr. Chairman, the answer is no. My  
673 concerns have been diminished. The Department of Homeland  
674 Security has been working with the Department of Health and  
675 Human Services to have a more inclusive process for  
676 developing the Material Threat Assessments, and this process  
677 is designed to address some of the concerns I addressed so  
678 that experts from Health and Human Services are more actively  
679 engaged in developing the Material Threat Assessments and  
680 Material Threat Determination.

681 Mr. {Murphy.} Let me try to understand. So you are  
682 saying that you don't agree with that statement anymore or  
683 you do agree with that statement?

684 Dr. {Merlin.} I believe steps have been taken to  
685 address my concerns. I believe what I said was true, and the  
686 existing Material Threat Assessments were performed by the  
687 Department of Homeland Security without the desired level of

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

688 consultation with individuals from Department of Health and  
689 Human Services who have more knowledge of the agents. I  
690 believe this has been corrected by DHS.

691 Mr. {Murphy.} Well, let me add a couple levels here  
692 and/or concerns. Dr. Merlin, isn't it true that more than  
693 46,000 State and local health departments have lost since  
694 2008 representing nearly 21 percent of the total State and  
695 local health department workforce?

696 Dr. {Merlin.} Yes, that is my understanding.

697 Mr. {Murphy.} And Dr. Merlin, if you go to tab 34, this  
698 document is a presentation to the CDC Director on the  
699 quarterly performance review of NCEZID May 25, 2011. Is this  
700 your presentation?

701 Dr. {Merlin.} Yes, it is.

702 Mr. {Murphy.} And according to this internal CDC  
703 document, CDC has concerns about Gen-3 because of potential  
704 workload impact on LRN, or the Laboratory Response Network,  
705 from increased number of devices that are continuously  
706 sampling and reporting. Do you agree that there would be  
707 concerns about Gen-3 from the potential workload impact on  
708 the LRN?

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

709 Dr. {Merlin.} Yes.

710 Mr. {Murphy.} Well, I see I am out of time. I may have  
711 to come back to some of these, but I will turn to my ranking  
712 member, Ms. DeGette, for 5 minutes.

713 Ms. {DeGette.} Thank you very much, Mr. Chairman.

714 Well, let us keep talking about this Gen-3 for a while.

715 As I noted in my opening statement, what we were told  
716 was this Gen-3 was supposed to provide automated biological  
717 threat detections so it would be sort of like a lab in the  
718 box, and there have been a number of issues around that. So  
719 I am wondering, Dr. Walter, first, can you describe briefly  
720 for us exactly what is BioWatch Generation 3?

721 Mr. {Walter.} Yes, ma'am. I would be happy to do that.  
722 If you look at the parts that make up the BioWatch program--  
723 filter collection, laboratory analysis and reporting out the  
724 results--and you were to take all of those pieces and put  
725 them into a machine, that is what Generation-3, the  
726 acquisition program, Generation-3, is to do.

727 Ms. {DeGette.} And how does that differ from the  
728 existing technology?

729 Mr. {Walter.} The existing technology is very labor-

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

730 intensive. Somebody has to go and collect the filter,  
731 somebody has to bring it to the laboratory, somebody has to  
732 analyze the filter, and somebody has to make a phone call  
733 with the result. What Generation-3 would do essentially  
734 would automate all of that.

735 Ms. {DeGette.} Right. So it would take the sample and  
736 it would do the test, and then if there was some abnormality,  
737 then they would notify the folks and then they would come in,  
738 right?

739 Mr. {Walter.} That is correct, if it identified a  
740 detection, essentially it creates a BAR. The other thing  
741 that Generation-3 does, would also do, is it continuously  
742 collects and analyzes, whereas now we have got one sample--

743 Ms. {DeGette.} You don't have to go in and collect it?

744 Mr. {Walter.} Right.

745 Ms. {DeGette.} Right. So how much do you think it will  
746 cost to implement Generation-3?

747 Mr. {Walter.} I currently don't know because the  
748 acquisition program has been on hold, and that would depend  
749 on what technologies are eventually selected for deployment.

750 Ms. {DeGette.} Well, before it was on hold, did you get

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

751 any kind of bids for it, any estimates?

752 Mr. {Walter.} We had a lifecycle cost estimate that was  
753 done as part of the acquisition process.

754 Ms. {DeGette.} And what did that show?

755 Mr. {Walter.} That showed a 20-year lifecycle of \$5.8  
756 billion, and the lifecycle cost estimate number goes from  
757 initial testing all the way through disposal.

758 Ms. {DeGette.} Of the 20 years?

759 Mr. {Walter.} Yes, ma'am.

760 Ms. {DeGette.} Now, the benefits of a system like this  
761 are obvious from your description but do you think that it  
762 would be worth the cost, given the fact that we haven't  
763 really found any--I mean, I agree, we need to have systems in  
764 place but given the fact over 10 years we haven't really had  
765 any large-scale bioterrorism, do you think it is worth the  
766 cost?

767 Mr. {Walter.} I think it is. I think the advantages  
768 that we would gain from such a system would make the cost  
769 worthwhile. I think the increased flexibility that we would  
770 get from such a system would make the cost worthwhile. I  
771 think the ability to take the system indoors would make the

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

772 cost worthwhile. And I believe that it would actually reduce  
773 the workload on State and local public health laboratories  
774 because currently we get a sample every day. With that  
775 system, we would only get a sample if something is seen.

776 Ms. {DeGette.} So it might be really cost-effective  
777 over the long run even though there would be a big initial  
778 investment?

779 Mr. {Walter.} Yes, ma'am.

780 Ms. {DeGette.} Now, you mentioned that the program has  
781 been stopped for now. Why, and how did we get to that point?

782 Mr. {Walter.} There was a Government Accountability  
783 Office review of the acquisition methods used as part of the  
784 acquisition program, and what they found was essential the  
785 Gen-3 acquisition program straddled the implementation of MD-  
786 102, which is, I believe, the acquisition directive that  
787 garners how the Department does its acquisitions. When  
788 BioWatch Gen-3, the acquisition program, was started, they  
789 weren't being deployed or they were just being implemented,  
790 so we kind of started in the middle, if you will, and when  
791 the GAO came in and did its assessment, they said well, you  
792 followed the acquisition processes that were in place at the

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

793 time but really it is a big program, you probably want to be  
794 careful and go back and kind of dot the i's and cross the  
795 t's.

796 Ms. {DeGette.} Are you going back and dotting the i's  
797 and crossing the t's? What steps are you taking now to  
798 evaluate and develop Gen-3 in a way that will not just  
799 satisfy the GAO but will also satisfy the budget hawks on  
800 this committee?

801 Mr. {Walter.} We have instituted an analysis of  
802 alternatives. That is being conducted independently of the  
803 Department. We have rewritten the mission needs statement  
804 and we have formulated what we call an acquisition con ops,  
805 which is part of the formal acquisition process, which  
806 essentially says if you had this technology, how would you  
807 use it.

808 Ms. {DeGette.} And what kind of a timeline are you on?

809 Mr. {Walter.} We are expecting the final briefing for  
810 the analysis of alternatives in the August-September time  
811 frame with a final report in September-October.

812 Ms. {DeGette.} Super. Mr. Chairman, I would suggest we  
813 bring these folks back to talk to us about that timeline and

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

814 see what they have looked at, see if they have looked at the  
815 alternatives, and see if they are planning to go forward with  
816 Gen-3. I yield back.

817 Mr. {Murphy.} Thank you. I now recognize Dr. Burgess  
818 of Texas for 5 minutes.

819 Dr. {Burgess.} Thank you, Mr. Chairman.

820 Dr. Merlin, let me just start out by thanking you and  
821 your organization. The CDC has unfailingly been helpful on  
822 not just this issue but any time there has been an issue that  
823 has affected the public health and welfare of the United  
824 States, and your director, Dr. Frieden, has of course come to  
825 this committee and discussed with us the nature of novel flu,  
826 called me personally when West Nile virus was a problem in  
827 north Texas, and then the fungal meningitis outbreak  
828 occurred, CDC was in fact the only federal agency that would  
829 talk to me and answer the telephone, so I thank you for that.  
830 It is good to know that you are there and on the job.

831 Dr. Walter, let me just ask you, you referenced  
832 something called the BioWatch Actionable Result and the role  
833 of the DHS. Could you kind of define for us what constitutes  
834 a BioWatch Actionable Result?

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

835           Mr. {Walter.} That is an excellent question, sir. A  
836 BioWatch Actionable Result is an analytical result, a  
837 laboratory result, and what we do is, we conduct--we don't  
838 look for the actual bacteria, we actually look for the DNA of  
839 the bacteria and we look for very specific pieces of DNA that  
840 we do a two-step process. The first essentially is kind of a  
841 screen. We look for signs of the agent, and if it shows up,  
842 then we run additional--look for additional pieces of DNA  
843 using the Laboratory Response Network agents or reagents that  
844 we get from the CDC. And then--

845           Dr. {Burgess.} So you do some confirmational activity?

846           Mr. {Walter.} Oh, absolutely, sir.

847           Dr. {Burgess.} Now, just from that, you can't confirm  
848 or deny that a terrorist attack has taken place, correct?

849           Mr. {Walter.} No, sir, and that is never the purpose of  
850 the BAR. The BAR is simply the detection of the DNA from the  
851 agent.

852           Dr. {Burgess.} And will it show whether or not people  
853 have actually been exposed or it just detects the presence of  
854 the sentinel DNA in the environment?

855           Mr. {Walter.} It just detects the DNA, and we have

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

856 modeling that we can look at to go back and look at where  
857 would this plume have gone. But the assessment as far as  
858 whether there is a threat to the public health, whether this  
859 is a terrorism attack or whether this is something that  
860 naturally exists in the environment is made following the  
861 BAR, and that is during the national conference call which  
862 brings a host of agencies together including the CDC that  
863 essentially discusses what the context of this detection is.

864 Dr. {Burgess.} So I guess that leads to my next  
865 question. What process is then put in place? Poor Dr.  
866 Merlin is sitting there at the CDC. You give him this  
867 information that oh, my gosh, we have got a real problem  
868 here, so Dr. Merlin is then looped in through a conference  
869 call? Is that what--

870 Mr. {Walter.} That is correct. Dr. Merlin or his  
871 designee is part of the conference call, and that discussion  
872 is, what do we have, where was it found, have we ever seen it  
873 before, is there a lot of it, is there a little of it. It  
874 includes the FBI and local and State and federal law  
875 enforcement and emergency responders.

876 Dr. {Burgess.} Now, you referenced in your testimony

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

877 the preventive measures that might be instituted. At what  
878 juncture at those triggered? You referenced the prophylaxis  
879 that might need to be administered. Where does that come in?

880 Mr. {Walter.} That would take place after this national  
881 conference call if the decision is made that we think this is  
882 a bioterrorism attack and/or there is a threat to the public  
883 health because they don't necessarily have to be linked.

884 Dr. {Burgess.} Then Dr. Merlin, when at the CDC level,  
885 I mean, you referenced the Laboratory Research Networks. Is  
886 this what you do to confirm or to gain additional knowledge  
887 about the information that you are given from DHS? Because  
888 at some point you have got to tell the doctors yes or no. I  
889 mean, DHS can't tell the doctors to prescribe something. You  
890 all have to play a role. Is that correct?

891 Dr. {Merlin.} Yes. We work with DHS and the local  
892 jurisdiction that has made the detection as well as other  
893 federal agencies to try to gather as much additional  
894 information as possible to determine whether the BAR  
895 represents an anomaly or a threat, and the sorts of things we  
896 will do is, we will ask the local jurisdiction to do  
897 additional testing on the sample that they have. We may ask

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

898 them to go out and perform environmental sampling in the area  
899 where the detector was located. We will query intelligence  
900 agencies to find out whether there is any indication that  
901 there might be a threat with this agent. We will ask  
902 subject-matter experts in the field if there are other things  
903 they think might be causing this positive, and we will try to  
904 quickly gather the information we need to sort of make an  
905 informed decision.

906 Dr. {Burgess.} Very good. In my opening statement, I  
907 referenced the data that was generated back in the early  
908 1950s. No one want to see that type of testing go on again  
909 but I think it does--the lesson from that is, there is a  
910 vulnerability here from a biologic agent, and certainly the  
911 work--we want you to get it right, and I was called a budget  
912 hawk a minute ago. Yeah, I am guilty as charged but at the  
913 same time, the primary role, my role defined in the  
914 Constitution is the defense of my Nation. I want you all to  
915 get it right. It is critically important that you do, and I  
916 agree with Ranking Member DeGette that we will need to hear  
917 from you again in the fall. So thank you.

918 Mr. {Murphy.} Thank you. The gentleman's time is

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

919 expired. We will now go to the gentleman from New York, Mr.  
920 Tonko, for 5 minutes. You are recognized.

921 Mr. {Tonko.} Thank you, Mr. Chair.

922 The whole issue of relationship between DHS and CDC and  
923 local public health partners is critical because the BioWatch  
924 program depends on local officials in order to execute many  
925 of these programs. In the very early days of BioWatch, as  
926 has been discussed, the relationship between federal agencies  
927 and local public health partners did not work as well as it  
928 should. Dr. Merlin, what would you cite as examples of  
929 improved communications amongst DHS, CDC and local officials  
930 over recent years?

931 Dr. {Merlin.} There are several things. I think DHS  
932 has made a concerted effort to include public health  
933 officials and public health responders in their national  
934 BioWatch meetings. They hold regular webinars that I believe  
935 are monthly for all stakeholders including public health, and  
936 whenever they have working groups, they reach out to public  
937 health participants, and I am impressed they reach out to  
938 public health participants including those whom they know are  
939 not their fans. So they try to have those voices at the

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

940 table. There is an IOM meeting scheduled, Institute of  
941 Medicine meeting scheduled next week to go over some BioWatch  
942 questions, and I notice there is a panel with a diverse range  
943 of public health officials on it. So I do think they  
944 actively reach out to include public health.

945 Mr. {Tonko.} And Dr. Walter, in terms of the overview  
946 of DHS's communication efforts with local public health  
947 officials, can you give us a sense of how that collaboration  
948 has been improved on a day-to-day basis?

949 Mr. {Walter.} I believe that it has improved in our  
950 routine communications because it does take place on a day-  
951 to-day basis. We spend a lot of time talking to our State  
952 and local partners, and it has been my business since coming  
953 into the program in 2009 to arrange the relationship that we  
954 have with our State and local public health community as  
955 partners in this program. I don't command the BioWatch  
956 program and they are not a subordinate command. We work in  
957 partnership with them. We have done our utmost to include  
958 them in all of the testing and evaluation that we have  
959 conducted so far in the acquisition program, the Gen-3  
960 acquisition. We hold focus groups because we have noticed

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

961 that when we get a large group of them on the phone, they  
962 don't say a lot, but when we bring them into a small room  
963 with a select group, they are very opinionated and there is a  
964 wealth of expertise that we can tap into there. We have  
965 brought their laboratories into the program. Prior to my  
966 coming into the program, there was--if technology  
967 improvements were put in, they were done at a national lab  
968 and handed to the State and local labs. Now we work with the  
969 laboratories themselves to bring those in. So we have done  
970 our utmost to make sure that they are part of the program and  
971 that communication is there.

972 Mr. {Tonko.} Thank you very much.

973 Last July, I believe it was, the President released a  
974 National Strategy for Biosurveillance, which outlined guiding  
975 principles for strengthening our capabilities, and it called  
976 for focusing on core functions, increasing integration and  
977 improving information sharing. To each of you, my question  
978 would be, how does BioWatch fit into the Nation's larger  
979 biosurveillance strategy?

980 Mr. {Walter.} BioWatch complements the national  
981 strategy. There is nothing about environmental surveillance

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

982 that precludes doing any other surveillance. BioWatch, I  
983 believe, complements medical surveillance, it complements  
984 syndromic surveillance, it complements point-of-care  
985 diagnostics, and it also provides the early detection that we  
986 would need because the downside of medical surveillance is,  
987 people have to get sick for us to be able to detect them  
988 using those methods. BioWatch provides us the opportunity to  
989 detect them before they show symptoms so that we get  
990 medicines to them before they are sick and start to overwhelm  
991 the public health infrastructure, integration as far as the  
992 exercising, but the big part of what we do too is the  
993 planning and preparedness side, and we know we are not going  
994 to be able to--or it is going to be very difficult to respond  
995 to a bioterrorism event on the fly. All of that has to be  
996 worked out in advance, and a big part of what the program  
997 does is work with our State and local jurisdictions to get  
998 them prepared, provide them exercises so we know their plans  
999 make sense.

1000 Mr. {Tonko.} Dr. Merlin, would you add to any of that?

1001 Dr. {Merlin.} Yes. I basically agree with Dr. Walter.

1002 When you look at the biosurveillance strategy, it addresses

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1003 the spectrum of biological threats to the American  
1004 population, and the threats can range from small threats that  
1005 threaten a small number of people to very large threats. The  
1006 BioWatch system addresses really the very far end of the  
1007 threat spectrum. It addresses the catastrophic aerosol  
1008 released, the sort of thing that would be really sort of an  
1009 act of war, a nation-state type of action. And that is part  
1010 of the threat spectrum that needs to be addressed. There are  
1011 of course other things in there, and much smaller attacks  
1012 like the anthrax letters of 2001, which were a much smaller  
1013 attack, are a high risk and also need to be addressed in our  
1014 strategy.

1015 Mr. {Tonko.} Thank you very much. Mr. Chair, I yield  
1016 back.

1017 Mr. {Murphy.} Thank you. We will now go to the  
1018 gentleman from Louisiana, Mr. Scalise. You are recognized  
1019 for 5 minutes.

1020 Mr. {Scalise.} Thank you, Mr. Chairman. I appreciate  
1021 you having this hearing. Thank you to our panelists.

1022 I want to really get into the BioWatch program, Mr.  
1023 Walter. It is my understanding from the reports I have read

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1024 that somewhere in the neighborhood of a billion taxpayer  
1025 dollars has been spent on developing BioWatch since it  
1026 started in, I think, 2003. Is that correct?

1027 Mr. {Walter.} I think a little less than a billion  
1028 dollars has been invested in running the BioWatch program,  
1029 not developing it.

1030 Mr. {Scalise.} How much total between both developing  
1031 and running?

1032 Mr. {Walter.} Oh, I don't think a lot was put into  
1033 developing it because the technologies that we use are  
1034 developed technologies. So--

1035 Mr. {Scalise.} Developed by whom, and how much money?  
1036 Who gets the money? Where does that money come from?

1037 Mr. {Walter.} Most of the technologies we use were  
1038 developed by the Department of Defense, the Centers for  
1039 Disease Control and Prevention, the technical aspects. We  
1040 are an operational program. We don't conduct research and  
1041 development. I take what is available to accomplish the  
1042 mission and use that. So most of the funding that--

1043 Mr. {Scalise.} When I read that the Department of  
1044 Homeland Security spent about \$300 million developing this

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1045 technology, you just said you don't develop technology.

1046 Mr. {Walter.} The BioWatch program doesn't develop it.

1047 A lot of that developmental work was done by the Science and

1048 Technology Group, which does do research and development and

1049 does develop.

1050 Mr. {Scalise.} So for a billion dollars, whether some

1051 of it was spent by the Department of Defense, I am sure you

1052 all coordinate because ultimately you are implementing it,

1053 the bottom line is, it hasn't worked yet. At least it hasn't

1054 worked the way it was supposed to. Is that accurate?

1055 Mr. {Walter.} I would respectfully disagree with that,

1056 sir. I think everything that we have shows that the process

1057 does work. We have instituted an extremely robust quality

1058 assurance program that tracks the ability of our laboratories

1059 to detect any agent that may be on a filter.

1060 Mr. {Scalise.} Do you get a lot of false positive

1061 tests?

1062 Mr. {Walter.} No, sir. What we get--what we have--what

1063 we detect are naturally occurring agents. All of the agents

1064 that we look for are naturally occurring somewhere in the

1065 environment. Most of them are out there endemic, and it

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1066 stands to reason that we will occasionally detect one or two  
1067 of them.

1068 Mr. {Scalise.} So I am looking at this report again.  
1069 It says Department of Homeland Security spent about \$300  
1070 million developing this technology as well as on Gen-2.5,  
1071 which was deployed for 2 years and then pulled. Was it  
1072 pulled because it was working so well or was it pulled  
1073 because it wasn't working?

1074 Mr. {Walter.} That was before my time, sir.

1075 Mr. {Scalise.} Are you familiar with what the status is  
1076 and why it was pulled?

1077 Mr. {Walter.} Everything I got was secondhand. My  
1078 understanding, and this is just my understanding, was that it  
1079 was pulled because it was expensive, it was pulled because of  
1080 preparation for the acquisition program, the Gen-3 program.

1081 Mr. {Scalise.} Do you know how much we have spent on  
1082 it?

1083 Mr. {Walter.} I do not, sir. I am sorry.

1084 Mr. {Scalise.} If you could get the committee that  
1085 information?

1086 Mr. {Walter.} Sure thing, sir.

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1087           Mr. {Scalise.} I wanted to ask you about the internal  
1088 investigation. It is our understanding that there has been  
1089 an internal investigation into BioWatch. First of all, are  
1090 you familiar? Did you all do an internal--maybe before you  
1091 were there, but I mean, are you aware of an internal  
1092 investigation?

1093           Mr. {Walter.} I am not aware of an internal  
1094 investigation into BioWatch itself.

1095           Mr. {Scalise.} Or an employee at BioWatch that may have  
1096 been removed for mismanagement?

1097           Mr. {Walter.} It may have been but that is before my  
1098 time, sir, and I can't comment on that.

1099           Mr. {Scalise.} Okay, but I mean, you are there now, you  
1100 are heading this up. We are trying to get more details.  
1101 Again, a lot of taxpayer money is involved in this. If there  
1102 was mismanagement by an employee, by many employees, if  
1103 someone was removed and maybe somebody that was removed is  
1104 now back working on the program, we are hearing about all  
1105 this secondhand but supposedly there is an internal  
1106 investigation that was done and some documentation about this  
1107 that we don't have. I think it is real important that this

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1108 committee get that information. Can you, number one, go and  
1109 find out if there was an investigation done by your agency,  
1110 and if so, can we get a copy of that information?

1111 Mr. {Walter.} I am aware of an investigation that was  
1112 undertaken. I don't know really the details of why it was  
1113 undertaken.

1114 Mr. {Scalise.} Can you at least assure us that you will  
1115 get us a copy of that investigation?

1116 Mr. {Walter.} I give you my word, I will try, sir.

1117 Mr. {Scalise.} Why would you not be able to get it to  
1118 us?

1119 Mr. {Walter.} I don't know.

1120 Mr. {Scalise.} If you tried, it would happen, so I am  
1121 just asking if you can make it happen.

1122 Mr. {Walter.} I will make it happen, sir.

1123 Mr. {Scalise.} I appreciate that very much because, I  
1124 mean, when we are hearing about all this and we are hearing  
1125 that maybe there was an employee involved in mismanagement  
1126 and that the employee was maybe removed but now the employee  
1127 is back over there, I mean, that raises a lot of questions  
1128 that we have about the program.

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1129           Mr. {Walter.} I can tell you that no one currently on  
1130 the BioWatch program was removed and then brought back into  
1131 the program.

1132           Mr. {Scalise.} So as long as you are going to get us  
1133 that information, that will at least help answer a lot of  
1134 these questions. We shouldn't have to wonder and speculate  
1135 about it if you have got an investigation somewhere in your  
1136 agency, you can get that to us and then that will remove the  
1137 cloud of speculation and we will know exactly what is going  
1138 on to be able to proceed from there. So I appreciate that,  
1139 and I thank the chairman for his discretion and yield back  
1140 the balance of my time.

1141           Mr. {Murphy.} The gentleman yields back. We will now  
1142 go to the gentleman from North Carolina, Mr. Butterfield.

1143           Mr. {Butterfield.} Thank you very much, Mr. Chairman,  
1144 and let me thank both of the witnesses for their testimony  
1145 today.

1146           Mr. Chairman, I always begin whenever I can asking  
1147 witnesses questions about the impact of sequestration is  
1148 having on their agency because so many of our constituents  
1149 really don't fully understand the full impact that

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1150 sequestration is having on the functions of government, and  
1151 so let me just start with sequestration and start with you,  
1152 Dr. Walter. It is my understanding that many DHS programs  
1153 are exempt from the impact of sequester but certain programs  
1154 related to the implementation of the BioWatch program may be  
1155 impacted. What impact has sequester had on DHS programs  
1156 related to the BioWatch program?

1157 Mr. {Walter.} The BioWatch program was not exempt from  
1158 sequestration. It has decreased our contact with our State  
1159 and local jurisdictions in that our travel budgets have been  
1160 reduced. It has decreased our ability to bring State and  
1161 local public health and emergency responders in for focus  
1162 groups and discussions with them. And it has decreased our  
1163 ability to carry out certain improvements to the program that  
1164 we had planned.

1165 Mr. {Butterfield.} Can you quantify this by percentage?  
1166 Is it 8 percent, 6 percent?

1167 Mr. {Walter.} We are looking at around--I think we are  
1168 looking at around 5 to 10 percent, in that range.

1169 Mr. {Butterfield.} And you do realize that unless  
1170 sequestration is reversed or repealed, this is a 10-year

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1171 proposition? It is not a 1-year deal.

1172 Mr. {Walter.} I understand.

1173 Mr. {Butterfield.} And does it have long-range

1174 implications for the program?

1175 Mr. {Walter.} Yes, sir, it does. As we move over time,

1176 obviously we have contracts that have inflation clauses built

1177 in that we will have to cover, and we will basically have to

1178 pare the program down to doing just the basics of what we

1179 need to do and not improve the program as we would like to.

1180 Mr. {Butterfield.} And I understand the GAO has made

1181 some recommendations to you that you would like to implement

1182 that this may impact. Has the GAO made any recommendations?

1183 Mr. {Walter.} Not that I am aware of, not relative to

1184 sequestration that I am aware of, sir.

1185 Mr. {Butterfield.} I mean to the actual programmatic

1186 part of your work.

1187 Mr. {Walter.} They have done that, and we have

1188 implemented them. This primarily was geared towards the

1189 acquisition program, the so-called Gen-3 program, and we have

1190 implemented those recommendations.

1191 Mr. {Butterfield.} And Dr. Merlin, can you speak to it

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1192 from the CDC aspect?

1193 Dr. {Merlin.} Yes, Congressman. I can tell you about  
1194 the immediate impacts it has on the work in my division. We  
1195 have decreased the number of proficiency testing challenges  
1196 that we provide to the members of our Laboratory Response  
1197 Network because those are--each one has a cost associated  
1198 with it. We have also had to decrease the amount of reagents  
1199 that we keep for surge, a potential surge in demand in  
1200 reagents that we would need in a large-scale event, and in  
1201 terms of the funding that we provide to State and local  
1202 health departments through my division and other parts of CDC  
1203 that contribute to the ability of those health departments to  
1204 respond to outbreaks in bioterrorism, the amount of money has  
1205 gone down. It has gone down through our budget constraints  
1206 because most of the money that CDC receives goes out to State  
1207 and locals. The response of the cut to us passed on to State  
1208 and locals.

1209 Mr. {Butterfield.} Are we talking between 5 and 10  
1210 percent as DHS has experienced?

1211 Dr. {Merlin.} For us, the number is around 5 percent.

1212 Mr. {Butterfield.} All right. Back to you, Dr. Walter.

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1213 Is it possible that newer and more efficient biosurveillance  
1214 technologies could reduce costs enough to enable the  
1215 expansion of the BioWatch program to new municipalities?

1216 Mr. {Walter.} Yes, sir, it is.

1217 Mr. {Butterfield.} And Dr. Merlin, the number of false  
1218 positive BAR results in 2013 has decreased to zero, and that  
1219 is probably good. Can you explain the CDC's role in  
1220 eliminating false positives and elaborate on the success of  
1221 the serial testing strategy?

1222 Dr. {Merlin.} We worked closely with Department of  
1223 Homeland Security to try to effectively reduce the number of  
1224 false positives that were being caused by an organism related  
1225 to one of the target organisms, Francisella tularensis, and  
1226 together we have implemented three changes in the testing  
1227 protocol that have caused a reduction in false positives.  
1228 One is that we reduced the number of cycles of reaction that  
1229 is used for detection. Another thing we have done is, we  
1230 have--DHS has actually implemented use of another reagent for  
1231 screening. They have used the Critical Reagents program  
1232 reagent rather than a CDC reagent for screening. And the  
1233 third thing and importantly--

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1234 Mr. {Butterfield.} I think the chairman is tapping on  
1235 the table there. Can you just give us the last sentence?

1236 Dr. {Merlin.} They have put in a test that  
1237 distinguishes this near neighbor from the target, which  
1238 enables us to say no, that is a near neighbor, and we know it  
1239 is not a target, and to not react to it.

1240 Mr. {Butterfield.} Thank you. Yield back.

1241 Mr. {Murphy.} The gentleman yields back. Now we will  
1242 recognize the gentleman from Texas, Mr. Olson, for 5 minutes.

1243 Mr. {Olson.} I thank the chair, and welcome to the  
1244 witnesses. Dr. Walter, Dr. Merlin, welcome. I am concerned  
1245 like we all are about an attack by a biological weapon. I am  
1246 a Member of Congress from Houston, Texas, about to be the  
1247 third largest city in America. There is no better target for  
1248 biological attack than Houston, Texas. We are the largest  
1249 foreign tonnage port in America lined by the largest  
1250 petrochemical complex in the world. We have the largest  
1251 medical center, the Texas Medical Center, just south of  
1252 downtown. There is no better target for biological attack by  
1253 terrorists either with conventional bombs, sort of dirty  
1254 nuclear weapon, chemical weapons or a biological weapon, and

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1255 the scariest of these may be a biological attack. Say let us  
1256 go to the Texas Medical Center and launch that weapon in the  
1257 air conditioning system and disappear, long gone before  
1258 anybody realizes that you have been attacked. The biological  
1259 weapon flows through the air conditioning system all over the  
1260 Texas Medical Center. Within hours, days, weeks, people are  
1261 becoming infected, and that is a big problem. Most  
1262 importantly, it is not just people being infected but the  
1263 people that are infected are the professionals that are  
1264 needed to recover from this attack.

1265         And so one other point for my colleagues: If you want  
1266 to lose some sleep, come down to Galveston, Texas, to the  
1267 Galveston National Laboratory on the campus of the University  
1268 of Texas medical branch. It is one of two bio 4 labs in  
1269 America, a very, very secure place with all sorts of very  
1270 dangerous chemical and biological weapons, mostly biological.  
1271 I have been down there on a tour. I put on this pressure  
1272 suit, negative pressure, went through a couple of locked  
1273 doors and watched these men and women working on agents that  
1274 if they got out in this room right now, many of us would not  
1275 walk out of here alive within minutes. So this is a very,

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1276 very scary proposition, and we need--it is so important that  
1277 we spend our limited resources on products that work. I am  
1278 concerned about Gen-2, more importantly, Gen-3.

1279           And my first question is for you, Dr. Walter. Is there  
1280 a concern that the BioWatch program doesn't fully understand  
1281 how the current generation Gen-2 works, that these concerns  
1282 are real? How we can be confident that Gen-3 will work?

1283           Mr. {Walter.} No, we are very confident in the way the  
1284 Generation-2 system works, sir. We track our performance  
1285 under our laboratory analysis. We know what we can detect at  
1286 what concentrations and with what statistical confidence. We  
1287 have recently actually just completed another test of our  
1288 collection and analysis operations out at Dugway, Utah, where  
1289 we looked at what is the minimum number of bacteria we could  
1290 collect in the atmosphere using chambers, of course, and then  
1291 how would we--how does that number translate through our  
1292 analysis. So we have a very good understanding of what our  
1293 technology is capable of doing.

1294           Mr. {Olson.} And you mentioned Dugway, sir. The  
1295 analysis on alternative testing done by this fall includes a  
1296 cost-benefit comparison between Gen-2 and Gen-3 but DHS won't

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1297 have the data from Dugway until sometime in the fall of this  
1298 year so you are bringing up online before you actually have  
1299 the data.

1300 Mr. {Walter.} No, the data that will be produced from  
1301 Dugway will be the technical performance of the technology.  
1302 That will be done in the July-August time frame. We expect  
1303 the analysis of alternatives that is going to include the  
1304 Gen-2 system to be done about the same time, and any  
1305 information that the performer for the AOA is requesting, we  
1306 are making sure that they get it as quickly as we can get it  
1307 to them.

1308 Mr. {Olson.} Dr. Merlin, how about your concerns about  
1309 Gen-3?

1310 Dr. {Merlin.} Congressman, my concerns about Gen-3 have  
1311 primarily to do with lack of information about the  
1312 performance of the assays, and Dr. Walter and I have had and  
1313 his staff have had exchanges about a number of concerns that  
1314 my colleagues at CDC had about particular technical aspects  
1315 of what was in the phase I of Gen-3, and we are just  
1316 concerned that the technology be right and that we know what  
1317 the limits of detection are likely to be and that we know

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1318 what the limits of detection are going to be in a performing  
1319 area. So my concerns are basically about the availability of  
1320 data on the performance and an appropriate review of the data  
1321 on the performance.

1322 Mr. {Olson.} I share those concerns. I am out of time.  
1323 I yield back.

1324 Mr. {Murphy.} I thank the gentleman from Texas. Now to  
1325 the other gentleman from Texas, Mr. Green, for 5 minutes.

1326 Mr. {Green.} Thank you, Mr. Chairman, and again, I  
1327 thank our witnesses for being here. I also have a district  
1328 just north of Galveston, and I have been to the bio lab. I  
1329 was impressed in watching it being built, and in 2008 when  
1330 Hurricane Ike literally went over that area, that was the one  
1331 building at the University of Texas Medical Branch that was  
1332 not damaged, and there was no issue because we have learned  
1333 in Texas, you don't put your generating equipment on the  
1334 bottom floor when you have four or five foot of water. So  
1335 you put it on top.

1336 But again, I am pleased that we are taking the time to  
1337 examine BioWatch because of how importance it is. Last  
1338 Congress, I worked with colleagues on this committee on the

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1339 legislation, the Pandemic and All Hazards Preparedness Act.  
1340 We worked together to make sure the relevant agencies had the  
1341 tools to identify threats including those originating from  
1342 terrorists and address those threats effectively, and I know  
1343 at the bio lab, as my colleague and my neighbor talked about,  
1344 the National Lab there in Galveston, does tests and working  
1345 on developing vaccines for SARS, West Nile encephalitis,  
1346 avian flu, influenza as well as microbes that are being  
1347 deployed by terrorists. That topic is important to me.

1348         The relationship between DHS, CDC and local public  
1349 health partners is critical because BioWatch programs depend  
1350 on our local officials. They execute many of the program's  
1351 most important functions. But in the early days of BioWatch,  
1352 the relationship between federal agencies and local public  
1353 health partners did not work as well as it should have.

1354         Dr. Merlin, have communications between DHS, CDC and  
1355 local officials improved in the last few years?

1356         Dr. {Merlin.} Congressman, I have been with this  
1357 program at CDC for 2 years, and I personally think there has  
1358 been substantial improvement in the communications. I  
1359 believe that we now regularly have very candid discussions

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1360 about concerns from local public health and that we have very  
1361 candid discussions about concerns that my colleagues at CDC  
1362 have about technical aspects of the BioWatch assays. I  
1363 admire the fact that Dr. Walter includes, as I mentioned  
1364 earlier, includes people in these discussions that he knows  
1365 are critical to the program, and I think that is a good  
1366 thing.

1367 Mr. {Green.} Do local public health labs have proper  
1368 federal guidance on what to do in the event of what appears  
1369 to be initial positive test result known as a BioWatch  
1370 Actionable Result?

1371 Dr. {Merlin.} Congressman, I think the answer to that  
1372 is both a yes and a no. The BioWatch program recently  
1373 released a new version of its outdoor guidance, which is  
1374 guidance to the BioWatch jurisdictions on how to respond to  
1375 an outdoor release. There is--and Dr. Walter is aware of  
1376 this, there is no indoor guidance, which means that there is  
1377 no formal guidance on how jurisdictions should respond to an  
1378 indoor release, and I know the program is working on that.

1379 There are also a number of important issues related to  
1380 environmental sampling and how to conduct the appropriate

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1381 environmental sampling that had been worked on collaborative  
1382 by DHS and EPA and CDC for a number of years but there is no  
1383 formal guidance out there that I think the locals really  
1384 need.

1385       Mr. {Green.} I only have another minute. Obviously the  
1386 partnership between the CDC and locals is very important. In  
1387 fact, just as we came up, welcome to the Gulf Coast in  
1388 summer, we have some our mosquitoes that have been tested and  
1389 found to have West Nile encephalitis, not in the Galveston  
1390 area but further north, and so this is important. And I know  
1391 from your testimony you have had to cut back some of your  
1392 public health meetings with local officials because of the  
1393 budget constraints but I know you also do conference calls.  
1394 Have you all increased that since you can't do the physical  
1395 presence?

1396       Mr. {Walter.} That is correct, sir. We have increased  
1397 our conference calls. We have started a webinar series. And  
1398 we are doing our best to keep our communications open. We  
1399 also have a number of liaisons, we call them jurisdictional  
1400 coordinators, who are in all of our BioWatch jurisdictions  
1401 who also serve to keep us informed and keep the program and

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1402 our State and locals informed as to what is happening.

1403 Mr. {Green.} And again, from a military perspective,  
1404 the troops on the ground are those public health agencies, so  
1405 obviously the more we can relate from what we do here and CDC  
1406 and what you all do. Thank you.

1407 Mr. {Murphy.} The gentleman's time is expired. Now we  
1408 will go to the gentleman from Ohio, Mr. Johnson, for 5  
1409 minutes.

1410 Mr. {Johnson.} Thank you, Mr. Chairman.

1411 Dr. Walter, I will try to look around you here and still  
1412 get to my microphone. According to the information provided  
1413 by DHS, there have been 149 BioWatch Actionable Results, or  
1414 BARs, since the BioWatch program started in 2003. is that  
1415 correct?

1416 Mr. {Walter.} That is correct, sir.

1417 Mr. {Johnson.} And these BARs represent naturally  
1418 occurring biological pathogens detected from environmental  
1419 sources. Is that correct?

1420 Mr. {Walter.} Yes, sir.

1421 Mr. {Johnson.} In a July 12, 2012, DHS blog posting,  
1422 DHS Assistant Secretary for Health Affairs, Alexander Garza,

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1423 wrote this. He said, ``Out of these more than 7 million  
1424 tests, BioWatch has reported 37 instances in which naturally  
1425 occurring biological pathogens were detected from  
1426 environmental sources.'' Given the figure of 149 BARs  
1427 reported to the committee, the 37 instances was an incorrect  
1428 number. Is that correct?

1429 Mr. {Walter.} That is correct, sir.

1430 Mr. {Johnson.} Okay. Were you involved in writing the  
1431 blog posting for Dr. Garza?

1432 Mr. {Walter.} I reviewed it, and I missed that.

1433 Mr. {Johnson.} Okay. Were you the one that provided  
1434 him with those statistics?

1435 Mr. {Walter.} No, I don't know where those statistics  
1436 came from but I should have caught it, and I didn't.

1437 Mr. {Johnson.} As the BioWatch program manager, didn't  
1438 you know you had over 149 BARs by July 2012?

1439 Mr. {Walter.} Yes, sir.

1440 Mr. {Johnson.} You got any thoughts if you reviewed it,  
1441 how did we miss it? I mean, this is an important system.

1442 Mr. {Walter.} I missed that number in his blog. I am  
1443 very aware of the performance of the system, and I am very

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1444 aware of any issues that come up with the system that impact  
1445 its performance.

1446 Mr. {Johnson.} Did you provide the correct statistics--  
1447 or let me go back. When did you find the error? When did  
1448 you realize that there was an error?

1449 Mr. {Walter.} It was shortly after the blog was posted.

1450 Mr. {Johnson.} Did you provide the correct statistics  
1451 to Dr. Garza?

1452 Mr. {Walter.} Yes, sir, I did.

1453 Mr. {Johnson.} Do you know if they corrected the  
1454 record?

1455 Mr. {Walter.} I believe they did.

1456 Mr. {Johnson.} Dr. Merlin, would you please go to tab  
1457 36 in your material? In this June 24, 2011, email, you  
1458 discussed, and I quote, ``the squishy definition of a BAR.''  
1459 You go on to write, ``What is the action here? Who has made  
1460 the final determination of the action to take? What is that  
1461 determination? There seem to be different definitions of a  
1462 BAR according to the jurisdiction, e.g., New York City versus  
1463 Houston.' ' How do definitions differ between New York City  
1464 and Houston?

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1465 Dr. {Merlin.} Congressman, the primary source of the  
1466 problem, I believe, is use of the word ``actionable'' because  
1467 without defining specifically what actions are taken on the  
1468 basis of this, it leaves it to the mind of the jurisdiction  
1469 on to what the appropriate action is, and I personally  
1470 believe that we should do a better job of defining of what an  
1471 appropriate action is and based on concerns like this, the  
1472 Department of Homeland Security in this most recent outdoor  
1473 guidance has become much more specific about what they mean  
1474 by an action. In the absence of a definition of an action,  
1475 some jurisdictions may feel that this means that the area  
1476 where the BAR is detected should be cordoned off and  
1477 evacuated. Other jurisdictions may simply feel that it means  
1478 that they send in a team to do sampling, and I think because  
1479 we know technically what testing is being done, I think we  
1480 need to tell people what we think is appropriate.

1481 Mr. {Johnson.} Are there still different definitions of  
1482 BARs today based on your concerns about ``actionable''?

1483 Dr. {Merlin.} I will defer to Dr. Walter. He may know  
1484 better than I do. I think we have gotten closer with the  
1485 most recent outdoor guidance in terms of situational

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1486 assessment but I am sure that all of the BioWatch  
1487 jurisdiction committees are on the same page.

1488 Mr. {Johnson.} Mr. Chairman, I yield back.

1489 Mr. {Murphy.} The gentleman yields back, and now to the  
1490 ranking member of the full committee, Mr. Waxman, for 5  
1491 minutes.

1492 Mr. {Waxman.} Thank you, Mr. Chairman.

1493 Last October, the Los Angeles Times reported on the  
1494 failed deployment of BioWatch Generation 2.5, which was  
1495 supposed to provide interim automated detection capability  
1496 before the deployment of Generation 3. The technology  
1497 suffered from delays and issues related to scientific  
1498 validation and I would like to hear from our witnesses today  
1499 about how this happened and what steps have been taken to  
1500 ensure that it won't happen again. The Los Angeles Times  
1501 reported that the BioWatch program put new testing assays  
1502 called multiplex assays into use without adequately  
1503 validating them. According to the article, the tests were  
1504 used for 2 years from 2007 to 2009 before it became clear  
1505 that they were so insensitive to the presence of bioterror  
1506 agents that they were unsuitable for BioWatch.

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1507 Dr. Walter, I know these programs occurred before you  
1508 became the head of the BioWatch program. Still, I would like  
1509 to get your views on the allegations of the L.A. Times story.  
1510 Was the BioWatch program relying on inadequate tests for two  
1511 full years?

1512 Mr. {Walter.} I honestly can't answer that question. I  
1513 would like to think they are not, but what I can tell you is  
1514 that before we deploy assays now, we have a very robust  
1515 testing and evaluation process in place. We track the  
1516 performance of those assays on a daily basis. We conduct  
1517 proficiency tests of our laboratories periodically throughout  
1518 the year and we conduct independent audits of our  
1519 laboratories periodically throughout the year.

1520 Mr. {Waxman.} And what actions were taken when the  
1521 program officials discovered these problems?

1522 Mr. {Walter.} I believe the system was withdrawn but,  
1523 like I said, this is before my time and I really can't speak  
1524 to it.

1525 Mr. {Waxman.} Well, this is an important development,  
1526 and it is like being told that the salesperson that defrauded  
1527 you was no longer here and therefore you don't know anything

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1528 about it, but you are the head of the program and you ought  
1529 to know what happened not that long ago, 2007 to 2009. Well,  
1530 there was a problem. What corrective measures were taken to  
1531 ensure that something like this won't happen again?

1532 Mr. {Walter.} For the Gen-3 program, which is the  
1533 acquisition program, which is the technology that would be  
1534 deployed in place of the Gen-2.5, we have instituted a  
1535 multiple-phase process that has an enormous amount of testing  
1536 and evaluation attached to it. That testing and evaluation  
1537 is decided upon in a committee that includes our interagency  
1538 partners including the CDC. Those results are made available  
1539 to all of the members of that group, and nothing goes forward  
1540 unless it meets the requirements that we have set forward for  
1541 the deployment of this technology.

1542 Mr. {Waxman.} Can Americans have confidence now that  
1543 the tests used in the BioWatch programs are capable of  
1544 detecting a bioterror attack so public health officials can  
1545 act quickly?

1546 Mr. {Walter.} I believe they can, sir. We have done  
1547 our best to make that happen.

1548 Mr. {Waxman.} You have done your best to make sure that

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1549 doesn't happen but you don't know what happened in the past.

1550 Mr. {Walter.} I mean, I am hesitant to speculate on  
1551 what happened to the program before I was here. I understand  
1552 that the technology was deployed. My understanding was that  
1553 it was essentially initially thought to be kind of a pilot to  
1554 look at developing con ops. It was then actually deployed,  
1555 from what I understand, and then there were issues that  
1556 developed relative to some of the assays that were used. I  
1557 am sorry I don't have the details of that.

1558 Mr. {Waxman.} Well, the BioWatch program has been  
1559 plagued by technical and management problems, and I hope you  
1560 and your team have put these problems behind us so that the  
1561 program can move forward.

1562 Mr. {Walter.} We are doing our best.

1563 Mr. {Waxman.} Thank you. Mr. Chairman, I yield back my  
1564 time.

1565 Mr. {Murphy.} The gentleman yields back. Now to Mr.  
1566 Harper for 5 minutes.

1567 Mr. {Harper.} Thank you, Mr. Chairman, and thank you,  
1568 gentlemen, for being here, and Dr. Merlin, I know we have had  
1569 a lot of concerns obviously and work done on the State and

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1570 local level as they try to look through this, and I would ask  
1571 if you would go to tab 35 in your notebook there. In a May  
1572 26, 2011, email, CDC scientist Michael Farrell wrote this in  
1573 part in that email that you are looking at: ``Bottom line  
1574 for me is that despite whatever changes they have done or  
1575 assay or systems validation that they performed, the Gen-3  
1576 system with these assays is going to be dead on arrival at  
1577 the public health service labs, especially and importantly at  
1578 NYC. This will be simply because of a lack of confidence due  
1579 to previous experience with environmental cross-reactivity  
1580 and the problematic APDS, or Gen 2.5 deployment. Confidence  
1581 in the system is going to be paramount with the current  
1582 actionable nature of the signal that is intended. I just  
1583 don't see how this is going to be possible.''

1584 Now, Dr. Merlin, do you agree with that statement or  
1585 disagree?

1586 Dr. {Merlin.} It is difficult to give a yes or no  
1587 answer. My colleague, Dr. Farrell, was talking about what he  
1588 knew about the development of Gen-3, the basis of the testing  
1589 and the signatures that were being used, and the similarities  
1590 of that system to the multiplex system that was just

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1591 referenced that had been withdrawn, and because that previous  
1592 system had failed, Dr. Farrell was very concerned that this  
1593 was going down the same line. What Dr. Farrell didn't know  
1594 at the time and we found out subsequently was that this  
1595 system was the first phase of a multi-phase development for  
1596 Gen-3 and was not intended to be the final product, and that  
1597 is what we found out in a meeting with Dr. Walter and his  
1598 staff. I am benefited by having people who report to me who  
1599 are quite candid about their concerns, and I take them  
1600 forward to the BioWatch program.

1601 Mr. {Harper.} Dr. Merlin, let me ask you this. Has  
1602 prior mismanagement by DHS and extended scientific disputes  
1603 with DHS negatively impacted the confidence the CDC and the  
1604 public health laboratories in working with BioWatch Gen-3?

1605 Dr. {Merlin.} I think the scientific community wants to  
1606 see data. They want to see data, and it needs to be conveyed  
1607 in a fashion that isn't ``trust me, I have the data, it  
1608 supports that this works.'' They really want to see the  
1609 data.

1610 Mr. {Harper.} Can you go to tab 46 and let us look at  
1611 that for a moment? And this is a May 2012 email where you

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1612 stated about the historical tensions in the BioWatch program,  
1613 and you said, in part, ``I think the bottom line is that NYC  
1614 public health feels that public health is struggling to be  
1615 heard in a program that is dominated by DHS and law  
1616 enforcement but which has huge implications for public health  
1617 departments.'' Is this still the case?

1618 Dr. {Merlin.} This references the particular situation  
1619 in New York City and the New York City jurisdictional  
1620 BioWatch Advisory Committee, and I know that both Dr. Walter  
1621 and I have struggled with this. New York City specifically  
1622 asked me to become personally engaged and to go there as a  
1623 CDC representative because they thought there wasn't a  
1624 sufficient scientific voice at the table of these  
1625 discussions. It is the nature of the constitution of these  
1626 individual BioWatch Advisory Committees and I think they vary  
1627 from jurisdiction to jurisdiction.

1628 Mr. {Harper.} So is this still the case?

1629 Dr. {Merlin.} I think it is still the case.

1630 Mr. {Harper.} Thank you. I will yield back the balance  
1631 of my time.

1632 Mr. {Murphy.} The gentleman yields back. Now to the

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1633 gentlelady from North Carolina, Ms. Ellmers, for 5 minutes.

1634 Mrs. {Ellmers.} Thank you, Mr. Chairman, and thank you  
1635 to our two gentlemen who are with us today.

1636 I am listening to the testimony, and I am listening to  
1637 the questioning, and you know, sometimes I end up with more  
1638 questions after I hear the discussion. I am concerned about  
1639 some of the issues with false positives or no false  
1640 positives, what has been detected in the past, what has not,  
1641 and you know, basically is this an effective system, and are  
1642 we, you know, developing a system for future use but not  
1643 necessarily taking into account things that have happened in  
1644 the past and making it the most effective plan as possible.

1645 Going back to some of the discussion that has already  
1646 taken place in association with Assistant Secretary of Health  
1647 Affairs, Dr. Alexander Garza, Dr. Merlin, do you agree with  
1648 the way that Dr. Garza articulated the performance record of  
1649 BioWatch by stating that BioWatch has never had a false  
1650 positive result?

1651 Mr. {Garza.} No, Congresswoman, I do not agree with  
1652 that characterization.

1653 Mrs. {Ellmers.} Okay. Great.

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1654 Dr. Walter, according to the GAO, in order to build user  
1655 confidence in the system, BioWatch has established a  
1656 stringent threshold of one in 10 million for the false  
1657 positive rate. That is the rate at which the system is  
1658 allowed to indicate a pathogen is present when one is not.  
1659 Is that still the threshold and is that correct?

1660 Dr. {Merlin.} I believe it is, yes, ma'am.

1661 Mrs. {Ellmers.} Okay. Moving on, in that thinking, a  
1662 pathogen, we mean the threat agent to be detected, not the  
1663 near neighbor background organism?

1664 Dr. {Merlin.} That is correct, ma'am.

1665 Mrs. {Ellmers.} Okay. That is two yeses. Wonderful.  
1666 So keeping that in mind with the development of Generation-3,  
1667 DHS has changed the definition of false positive from the one  
1668 used in Generation-2 in which the definition of false  
1669 positive means the system indicated the DNA of the bacteria  
1670 including those of the near neighbor. Is that correct? Is  
1671 that the change--has that change occurred in relation to the  
1672 Generation-3 or is that yet to be determined?

1673 Dr. {Merlin.} No, I think that has yet to be determined  
1674 but when we look at a detection, we believe we are detecting

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1675 the actual organism, not the near neighbor. With Francisella  
1676 tularensis, the DNA assays we had deployed weren't specific  
1677 enough to go down into what are known in--and I am sorry I am  
1678 going to throw microbiology at you but the subtypes of these  
1679 organisms that actually cause the disease, and so what we  
1680 were detecting was actually there. It was Francisella  
1681 tularensis. It is not a near neighbor. It is potentially  
1682 not the pathogenic form, that subtype of Francisella  
1683 tularensis.

1684 Mrs. {Ellmers.} I guess that brings me to the question  
1685 of specificity. So the Generation-3 operational requirement  
1686 document defines specificity as the ability to detect strains  
1687 of the target species without detecting near neighbor or  
1688 background organisms. So under that definition, the BioWatch  
1689 systems detection of near neighbors would be false positives?

1690 Dr. {Merlin.} That is correct.

1691 Mrs. {Ellmers.} That is correct? Okay. And then one  
1692 last question, I have about a minute left.

1693 Dr. Merlin, during the interview with the committee  
1694 staff, you compared BioWatch to the Magna Line. What did you  
1695 mean by that?

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1696 Dr. {Merlin.} I compared it to the Maginot Line, which  
1697 was a French defensive line built prior to World War II to  
1698 protect against a German invasion where the French general  
1699 staff believed that the Germans were most likely to invade.

1700 Ms. {Ellmers.} Right.

1701 Dr. {Merlin.} And it was a wonderful defensive  
1702 mechanism. The problem was, it wasn't where the Germans  
1703 chose to invade; they invaded through Belgium and the  
1704 Netherlands into northern France. And I made the comparison  
1705 because we need to be careful that we build our defenses  
1706 across the entire spectrum of where attacks might come, not  
1707 where we think, you know, this is going to be, and that is  
1708 what--in reference to the earlier strategy, biosurveillance  
1709 strategy, we need to a strategy that cuts across a spectrum  
1710 of threats.

1711 Mrs. {Ellmers.} Right, not just where we might assume  
1712 something would happen.

1713 Dr. {Merlin.} Or we most fear.

1714 Mrs. {Ellmers.} Okay. Thank you very much. Thank you  
1715 both very much. I yield back the remainder of my time.

1716 Mr. {Murphy.} On your time, I want to ask a follow-up

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1717 question to what she said. Do we have actual numbers on the  
1718 specificity and sensitivity of the Gen-2 and the Gen-2.5 and  
1719 Gen-3 in term of these, you know, similar to other medical  
1720 tests that we have some sense of, is it 20 percent, 50  
1721 percent, 80 percent? Where are we with those?

1722 Mr. {Walter.} We conducted--as part of the first phase  
1723 of the Gen-3 acquisition, we conducted a number of assay  
1724 evaluations using the CDC assays and the critical reagent  
1725 assays that we employ operationally to test the assays that  
1726 were being proposed for the first phase of the Gen-3 systems  
1727 that we were testing, and that data essentially looked at the  
1728 specificity and the sensitivity of the assays that we employ  
1729 under laboratory conditions, and that information was  
1730 compiled and actually transferred to the CDC for their use as  
1731 well.

1732 Mr. {Murphy.} Well, do we have those numbers?

1733 Dr. {Merlin.} Yes. We have turned over to the  
1734 committee staff information related to the testing we  
1735 performed on the LRN assays that are used in the Generation-2  
1736 system, and you can certainly--if you don't have it--

1737 Mr. {Murphy.} We will put it out then. Thank you.

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1738 I now recognize the gentleman from Florida, Mr.

1739 Bilirakis from the full committee, for 5 minutes.

1740 Mr. {Bilirakis.} Thank you, Mr. Chairman. I appreciate

1741 it very much. Thank you for allowing me to sit on this

1742 panel. I have been actively interested and involved in

1743 oversight over BioWatch, the program, for a couple years now.

1744 We all wish to ensure a comprehensive biosurveillance

1745 capability. However, we must be smart about how we

1746 accomplish that goal. I think we all agree, this capability

1747 must be reached in the most effective and efficient manner,

1748 must be based on sound science and must ensure an appropriate

1749 return on taxpayers' investment. We must not lose sight of

1750 the greater goal of overall preparedness by harnessing all of

1751 our resources toward a single static technology.

1752 I have a question for Dr. Walter. When it used this

1753 report on BioWatch last year, the GAO confirmed that there

1754 has been no comprehensive cost-benefit analysis done to

1755 ensure that the \$5.8 billion that have been spent over

1756 BioWatch's lifecycle will buy down risk sufficient to justify

1757 such a large expenditure. Doctor, can you please update the

1758 subcommittee on any efforts to measure the cost-effectiveness

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1759 of the BioWatch program?

1760 Mr. {Walter.} We are currently conducting an analysis  
1761 of alternatives relative to the Gen-3 acquisition, and part  
1762 of that analysis of all alternatives will include a cost-  
1763 benefit analysis.

1764 Mr. {Bilirakis.} Okay. When are we going to have any-  
1765 -

1766 Mr. {Walter.} We should be getting the final briefing  
1767 on that in August. We expect that with a final report in the  
1768 September-October time frame.

1769 Mr. {Bilirakis.} And you will report back to us?

1770 Mr. {Walter.} I will do that, sir.

1771 Mr. {Bilirakis.} Okay. How much more certainty is  
1772 gained from Generation-3 machines? Do we know the decrease  
1773 in human morbidity and mortality? I know most of the members  
1774 have touched on this, but if you can expand.

1775 Mr. {Walter.} Currently, there is no Gen-3 program,  
1776 acquisition program. It has all been placed on hold. So  
1777 that would depend on the acquisition, the technology that  
1778 would be eventually deployed. As originally advertised, we  
1779 would be increasing the number of systems that were deployed

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1780 and actually increasing the number of cities to which the  
1781 systems were also deployed in and then also taking the system  
1782 indoors. Based on all of that, you would expect that our  
1783 resolution of where the attack took place would be better  
1784 because we have more sensors out. We would be getting more  
1785 frequent analysis during the day. We would be getting up to  
1786 eight analyses as opposed to one, so our timeliness would be  
1787 improved and we can take the system indoors so we would know  
1788 a lot more a lot faster and able to reduce morbidity and  
1789 mortality if we can respond appropriately.

1790 Mr. {Bilirakis.} Dr. Merlin, do you want to comment on  
1791 that?

1792 Dr. {Merlin.} I agree with Dr. Walter's assessment that  
1793 the transition from Generation 2 to Generation 3 would  
1794 increase the testing frequency and increase the number of  
1795 testing sites, and would decrease the amount of time  
1796 available, and those are essential features. What we need to  
1797 know is how sensitive the system would be, what its lower  
1798 limits of detection would be, and how specific it would, how  
1799 many false positives it would give in an operating  
1800 environment in order to know how it truly performs. There

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1801 are a number of determinants of performance. One is how many  
1802 you have, how often you do it, and the other is how well it  
1803 works, and what we don't know is how well it would work.

1804 Mr. {Bilirakis.} Okay. Thank you. Next question.

1805 BioWatch comprises about 80 percent of the Office of Health  
1806 Affairs' budget but constitutes just a single niche of the  
1807 very broad mandate that is biosurveillance. Aside from  
1808 BioWatch, are there other things we need to be doing to fill  
1809 other capability gaps, Dr. Walter?

1810 Mr. {Walter.} I think we need to make sure that  
1811 BioWatch is not mutually exclusive of other surveillance  
1812 systems. BioWatch needs to complement medical surveillance.  
1813 BioWatch needs to complement syndromic surveillance.  
1814 BioWatch needs to complement point-of-care diagnostics.  
1815 Also, out of the detection realm but into the preparedness  
1816 and training realm, we need to make sure that our  
1817 jurisdictions, our State and locals, know what they are going  
1818 to do in the event of a biological attack, which is a major  
1819 part of what the BioWatch program spends its time doing. It  
1820 is not our responsibility nor do we want to develop their  
1821 response cutoffs but we do provide them with guidance

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1822 documents, points to consider, and we do provide them with a  
1823 robust exercise program to see if those plans they put in  
1824 place make sense. All of that together is a big part of how  
1825 we are going to--what we need to do improve biodefense in the  
1826 country.

1827       Mr. {Bilirakis.} Very good. I understand that Gen-3  
1828 BioWatch system uses local laboratories to manually analyze  
1829 filter samples for the presence of suspicious bacteria. I  
1830 can imagine that there are likely several hundreds of  
1831 scientists and laboratory technicians involved in this  
1832 activity across the United States. If Gen-3 technology works  
1833 as planned, then the need for manual analysis would be most  
1834 likely eliminated. Would this result in reduction of  
1835 BioWatch laboratory workforce and thereby saving taxpayer  
1836 dollars, or does it not save money because the system is so  
1837 expensive? Either one of you.

1838       Mr. {Walter.} I think that is probably mine. You are  
1839 correct in that as we envision it, the only laboratory  
1840 analysis that would need to be done is in the event of an  
1841 automated system detecting something, and either going  
1842 forward and collecting additional samples or getting an

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1843 archived sample from the unit or units that have shown a  
1844 positive in doing that analysis. So we would actually need  
1845 less support on our field operations and also less support in  
1846 our laboratory operations. We would still need to support  
1847 State and local public health because we would basically be  
1848 trading the manual part in for interpretation of results.  
1849 What is the machine telling us? Who do I need to make sense  
1850 of that. So there wouldn't be a wholesale--we couldn't  
1851 subtract off the funding that we need to support the field  
1852 and laboratories but I believe that would be reduced.

1853 Mr. {Bilirakis.} What do you think, Dr. Merlin? Do you  
1854 think we will save some money?

1855 Dr. {Merlin.} I think the jury is out on that. I think  
1856 almost invariably new technology programs are offered with  
1857 the promise that they are going to save money by saving labor  
1858 and decreasing costs, and often that doesn't turn out to be  
1859 the case. One question will be the actual acquisition costs,  
1860 and from the numbers I have heard, the actual acquisition  
1861 costs and operating costs are greater than the current Gen-2  
1862 costs. I don't see how there could be a net savings of  
1863 money. There is going to be an increase anyhow. And then

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1864 there is a question in the rollout period once it is rolled  
1865 out what the implications are of the downstream effects on  
1866 public health departments and the need to support it. I  
1867 think it is just very hard in a program like this to  
1868 speculate what the operating costs are truly going to be.

1869 Mr. {Bilirakis.} I appreciate that. Thank you very  
1870 much. I yield back, Mr. Chairman.

1871 Mr. {Murphy.} Thank you. Just a quick question. The  
1872 President in July of 2012 released the National Strategy for  
1873 Biosurveillance. He said he would have a strategic  
1874 implementation plan in 120 days. Do either of you gentlemen  
1875 know if we have one yet?

1876 Dr. {Merlin.} On the way here yesterday from Atlanta, I  
1877 got an email saying that the implementation plan had been  
1878 posted. I didn't have a chance to look but it should be--if  
1879 it is there, it should be on the Executive Office of the  
1880 President Web site.

1881 Mr. {Murphy.} Would you please help make sure we see  
1882 that too? And also about the costs. On July 16, 2008, the  
1883 GAO testified at the House Homeland Security Subcommittee  
1884 hearing that the Generation-2.5 lab-in-a-box units would cost

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1885 \$120,000 per unit and \$65,000 to \$72,000 annually per unit to  
1886 operate and maintain. According to a slide from DHS  
1887 scientists in December of 2011, the cost estimates for a Gen-  
1888 3 showed \$117,000 per unit, which is comparable to Gen-2.5,  
1889 but a much higher \$174,000 per unit for operation and  
1890 maintenance for Gen-3 lab-in-a-box services. So Dr. Walter,  
1891 why is the operation and maintenance for Gen-3 devices more  
1892 than \$100,000 higher per unit than the Gen-2.5? Do you know?

1893 Mr. {Walter.} I do not know that. Like I said, Gen-2.5  
1894 predates me. I know Gen-2.5 was a fairly expensive system to  
1895 maintain but we are also looking as part of the acquisition  
1896 to reduce the costs of maintaining those systems. Most of  
1897 the costs in maintaining or fielding an automated detection  
1898 system is going to be in operations and maintenance, and  
1899 anything we can do to reduce those costs is going to work in  
1900 our favor.

1901 Mr. {Murphy.} Well, thank you. I think we heard today  
1902 on both sides the concern about these costs, the  
1903 effectiveness, the sensitivity and specificity, and we will  
1904 want to continue to work with you to make sure that we have  
1905 that information.

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1906 I ask for unanimous consent that the written opening  
1907 statements of members be introduced into the record, and  
1908 without objection, the documents will be entered into the  
1909 record.

1910 I also ask unanimous consent that the contents of the  
1911 document binder be introduced into the record and authorize  
1912 staff to make any appropriate redactions. So without  
1913 objection--

1914 Mr. {Tonko.} Without objection.

1915 Mr. {Murphy.} The documents will be entered into the  
1916 record with any redactions staff determines are appropriate.

1917 I also ask for unanimous consent to put them majority  
1918 staff's supplemental memorandum into the record, so without  
1919 objection, this memorandum will be put into the record.

1920 So in conclusion, I would like to thank the witnesses  
1921 and the members for their hard work and thoughtful  
1922 participation in today's hearing. I remind members they have  
1923 10 business days to submit questions for the record, and I  
1924 ask that the witnesses all agree to respond promptly to the  
1925 questions.

1926 So with that, the subcommittee is adjourned.

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

1927            [Whereupon, at 11:49 a.m., the subcommittee was  
1928 adjourned.]