

NATIONAL BIODEFENSE SCIENCE BOARD

+ + + + +

TELEPHONIC MEETING

+ + + + +

FRIDAY,
JULY 17, 2009

+ + + + +

The meeting convened telephonically at 12:00 p.m., Member John Grabenstein moderator, presiding.

VOTING MEMBERS PRESENT:

RUTH BERKELMAN, M.D.
STEPHEN CANTRILL, M.D.
ROBERTA CARLIN, M.S., J.D.
ALBERT J. DI RIENZO
KENNETH DRETCHEN, Ph.D.
JOHN GRABENSTEIN, R.Ph., Ph.D.
JAMES JAMES, Brigadier General (Retired),
M.D.,

Dr.PH., M.H.A.

THOMAS MacVITTIE, Ph.D.

JOHN PARKER, M.D., Major General (Retired)

ANDREW PAVIA, M.D.

ERIC ROSE, M.D.

PATRICK SCANNON, M.D., Ph.D.

EX OFFICIO MEMBERS PRESENT (or designee):

TERRY ADIRIM, M.D., M.P.H., Department of
Homeland Security

JOSEPH ANNELLI, D.V.M., Animal and Plant

Health Inspection Service

DIANE BERRY, Ph.D., Chief Scientist, Director,
Threat Characterization and
Countermeasures, Office of Health
Affairs, Department of Homeland Security

RICHARD BESSER, M.D., Director, Coordinating
Office for Terrorism Preparedness and

Emergency Response, Centers for Disease
Control and Prevention

BRUCE GELLIN, M.D., M.P.H., Director, National
Vaccine Program Office

ROSEMARY HART, Special Counsel, Office of
Legal Counsel, Department of Justice

PETER JUTRO, Ph.D., Deputy Director, National

Homeland Security Research Center,
Environmental Protection Agency

VINCENT MICHAUD, M.D., M.P.H., Office of the
Chief Health and Medical Officer,
National Aeronautics and Space
Administration

DIANE POSTER, Ph. D., National Institute of
Standards and Technology, U.S.

Department of Commerce

COL. JOHN SKVORAK, D.V.M., Ph.D., Commander,
U.S. Army Medical Research Institute
for Infectious Diseases

PATRICIA WORTHINGTON, Ph.D., Director, Office
of Health and Safety, U.S. Department of
Energy

DESIGNATED FEDERAL OFFICIAL:

LEIGH SAWYER, D.V.M., M.P.H., Captain, USPHS,
Executive Director

A G E N D A

ADMINISTRATIVE MATTERS

CALL TO ORDER AND CONFLICT OF INTEREST

RULES 4
Capt. Leigh Sawyer, DVM, MPH
Executive Director, National
Biodefense Science Board

OPENING REMARKS 13
Nicole Lurie, MD, MSPH

Assistant Secretary for Preparedness
and Response

AGENDA OVERVIEW AND GOALS 22
John Grabenstein, RPH, PHD

REVIEW AND DISCUSSION OF THE PANDEMIC

INFLUENZA WORKING GROUP EXECUTIVE
SUMMARY OF THE H1N1 STRATEGY AND
DECISION MAKING FORUM 38
Andy Pavia, MD
Chair,

PUBLIC COMMENT AND DISCUSSION 101

NATIONAL BIODEFENSE SCIENCE BOARD VOTE . . . 120

Capt. Leigh Sawyer, DVM, MPH

WRAP UP AND ADJOURN 125

Capt. Leigh Sawyer, DVM, MPH

P R O C E E D I N G S

(12:02 p.m.)

1
2
3 CAPT. SAWYER: Thank you very
4 much. I am Leigh Sawyer, the Executive
5 Director of the National Biodefense Science
6 Board. I serve as the Designated Federal
7 Official for this Federal Advisory Committee.

8 We have convened this meeting by
9 teleconference to discuss comments on the
10 findings from the June 18-19, 2009 H1N1
11 Countermeasures, Strategy, and Decision Making
12 Forum hosted by the Pandemic Influenza Working
13 Group at the National Biodefense Science
14 Board. The public teleconference is being
15 convened to assure the public it's given an
16 opportunity to hear the deliberations, and to
17 provide comments.

18 Now, I've learned that the meeting
19 documents have not been, or were posted late
20 to the website, so if you're at your
21 computers, I'm going to direct you as to how
22 to get the meeting information. If you would

1 like to email NBSB@HHS.gov, those documents
2 will be emailed to you immediately. If you
3 are at a computer and want to access by the
4 internet, please go to
5 WWW.HHS.gov/aspr/omsph/nbsb. A simple way to
6 do it is also to Google NBSB. So, I will go
7 ahead with the meeting announcement, and
8 hopefully you will be able to get the
9 documents in the next few minutes.

10 This meeting is being transcribed,
11 so when you speak, I would appreciate your
12 indicating who you are by name.

13 Now I'd like to take the roll call
14 of the NBSB.

15 (Roll Call.)

16 CAPT. SAWYER: Patty Quinlisk,
17 Ruth Berkelman, Steve Cantrill.

18 MEMBER CANTRILL: Present.

19 CAPT. SAWYER: Roberta Carlin.

20 MEMBER CARLIN: Present.

21 CAPT. SAWYER: Al Di Rienzo.

22 MEMBER DI RIENZO: Present.

1 CAPT. SAWYER: Ken Dretchen.

2 MEMBER DRETCHEN: Present.

3 CAPT. SAWYER: John Grabenstein.

4 MEMBER GRABENSTEIN: Present.

5 CAPT. SAWYER: Jim James.

6 MEMBER JAMES: Here.

7 CAPT. SAWYER: Tom MacVittie, John

8 Parker.

9 MEMBER PARKER: Present.

10 CAPT. SAWYER: Andy Pavia.

11 MEMBER PAVIA: Present.

12 CAPT. SAWYER: Eric Rose.

13 MEMBER ROSE: Present.

14 CAPT. SAWYER: Pat Scannon.

15 MEMBER SCANNON: Present.

16 CAPT. SAWYER: Now I'd like to

17 call the names of the ex-officios. If you are

18 on as a representative or a designee, please

19 indicate it at that time.

20 (Roll Call.)

21 CAPT. SAWYER: Dan Fletcher, Peter

22 Emanuel, Larry Kerr, Richard Williams.

1 MEMBER MICHAUD: Vince Michaud for
2 Richard Williams.

3 CAPT. SAWYER: Thank you, Vince.
4 Frank Scioli, Joe Anelli.

5 MEMBER ANNELLI: Present.

6 CAPT. SAWYER: Willie May.

7 MEMBER POSTER: Diane Poster for
8 Willie May.

9 CAPT. SAWYER: Thank you, Diane.
10 Colonel Skvorak.

11 COL. SKVORAK: Present.

12 CAPT. SAWYER: Patty Worthington,
13 Bonnie Richter, Richard Besser, Hugh
14 Auchincloss, Carol Linden, Bruce Gellin, Boris
15 Lushniak, Diane Berry.

16 MEMBER BERRY: Here.

17 CAPT. SAWYER: Sue Haseltine,
18 Rosemary Hart.

19 MEMBER HART: Present.

20 CAPT. SAWYER: Claudia McMurray,
21 Lawrence Deyton, Shawn Fultz, Peter Jutro.

22 MEMBER JUTRO: Present.

1 CAPT. SAWYER: Patricia Milligan.

2 Thank you.

3 As, is apparent, the Chair, Dr.
4 Patricia Quinlisk is not on the phone. She is
5 actually on vacation in a remote area, and she
6 may try to call in, but for the purposes of
7 this meeting, I, as the Designated Federal
8 Official, will serve as Chair for this
9 meeting.

10 I've also asked Dr. John
11 Grabenstein to serve as moderator for this
12 call in the absence of the Chair being here,
13 so he will also be greatly involved in this
14 call.

15 Now, I'd like to take a moment for
16 Federal Advisory Committee Overview. The NBSB
17 is an Advisory Board that is governed by the
18 Federal Advisory Committee Act. FACA is a
19 statute that controls the circumstances by
20 which agencies or officers of the federal
21 government can establish or control committees
22 or groups to obtain advice or recommendations

1 where one or more members of the group are not
2 federal employees. The majority of the work
3 in the NBSB, including information gathering,
4 drafting of reports, and the development of
5 recommendations is being performed not by the
6 full Board, but by working groups who, in
7 turn, report directly the Board. And that is
8 the situation today.

9 In terms of conflict of interest,
10 the Standards of Ethical Conduct for Employees
11 of the Executive Branch document has been
12 received by all the Board members who, as
13 government special employees, are subject to
14 conflict of interest laws and regulations
15 therein. Board members provide information
16 about their personal, professional, and
17 financial interests. This information is used
18 to assess real, potential, or apparent
19 conflicts of interest that would compromise
20 Member's ability to be objective in giving
21 advice during Board meetings.

22 Board members must be attentive

1 during the meeting to the possibility that an
2 issue may arise that could affect, or appear
3 to affect their interest in a specific way.
4 Should this happen, it will be asked that the
5 affected member recuse himself or herself from
6 the discussion by refraining from making
7 comments and leaving the telecon.

8 So, I would like to welcome the
9 members of the public who are able to join us
10 by teleconference today. There is a public
11 comment period scheduled from 1:30 to 1:50.
12 You will be given instructions by the operator
13 as to how to queue up so that your phone line
14 will be open for you to speak.

15 The Federal Register notice that
16 was posted announcing the July 17th NBSB
17 public meeting stated that any public comments
18 could be addressed to the Board, and sent to
19 the NBSB email prior to the meeting. Two
20 written comments have been received. One was
21 received on July 10th, and is among the
22 documents sent out for the meeting. The other

1 was received this morning, and has been
2 distributed to the Board members this morning,
3 and will be read during the public comment
4 period.

5 We will be hearing from the
6 Pandemic Influenza Working Group of the
7 National Biodefense Science Board today, and
8 the Working Group convened a meeting of
9 experts on vaccines, diagnostic methods, and
10 antivirals. Those experts have been invited
11 to participate today in the meeting, and they
12 will be available to address questions from
13 the Board. Many of them are on the line. The
14 ex officio members, of course, are encouraged
15 to join in the discussions of the Board.

16 So, I also want to remind you, we
17 do have a transcriber, so please be sure to
18 state your name when you speak. And now I
19 have the special pleasure of introducing our
20 new Assistant Secretary for Preparedness
21 Response, Dr. Nicole Lurie.

22 As Chair of the National

1 Biodefense Science Board, I am welcoming her
2 on their behalf. She was unanimously
3 confirmed by the Senate on July 10th, and was
4 sworn in yesterday as the Assistant Secretary.

5 Dr. Lurie is an internationally
6 recognized leader in public health, who has
7 spent the past six years working with agencies
8 at every level of government on pandemic
9 influenza preparedness. Her knowledge and
10 experience will be critical to ASPR, and to
11 the entire department, as we continue to
12 develop and implement an action plan for
13 coordinated national response to H1N1 virus.

14 Dr. Lurie has spent the last
15 several years working with HHS, the Department
16 of Veterans Affairs, and state and local
17 health departments on pandemic influenza
18 preparedness, and other public health issues.

19 Previously, she served as
20 principal Deputy Assistant Secretary of Health
21 at HHS. She has a long history in the health
22 services research field, primarily areas of

1 access to and quality of care, managed care,
2 mental health, prevention, public health
3 infrastructure and preparedness, and health
4 disparities.

5 Dr. Lurie is known to many of the
6 Board members, and I know the Board is very
7 much looking forward to working with her. Dr.
8 Laurie.

9 DR. LURIE: Well, thanks so much.
10 It's really a privilege to be able to be here
11 today. I'm sorry I can't see all of you in
12 person, and I look forward to your next in-
13 person meeting, so I can say hello in person.
14 But I just want to start by expressing how
15 grateful I am for your meeting today, to
16 discuss the findings from the June 18-19th
17 Working Group.

18 It's really terribly important,
19 and I think what I want to share with you
20 first and foremost is that you're really
21 making a difference in this. I think a lot of
22 people sit on advisory committees, and they

1 say oh, we make recommendations. What happens
2 with those recommendations? And often they
3 don't know, and often they don't hear back,
4 and they don't know if what they're
5 recommending or saying is going into a black
6 hole, or people are really doing something
7 with it. I want to tell you that in the very
8 short time that I've been here, it's really
9 clear to me that you're making a difference.
10 And that's really the first thing that I want
11 to say.

12 Obviously, in my role as Assistant
13 Secretary for Preparedness and Response, I am
14 the principal advisor on these issues to the
15 Secretary, and she is really counting on us to
16 provide ongoing advice and policy coordination
17 as we move through this H1N1 experience,
18 whatever twists and turns it chooses to make.

19 In the short time I've been here,
20 and I'll say that I've been working here as a
21 consultant for the past couple of weeks until
22 I was confirmed, so I know, I didn't do all

1 this in the last two days, and I've had
2 tremendous staff to help me. But we've put
3 together really a cross-agency task force that
4 involves every part of HHS that has something
5 to do with H1N1. We meet daily for updates,
6 and we have a host of sort of working groups,
7 and subgroups, that are taking on issues
8 related to surveillance, to antivirals, to
9 vaccines, to personal protective equipment, to
10 community mitigation, to medical care, and to
11 communications. So, we're working on all of
12 those aspects simultaneously, and Captain
13 Clare Helminiak is Chairing that task force
14 for me.

15 As we move forward, as I think all
16 of your are acutely aware, we are making
17 decisions about how to proceed on an almost
18 daily basis, and need to make some decisions
19 coming up that are going to be really
20 important, and are going to impact the health
21 of not only this country, but have, frankly,
22 global impacts.

1 I feel pretty strongly about the
2 need for an advisory board to get outside
3 advice on this set of policy actions. And,
4 quite honestly, to shake things up a little
5 bit, to be sure that we are thinking about the
6 right things, and the right issues, to be sure
7 that the things that we need advice from,
8 we're getting advice from, but, also, to be
9 sure that in your work, you're not just taking
10 keys from us, and being like the drunk looking
11 under the lamp post for their keys. But if
12 there's issues that you don't think we're
13 paying attention to, or need to be on our
14 radar screen, I think we need to hear about
15 them. I mean, I think working through one of
16 these experiences can be a bit like the fog of
17 war, and I think the only way that we can do
18 a really good job serving the American people
19 is to rely on continuous advice from experts.

20 So, to that end, I'm working with
21 Leigh, and Mary, and others to try to set up
22 a structure where if you're willing, we can

1 call on you, a working group of you early and
2 often as we go through the summer and into the
3 fall to take a look at what it is that we're
4 doing, and to provide us some advice. And I
5 know that we'll have more opportunity to
6 discuss what that should look like, as we go
7 forward.

8 Already, quite honestly, your June
9 meeting really helped us shake up our own
10 thinking a little bit, and really helped us to
11 think about whether we were doing everything
12 we could do to accelerate our time lines, and
13 to sharpen our focus on potentially target
14 groups for vaccination. I think many of you
15 know that last week CDC put out an initial set
16 of recommendations for planning purposes about
17 the kinds of target groups for vaccine that
18 they want states to be preparing for. And I
19 think many, or all of you know that last week
20 we had a summit with all of the states to ask
21 them to prepare for the fall preparation,
22 including the potential for a mass vaccination

1 campaign, if it turns out to be in order.

2 So, the other thing, and I know
3 Robin Robinson can get more into this, that we
4 actually went back and looked at a number of
5 our time lines. Now, we can't do anything to
6 speed when antigen is first going to come out
7 of the pipeline here. I mean, that's an issue
8 above and beyond our control, and in the
9 control of both the manufacturers and the
10 winds of the virus. But, from that point
11 onward, we're taking a really close look at
12 our time lines, and everything necessary to
13 figure out how quickly, if needed, could we
14 get vaccine into people.

15 So, some things that I'm hoping
16 that you'll take on over the coming weeks
17 include, but aren't limited to, the following.
18 You know that we will have vaccine at some
19 point. Right now, our best guess is October
20 15th, could be earlier, could be later, but
21 ACIP will be providing recommendations about
22 how we should optimally use vaccine once it's

1 available.

2 I would very much welcome your
3 input regarding a critically important issue,
4 which is what's the threshold to cross for
5 deciding when to go ahead with an immunization
6 program, and what kind, and how intense an
7 immunization program we should go ahead with.
8 We all know we're going to have to make
9 decisions with imperfect data, and under a lot
10 of uncertainty. And feedback from you about
11 sort of how to balance those things, and what
12 you all think the triggers should be would be
13 welcome. And, frankly, we're going to have to
14 revisit that on a regular basis, and that's
15 one of the reasons that we'll be asking for
16 your input regularly.

17 Right now, we've purchased a bunch
18 of vaccine antigen, and adjuvant, should it be
19 needed. I think there's an open question
20 about what should the national target be for
21 how many vaccine doses we ought to buy, and
22 have available. Is being able to vaccinate

1 600 million people with two doses the right
2 answer, or is there something short of that,
3 based on what we know about both the epidemic
4 so far, the full array of scenarios that could
5 unfold, and people's interest, willingness,
6 and tolerance for vaccinations. What are the
7 conditions under which we should use an
8 adjuvant, realizing that it probably won't be
9 licensed this fall, but could be used under an
10 emergency use authorization.

11 And, on the non-vaccine front, how
12 should we be thinking about right now our
13 antivirals? We've seen the emergence of
14 Oseltamivir resistance. Should we be trying
15 to either limit its use, or limit the uses in
16 Amivir to save it for a potentially worsening
17 situation for the fall?

18 So, those are some of the kinds of
19 things that we'll be needing feedback on. I'm
20 sure, and I hope that there are other things
21 that you think we need feedback on, as well.
22 And I really look forward to working with you,

1 and hearing from you.

2 I will tell you that my intent,
3 once we receive your recommendations today,
4 will be within a couple of days of receiving
5 them, to take them to our daily H1N1 Task
6 Force for review, and then following a
7 discussion there, to take them to the
8 Secretary. And between our task force, our
9 group here, and the Secretary, decide whether
10 there are additional actions that we need to
11 take, that we haven't already taken based on
12 your thoughtful deliberations to-date.

13 Let me stop here. If any of you
14 have any questions, I'm happy to take them
15 now. Otherwise, I'm going to listen on a
16 speaker phone upstairs to the rest of this.

17 OPERATOR: At this time, if you
18 would like to ask a question, please press *,
19 then the number one on your telephone keypad.
20 Again, if you would like to ask a question,
21 please press * and the number one on your
22 telephone keypad. Hold on for just a moment

1 to compile the Q&A roster. Are there other
2 questions at this time?

3 MEMBER GRABENSTEIN: This is John
4 Grabenstein. Dr. Lurie, I'll speak for the
5 Board in saying thank you for your remarks,
6 and your willingness to work with us. We
7 pledge to fulfill our role in providing
8 advice, and seeking expert input, and the
9 public's input in that process. We look
10 forward to working with you.

11 DR. LURIE: Good. Well, thanks so
12 much for all of your hard work to-date and
13 going forward. I know when you sign up for
14 these things, you sign up with the hope that
15 nothing is going to happen, and we all hope
16 that it doesn't get much worse. But the
17 situation we're in now is a great example of
18 why we need this Board, and this Working
19 Group, and the input of people like you, so
20 thanks.

21 CAPT. SAWYER: I believe that the
22 Board members should be able to speak without

1 pressing a button. Could I just hear any of
2 you, Pat, are you able to speak? Andy, are
3 you able to speak without pressing a button?

4 MEMBER PAVIA: I believe so.

5 CAPT. SAWYER: Okay. Good. I
6 just wanted to make sure that you understood
7 that all of you are able to speak without that
8 kind of requirement.

9 The other thing is, I understand a
10 couple of the NBSB members have joined the
11 phone. If you were not here for roll call,
12 will you please let me know your names now.

13 MEMBER ADIRIM: Yes. This is
14 Terry Adirim for DHS.

15 CAPT. SAWYER: Thank you.

16 MEMBER HATCHETT: This is Richard
17 Hatchett from National Security.

18 CAPT. SAWYER: Hi, Richard. Okay.
19 Well, thank you very much, and now I'm going
20 to turn the Agenda Overview and Goals to John
21 Grabenstein. Thank you.

22 MEMBER GRABENSTEIN: Okay. I'm

1 sorry. Thank you very much. What we will be
2 doing today is reviewing, to the greatest
3 extent, that information gathering meeting
4 held one entire month ago, and in the speed of
5 this pandemic that, of course, is an aeon of
6 time, so Robin Robinson from BARDA has offered
7 to give us an update of what's new since we
8 last gathered in Bethesda, and I'll invite any
9 other HHS or other government department
10 people who have information updates to give us
11 that might have transpired in the last month,
12 to do so in a few minutes.

13 The purpose of the call is to
14 discuss a report from the Pandemic Influenza
15 Work Group. That Work Group was formed well
16 before April of 2009, well before the
17 California and Mexico cases caught the public
18 attention and galvanized a lot of prior
19 federal planning, and took advantage of a lot
20 of prior federal planning. So, we're going to
21 be discussing a report that is coming from the
22 Work Group to the full Board. The full Board

1 will consider it, and amend it, if needed.
2 And, if it approves it, would relay it on to
3 the Assistant Secretary, and then on to the
4 Secretary, as you heard Dr. Lurie describe.

5 The goal is to provide useful and
6 timely advice to the Secretary, and to the
7 Department of Health and Human Services, and
8 much of that came from that information
9 gathering session. So, I think I'll ask Dr.
10 Robinson if he wishes to provide us an update
11 on what might have transpired over the last
12 month.

13 DR. ROBINSON: Thank you, John. I
14 want to thank the Board for allowing me to
15 have a few remarks. And I want to salute the
16 Board for its deliberations at the last
17 meeting. They were very meaningful, and I
18 think very productive discussions that
19 certainly were very helpful to us.

20 First, I'd like to give you an
21 update on where we are with our H1N1 vaccine
22 production. All five manufacturers that we

1 have contracted are producing at commercial
2 scale the H1N1 vaccine, both the antigen or
3 the bulk virus concentrate, and, also, the
4 bulk adjuvant products.

5 On the antigen front, you probably
6 heard the news that there's been some concern
7 that the reports and the tables say virus
8 grows slow. The virus doesn't grow slow,
9 okay? What we see is normal. What does seem
10 to be different, though, is that the 2009 H1N1
11 virus apparently has fewer hemagglutinins on
12 the virion than some of the other strains, and
13 that its ability to purify is a little bit
14 more difficult than some of the other strains
15 in the past, so that the number of doses per
16 head - remember, all of these are
17 manufacturing processes for seasonal
18 influenza, vaccines that are licensed in the
19 United States are on the lower end. The
20 numbers that I gave you of production
21 schedule, at that time it was production
22 schedule of looking at what we estimated with

1 about 1.4 doses per head. And, as it turns
2 out, that's almost exactly what we receive by
3 right now, about 1.4 to 1.5 doses per head.
4 The reason we thought that, people said we
5 just guessed. It was actually not a guess.
6 It was based on the fact that we had the H5N1
7 virus vaccines, and then when we started
8 producing those in the very beginning of 2004,
9 we saw that the yields were very low. And as
10 you go through this process of passaging the
11 viruses, and finding a virus seed that's
12 harder than others that could produce more, it
13 takes four or five passages to get there. So,
14 one of the things that will happen as we go
15 through this campaign production, the virus
16 yield will probably go up because the
17 manufacturer will understand better, have
18 better seeds, and so forth.

19 I should say the CDC is also
20 providing some more virus reference strains,
21 so that if they want to change to a different
22 strain to see if it works better at

1 manufacturing, then those will be available.
2 Their antigenicity are the same as the
3 California 409 strain that is currently being
4 used by the manufacturer. This is, I should
5 say, about the inactivated vaccines, so the
6 story you're hearing in the papers about four
7 yields and so forth is for the inactivated.
8 But it is within what we thought it would be,
9 and so our target numbers are about the same
10 as far as production.

11 We have now two and a half weeks
12 of production. We have 18 million doses in
13 the can, so to speak, of both vaccine. We
14 have contracted for 193 million doses thus
15 far. Basically, it's procuring the amount of
16 vaccine antigen through the September 30th
17 window of production.

18 The live attenuated vaccine, I
19 actually am able to report that the first
20 attempt at commercial-scale production was met
21 with some limited success, and that the virus
22 yields were much poorer than anticipated, and

1 poorer than really could be used. So, the
2 second seed they went to that they made, and
3 this is the flu-mist-like product. They have
4 actually made a really super virus seed that
5 actually is getting about two logs higher of
6 the virus titer than normally you would see,
7 so that the number of doses that will be
8 available would only be limited by the amount
9 we could put in the sprayers. And that's what
10 we did. And what that also means is there's
11 going to be more bulk product available than
12 we can actually fill, and we're looking with
13 the manufacturer at other sites within the
14 United States to fill those products, and look
15 at alternative ways of delivering the flu-
16 mist-like product from the sprayer to some
17 other forms, so we may be able to have more
18 live attenuated vaccine than anticipated
19 earlier. So, that's good news, certainly not
20 only for the United States, but this may be
21 also something that could help others around
22 the globe.

1 On the adjuvant front, they are
2 producing, as we had anticipated. There have
3 been no changes in the schedule, nor in the
4 amount produced, and we have contracted thus
5 far 119 million doses of that, so that's on
6 track.

7 You should know that if we wanted
8 to have product available, as indicated in
9 your draft report, at this point in September,
10 then we would have to make a decision to start
11 filling that by the 15th of August, have
12 product by September 15th. Certainly, the
13 Department, including the regulatory arm of
14 the FDA are seriously considering how this can
15 be done, so some of the discussion at the last
16 meeting has really moved us to very intense
17 deliberate discussions on this. And maybe FDA
18 would like to comment more about that, but it
19 is, certainly, an option for us being able to
20 license the vaccine, have the clinical studies
21 go on after the licensure, and then have
22 product formulated 15 micrograms for the

1 inactivated vaccine, and 10 to the 7th virus
2 particles PFUs per dose for the live
3 attenuated.

4 So, I'll stop there on the
5 vaccines just to answer any questions, and
6 then I'll move up to the antivirals.

7 MEMBER GRABENSTEIN: This is John
8 Grabenstein. I'll ask the first couple of
9 questions, and then ask the Board what other
10 questions they have.

11 You said 18 million, and 193
12 million, that was assuming a 15 microgram
13 dose. Right?

14 DR. ROBINSON: That's correct.
15 That's right.

16 MEMBER GRABENSTEIN: So, at the
17 August 15th point, I assume, from what you
18 said, that you would have several tens of
19 millions of doses of bulk available to work
20 with, if you chose to go down that pathway.

21 DR. ROBINSON: Yes. There would
22 approximately be around 60-80 million doses

1 available in September, if we were to go that
2 way.

3 MEMBER GRABENSTEIN: And you said
4 119 million something, but I didn't catch what
5 it was.

6 DR. ROBINSON: Doses of adjuvant,
7 MF59 and ASO3.

8 MEMBER GRABENSTEIN: Other
9 questions from Board members?

10 MEMBER PAVIA: Yes. Robin, can
11 you tell us about the progress of the clinical
12 studies, and where the tests and the vaccines
13 stand?

14 MEMBER GRABENSTEIN: That was Andy
15 Pavia.

16 DR. ROBINSON: Yes. Andy, this is
17 Robin again. If the NIH is not on, I will
18 answer that. Where we are, the NIH studies
19 will start very soon. The first clinical
20 studies with the companies are starting next
21 week, in fact, if all goes well. And then
22 they will start all within about a couple of

1 weeks of one another.

2 There were two sets of studies.

3 There are studies for immunogenicity, or

4 smaller studies to inform formulations, both

5 with and without adjuvant. And then there are

6 the more traditional longer term IND-type

7 studies for safety, immunogenicity that will

8 tell us many more things that will go on in

9 parallel, so they'll be starting at the same

10 time. It's just that we'll have data back

11 from the smaller studies sooner to tell us

12 what the immunogenicity is after one dose, the

13 intervals between the first and second dose,

14 and then after the second dose what we see.

15 So, there are many things that are possible

16 from those data going forward, so you should

17 take note that that came directly out of the

18 meeting that the Board had, so take that and

19 move forward with an idea that it had been

20 there, but to move forward aggressively with

21 that. So, the manufacturer and NIH are moving

22 very rapidly, at this point, for all these

1 studies. As NIH has indicated before, there
2 are a number of policy type or just clinical
3 trials that address policy issues going
4 forward.

5 MEMBER GRABENSTEIN: Does anybody
6 from NIH have anything to add? And how about
7 FDA?

8 PARTICIPANT: From FDA, we don't
9 have anything to add.

10 MEMBER GRABENSTEIN: Okay. Any
11 other -

12 MEMBER ROSE: This is Eric Rose.
13 Do we have some sense of the time line as to
14 when we'd know if the 15 microgram dose was
15 effective?

16 DR. ROBINSON: For the first dose,
17 we're looking in September.

18 MEMBER ROSE: So, you won't know
19 that until after that August 15th decision
20 point?

21 DR. ROBINSON: That's correct.

22 MEMBER ROSE: Okay.

1 MEMBER GRABENSTEIN: All right.
2 Other questions? All right. Then, I believe
3 the appropriate thing to do now is to move to
4 Dr. Pavia for - oh, I'm sorry, Dr. Robinson.
5 I'm sorry.

6 DR. ROBINSON: There's an update
7 to the antivirals. You should know what we
8 actually have in our inventory, and when we
9 will have more. As you remember, we thought
10 before that 11 million treatment courses of
11 Tamiflu and Relenza were pulled from the
12 strategic national stockpile to the states.
13 They were then distributed amongst the states
14 to the local areas, and very few of them were
15 actually used in the months of May and June.
16 So, the 24.5 million treatment courses that
17 the states have already in their stockpile now
18 can be -- with the 11 million will give you
19 over 35 million that are already there in the
20 states. We are replenishing the 11 million
21 that were taken out of the stockpile, to come
22 up to 44 million, so that the total amount we

1 will have probably by early August will be the
2 44 million of the federal, and then the 35
3 million in the states.

4 And you should know that there is
5 a consideration on the table right now, it's
6 being recommended to the Secretary that we go
7 forward with it, and purchase more Zanamivir,
8 and more pediatric formulations of Tamiflu.
9 The amount of pediatric dosages going forward
10 would give us about 20 percent of the entire
11 federal stockpile would be for children, which
12 would then have us in accord with the
13 population for those ages. And the reason we
14 went with Zanamivir was the previous
15 acknowledgment that the virus had already
16 started to change for H1N1, and then we
17 started to see isolated incidents of
18 resistance to Oseltamivir with these 2009 H1N1
19 viruses. So, ultimately, we wanted to move
20 from an 80-20 split to a 50-50, and so the
21 next procurement we have will be moving toward
22 that. We will not get there this year,

1 because there's not enough capacity in
2 production to allow that to happen. So,
3 basically, again we're buying what we'll be
4 able to produce in the United States at this
5 time.

6 And there's one other thing,
7 there's the consideration for emergency use
8 authorization of at least one drug that's been
9 tested in humans through Phase II clinical
10 trials for severely ill influenza patients.
11 This is a drug called Peramivir. There are
12 clinical studies that will go on for
13 intravenous uses. For Phase III of that drug,
14 also is under consideration whether we should
15 have some of that product available for
16 individuals that are in desperate need. IV
17 forms of Tamiflu and Relenza will be
18 undergoing further Phase I clinical studies,
19 and it's probably unlikely that they will be
20 available at all until late in the season, or
21 maybe even next year, so that's where we are
22 with the antivirals.

1 MEMBER GRABENSTEIN: All right.
2 Thank you very much for the update. Things
3 move fast if you're not paying attention. So,
4 let's turn to Dr. Pavia now to review and
5 discuss the report from the workers.

6 MEMBER PAVIA: Thanks to you,
7 John, for taking the role as Chair. I want to
8 thank Dr. Lurie and Dr. Sawyer for the
9 introduction, and in the interest of time, I
10 will read through the Executive Summary of the
11 report, and then I don't believe we'll have
12 time to read the entire report, so I'll hit
13 some key points that may require some further
14 discussion.

15 MEMBER GRABENSTEIN: Andy, I want
16 to stop you, and make sure we've given the
17 instructions on how to get to the document for
18 those who haven't found it yet. If you call
19 up your internet browser, we will get you to
20 that place.

21 Okay. The easiest way is to dial
22 up your browser, type in www.hhs.gov/aspr. On

1 the left side of the page, select "Office of
2 Medicine, Science, and Public Health." Once
3 you click on that, underneath you'll see
4 another hyperlink for the National Biodefense
5 Science Board. That will take you to the NBSB
6 page. On the right side of that page will be
7 the NBSB meetings hyperlink. Under "Upcoming
8 Meetings", you will see today's meeting, July
9 17th teleconference button. Click on that,
10 and the PDF versions of all the documents will
11 be there for you to download. So, that was
12 hhs.gov/aspr, Assistant Secretary for
13 Preparedness and Response, then Medicine,
14 Science, and Public Health, then NBSB, then
15 meetings, and go to today.

16 Okay. Andy, thank you.

17 MEMBER PAVIA: Very good. Thanks.
18 The Pandemic Influenza Working Group of the
19 National Biodefense Board convened a group of
20 experts, government scientists, and
21 stakeholders in Bethesda, Maryland on June
22 18th-19th, 2009 to identify key areas around

1 which the United States Department of Health
2 and Human Services should focus its decision
3 making on countermeasures for novel H1N1
4 influenza virus. We heard presentations from
5 government, industry representatives, invited
6 experts on vaccines, diagnostic methods, and
7 antivirals. We identified relevant
8 challenges, considerations, progress, and
9 projections.

10 Next, it is important to improve
11 the process of identifying key decision points
12 and preparing to make those decisions, the
13 working group felt it was critical to clarify
14 the key assumptions, to identify the specific
15 goals, and principles for a response.
16 Specific contemporary responses take advantage
17 of the foundation of preparedness efforts that
18 have been underway for the last five years;
19 however, these responses must be adapted to
20 the specific epidemiology, circumstances, and
21 the existing resources of the current
22 pandemic.

1 In brief, the key findings of the
2 meeting and the subsequent deliberations
3 include the following. If the United States
4 government wants to have a novel H1N1 vaccine
5 available in September 2009, parenthetically,
6 it may be that the second wave of the pandemic
7 will occur as early as September, it should
8 pursue a simplified testing program to achieve
9 that goal. Additional studies may be
10 appropriate for additional supplies in
11 subsequent months, but the time of
12 availability seems to be the dominant
13 criterion for vaccine decision making.

14 Decades of experience with A/H1N1
15 influenza viruses provides a basis for
16 selecting an initial antigen quantity and
17 dosing. If the U.S. goal is vaccine
18 availability on the shelf in September 2009,
19 15 microgram unadjuvanted subunit vaccine and
20 live attenuated intranasal vaccine for
21 children may be a rational approach. If the
22 second wave is delayed or production is slower

1 than expected, mix-and-match studies of
2 vaccine plus separate adjuvant may yield
3 information that may stretch the available
4 vaccine supply.

5 For antivirals, the key messages
6 were H1N1 strains appear to be sensitive to
7 neuraminidase inhibitors, and these are
8 effective in reducing symptoms and progression
9 in early stage disease, and for post-exposure
10 prophylaxis in asymptomatic exposed patients.

11 If H1N1 vaccine is not available
12 at the time of an early wave of disease, the
13 use of antiviral drugs for post-exposure
14 prophylaxis should be considered, but this was
15 not extensively discussed at the conference.

16 Evidence for the effectiveness of
17 antivirals in advanced disease is less robust,
18 that is, in terms of the evidence quality, but
19 there are substantial data supporting the
20 benefit in this population. There will be no
21 approved IV formulation of any influenza
22 antiviral available that could be used in the

1 fall of 2009.

2 Novel antiviral drugs effective
3 against resistant strains and advanced disease
4 will not be available for the existing
5 pandemic, but they should be developed
6 vigorously for future pandemics, or for
7 continuation of this one.

8 HHS should reassess its current
9 and anticipated supply of approved antiviral
10 products and other therapeutic agents, such as
11 antibiotics, seasonal influenza vaccine,
12 pneumococcal vaccine, where surge demand might
13 overwhelm the normal supply.

14 For diagnostics, the key points
15 where the public health laboratories are not
16 equipped to meet the clinical diagnostic needs
17 posed by the present pandemic. Assays with
18 clinical utility should be more widely
19 distributed among clinical-care laboratories.
20 Existing rapid diagnostic tests have
21 unacceptably low sensitivity to rule out H1N1
22 infection in individual patients. Clinical

1 criteria will likely be the primary diagnostic
2 tool in many settings, I'm sorry, in the
3 upcoming fall outbreak. Better diagnostic
4 tests should be developed and deployed. HHS
5 should reassess its current and anticipated
6 supply of laboratory reagents, and their
7 availability to clinical-care laboratories.

8 The Pandemic Influenza Work Group
9 recommends that NBSB relay this report to the
10 Secretary for appropriate action with timing
11 appropriate to the pandemic situation.

12 I'm now going to take a few
13 minutes to selectively read through key
14 assumptions, goals, and principles and the
15 implications. I think that it would be
16 laborious to read through every point here,
17 but we have to understand the assumptions that
18 go into the report, and the recommendations.

19 We assume novel H1N1 viruses will
20 continue to circulate. And the second wave is
21 likely to occur in the fall of 2009. Best
22 estimates suggest that infection rates in the

1 second wave will be two to three times higher
2 than expected with seasonal influenza. The
3 timing of the second wave is unknown. It
4 could peak in October, but we must anticipate
5 a response to a wave as early as September.

6 For the purposes of assumptions,
7 attack rates will continue to be highest in
8 children and young adults. Hospitalizations
9 and deaths will continue to be concentrated
10 among children, and those younger adults with
11 underlying medical conditions. Moreover,
12 children are important because they will
13 continue to act as amplifiers in the community
14 spread of the virus.

15 For the purposes of planning, we
16 assume severity will continue to be similar
17 to, or somewhat greater than the current wave,
18 but with a larger number of cases. And a
19 catastrophic disruption of societal function,
20 as anticipated in some planning scenarios for
21 severity index four or five pandemics, is
22 unlikely.

1 Having vaccine only after the peak
2 of a fall wave may in fact be worse than
3 having no vaccine at all. It incurs all of
4 the risks, and all of the costs, with no
5 potential public health benefit.

6 Early on in the deployment of
7 vaccines, licensed vaccines or vaccines
8 similar to licensed products will be most
9 acceptable, and the safety of vaccines, both
10 real and perceived, will shape the risk
11 benefit calculations, and the acceptance.
12 This will be true for public health officials
13 applying a collective perspective, and for
14 individuals deciding whether to be vaccinated.

15 It's already been stated, but it's
16 worth restating, the decisions about
17 formulation must be made rapidly on the basis
18 of available data, and strategies can and
19 should be changed as more data become
20 available, since the initial decision making
21 will be made with incomplete data.

22 It's also important to add the

1 assumption that the strategic goal of BARDA
2 that was to be able to produce enough vaccine
3 for all 300 million Americans was an
4 appropriate goal for developing capacity, but
5 it does not follow that that is the same as
6 the strategic goal for vaccination in this, or
7 any other specific pandemic.

8 Now, there's some underlying goals
9 and principles that we consider essential.

10 It's critical to have a monovalent novel H1N1
11 vaccine available as early as possible,
12 ideally by mid-September, should it be needed.
13 The goal can take advantage of the decades of
14 experience with other H1N1 subunit vaccines,
15 typically at a 15 microgram dose. We can
16 begin with goals targeting the available small
17 amount of vaccine to the group where it will
18 do the most good. This group will be smaller.
19 To the extent possible, this should be driven
20 by sound epidemiologic data. This likely
21 means focusing on infants, toddlers, school-
22 age children, pregnant women, and adults with

1 risk factors applicable to the current novel
2 H1N1 virus. And I believe you saw that
3 parenthetically in the finding documents
4 released last week by CDC.

5 Manufacturing of vaccine for
6 additional cohorts of the U.S. population and
7 for the world should proceed, but this
8 shouldn't interfere with the primary goals
9 listed above.

10 Safety monitoring must be in place
11 before novel H1N1 vaccinations begin, and it
12 must have the sensitivity, power, and speed to
13 detect signals and determine causal relations
14 in a timely manner to aid policy and
15 communication.

16 HHS should consider recommending
17 school-based immunization delivery for
18 children for logistical simplicity, and
19 decision making for this and the other areas
20 of pandemic response should remain flexible,
21 based on clearly articulated principles, and
22 scientific evidence, and should be

1 transparent.

2 The implications of the above are
3 that a pathway to licensing egg-grown subunit
4 vaccine and perhaps live attenuated vaccine by
5 September should be identified. The minimum
6 early data set needed for decisions by the
7 Advisory Committee on Immunization Practices
8 should be identified, e.g., risk factors for
9 infection, age-stratified immunogenicity
10 response to vaccination. The primary studies
11 should be designed to provide these data.
12 They might include immunogenicity and safety
13 of one dose of 15 microgram unadjuvanted
14 vaccine. These studies should include
15 explicit sub-studies among infants, children,
16 and pregnant women. Two dose studies may be
17 needed early on for infants and children.
18 And, of course, this does not exclude the need
19 to perform these in adults.

20 More detailed studies to determine
21 an optimal dose, the potential need for
22 multiple doses by age strata, the effects of

1 adjuvants are also important. However, these
2 studies should not delay early licensure of a
3 traditional-process product.

4 Alignment of the strategic goals
5 with the process can be improved. This may
6 require close coordination among government
7 leaders of the National Vaccine Program
8 Office, Centers for Disease Control and
9 Prevention, Biomedical Advanced Research and
10 Development Authority, National Institutes of
11 Health, and the Food and Drug Administration.

12 Epidemiology data, modeling, and
13 early evidence of vaccine safety and
14 immunogenicity will inform ACIP
15 recommendations, but it will be necessary to
16 make decisions before all of the data are
17 available. Modifications will be made if
18 indicated by evolving knowledge.

19 I want to move now to the arena of
20 antivirals. Again, you'll have the document
21 in front of you and see that I am not reading
22 every line.

1 The key assumptions are that there
2 is substantial evidence that antivirals
3 against influenza ameliorate symptoms, speed
4 return to work, decrease secondary pneumonia,
5 antibiotic use, hospitalizations, and
6 mortality. The quality of the evidence is of
7 lower quality for more severe disease.
8 Although randomized trials did not address
9 hospitalized patients and prevention of
10 mortality, existing observational studies are
11 well designed, show consistent benefits, and
12 are consistent with our understanding of
13 influenza pathogenesis. The consensus of
14 expert opinion is that antiviral drugs are
15 likely to offer substantial benefit to
16 patients at risk for or with severe disease.

17 Antivirals must be used early for
18 patients with uncomplicated disease. For
19 severe disease, delayed treatment, however,
20 may confer benefits.

21 The emergence of resistance to
22 existing agents must be anticipated,

1 particularly with Oseltamivir. At the least,
2 co-circulation of Oseltamivir-resistant season
3 H1N1 virus containing H274Y mutation, and
4 resistant to the adamantines for novel H1N1
5 influenza A/H3N2, and influenza B will
6 complicate treatment decisions.

7 If novel H1N1 influenza virus
8 becomes widely resistant to Oseltamivir within
9 the next few months, healthcare providers will
10 have few treatment options. This is likely to
11 lead to increased morbidity and mortality.
12 Intravenous Zanamivir could be the best option
13 in the short for Oseltamivir-resistant novel
14 H1N1 in hospitalized and severely ill
15 patients. The future development of this drug
16 by its sponsor remains uncertain.

17 I'm going to skip some of the
18 comments about future drug development. You
19 can read them, and we're going to come back to
20 them if people have questions.

21 The goals and principles includes
22 that all treatment approaches must be

1 considered, including alternate routes of
2 administration and doses for existing drugs,
3 combination therapy, new agents in existing
4 classes, and new classes of antivirals.

5 Treatments that could modify the
6 immunologic cascade and the clinical impacts
7 of influenza are also attractive. At present,
8 however, there do not appear to be any such
9 attractive candidates for immunologic or anti-
10 inflammatory treatment in late stage of
11 development, with the possible exception of
12 celecoxib.

13 High barriers exist, including the
14 need for achievable pathways to approval, and
15 that is, high pathway to the developer of
16 novel approaches. Antiviral treatment
17 approaches must be developed and available
18 specifically for Oseltamivir-resistant virus,
19 use in persons with severe disease, use in
20 pregnant women, young children, and infants.

21 Regulations and/or incentives must
22 be improved that will insure the

1 pharmacokinetic and safety testing in pregnant
2 women and children early in the development
3 process. Development of the FDA draft
4 guidance for the development of influenza
5 antivirals is an important first step. There
6 are fundamental issues that remain to be
7 resolved. A reasonable pathway to approval
8 for antivirals in severe disease must be
9 developed. Scientific and methodologic
10 barriers will need to be overcome.
11 Appropriate endpoints and surrogate markers
12 need to be developed.

13 If intravenous Zanamivir is not
14 further developed by its manufacturer, the
15 U.S. government should give strong
16 consideration to purchasing the rights, and
17 pursuing development under an alternate
18 pathway. HHS should reassess its current and
19 anticipated supply of approved antiviral
20 products, and this should be done on a
21 continual basis. HHS should reassess the
22 current and anticipated supply of other

1 therapeutic agents, e.g., antibiotics,
2 seasonal influenza vaccine, pneumococcal
3 vaccines where surge demand may overwhelm
4 normal supply.

5 The third area of our discussions
6 were in diagnostics. The key assumptions here
7 are that public health and clinical
8 laboratories play an important role to detect
9 and quantify viral circulation in the
10 community, identify outbreaks, provide samples
11 to detect viral drift and detect drug
12 resistance.

13 Public health laboratories'
14 primary role is to inform community level
15 actions. Clinical laboratories also inform
16 community level actions, but, in addition,
17 they inform infection control, appropriate
18 choices of treatment and use of limited
19 resources, and allow prophylaxis among
20 contacts. Laboratory resources and capacity
21 in both the public sector and the clinical
22 sector are limited. They are likely to again

1 be rapidly overwhelmed as they were in May and
2 June of 2009. Co-circulation of novel H1N1
3 with seasonal influenza viruses, as well as
4 other respiratory viruses, will occur.

5 The goals and principles include,
6 it is essential to increase the capacity,
7 throughput, and efficiency of high-quality
8 diagnostics for pandemic response, and to
9 sustain those improvements over the course of
10 decades.

11 Public health laboratories should
12 not function for clinical needs. Therefore,
13 diagnostic capacity in the clinical arena
14 needs to be strengthened to guide individual
15 care. However, data from clinical
16 laboratories are also essential to public
17 health. They can detect outbreaks, define
18 clinical illness, provide clues to the
19 efficacy of vaccines and antivirals.

20 Improved platforms for detection
21 and typing of influenza viruses should be
22 rapidly developed and deployed. These can

1 improve throughput in public health
2 laboratories, and bring greater capacity to
3 the clinical arena. It will be critical to
4 have future surveillance for neuraminidase
5 inhibitor-resistant seasonal influenza
6 viruses, as well as possibly NAI-resistant
7 novel H1N1 virus.

8 The implications are that the
9 capacity of public health laboratories should
10 be augmented above current levels. This
11 expansion of capacity needs to be sustained.
12 Assays with clinical utility should be more
13 widely distributed among clinical care
14 laboratories. Accurate molecular diagnostics,
15 e.g., nucleic acid amplification-based tests
16 need to be available for the management of
17 hospitalized patients. Improving diagnostic
18 capacity for hospitalized patients contributes
19 to the public health readiness, because it
20 improves containment, efficient use of
21 resources, and unburdens the public health
22 laboratories.

1 The capacity for resistance
2 testing needs to be dramatically increased.
3 Programs to share diagnostic reagents and
4 perform cross validation are critical.
5 Barriers to increasing capacity, such as
6 restrictions that arise for licensed tests or
7 the desire to achieve licensure should be
8 identified. These barriers will need to be
9 resolved or eliminated. Examples include from
10 previous experience, restrictions on migrating
11 the CDC protocol for typing of influenza and
12 confirming novel H1N1 onto high-throughput
13 platforms. Restrictions on divulging sub-
14 typing information sub-typing information that
15 is produced by existing licensed platforms, if
16 that was not in the licensure. Restriction on
17 sample type, and I won't go into the details
18 of the unfortunate examples here.

19 The impact of improved diagnostic
20 availability on infection control, optimal use
21 of antiviral stockpiles, slowing of resistance
22 and appropriate use of antibiotics requires

1 further study. Mechanisms to fund these
2 studies are needed. HHS should reassess its
3 current and anticipated supply of laboratory
4 reagents, and their availability to clinical-
5 care laboratories.

6 I'll stop there, and turn it back
7 to John.

8 MEMBER GRABENSTEIN: Thank you
9 very much, appreciate that review. I'll take
10 comments or discussion from the speakers, the
11 Board in four segments. Just first, overall,
12 and then each of the three segments, the H1N1
13 vaccine, antivirals, and therapeutics, and
14 then finally diagnostics. So, any discussion
15 or general comments about the document as a
16 whole? Okay. So, just to clarify, this is a
17 segment of time for the Board members and the
18 ex officio and other people, and the speakers.

19 All right. Let's talk about the
20 H1N1 vaccine, specifically, and those portions
21 of the report. And this might be the time to
22 discuss Dr. Robinson's comments about the

1 status of vaccine production, and what may or
2 may not be available on August 15th that would
3 then lead to what may or may not be available
4 on September 15th.

5 MEMBER PAVIA: Hey, John, this is
6 Andy. It's already been stated, but it's
7 worth restating and clarifying that this is a
8 report generated from work on June 18th and
9 19th, response to that work and really that
10 evening. And you heard from Robin some of the
11 changes that he made, so there's clearly many
12 areas in which some of these recommendations
13 are outdated, because they've already been
14 adopted and changes are underway.

15 MEMBER GRABENSTEIN: True. I
16 mean, it still is our conclusion that they
17 were worthy things to do, so I don't feel the
18 need to remove them from the report; although,
19 obviously -

20 MEMBER PAVIA: Not at all. Just
21 for people who were hearing the report for the
22 first time, and wondering why -

1 MEMBER GRABENSTEIN: Sure.

2 MEMBER PAVIA: I just wanted to
3 clarify.

4 MEMBER GRABENSTEIN: Good. Thank
5 you.

6 MEMBER DRETCHEN: John, Ken
7 Dretchen. John, one of the things that we had
8 talked about in a meeting was the idea that
9 the CDC would be thinking about giving the
10 vaccine to school-age children. The idea now
11 is also about seasonal vaccine being ready
12 somewhere around the same time. Do you think
13 CDC might have a consideration of thinking
14 about also doing the seasonal vaccine also in
15 the school setting once they have the choices
16 now in terms of how to move forward with the
17 procedures?

18 MEMBER GRABENSTEIN: Good
19 question. I was not able to attend the summit
20 meeting that involved the Secretary of
21 Education and a variety of other people
22 informed on the school setting, so I'll ask if

1 any of the other CDC or HHS people wish to
2 comment on that point.

3 CAPT. FIORE: Hi, this is Tony
4 Fiore from the Influenza Division of CDC. I
5 think that the question was whether seasonal
6 vaccine efforts can also be focused in
7 schools. Is that correct?

8 MEMBER DRETCHEN: That's correct.

9 CAPT. FIORE: Right. So, we
10 certainly do encourage school settings as a
11 good place to vaccinate, and many areas do
12 that. I don't think there will be the sort of
13 formal efforts that might go into providing
14 novel H1N1 vaccination in school settings also
15 done for the seasonal vaccine this year. But
16 there are a lot of school settings that do
17 give seasonal vaccine.

18 MEMBER GRABENSTEIN: And, for the
19 purposes of the report, on page 5 we have a
20 bullet saying HHS should consider recommending
21 school-based immunization delivery for
22 children for logistical simplicity. If

1 anybody sees the need to revise that, please
2 speak up.

3 Okay. Other comments about H1N1
4 vaccine segments of the report?

5 MEMBER ROSE: John, this is Eric
6 Rose. Beyond the report, it sounds like we
7 heard today that there's been a lot of
8 progress in terms of production of vaccine,
9 but it also sounds like by the point the
10 decision needs to be made around August 15th,
11 that clinical data are not going to be
12 available. So, I think it's worth discussing
13 what additional information ought to be
14 brought to bear at this point to make a
15 decision, or to go ahead, or not to go ahead
16 on August 15th.

17 MEMBER GRABENSTEIN: So, I'll
18 propose what I would believe to be true, and
19 let somebody correct me if I'm wrong, and that
20 is that a decision might be made to produce
21 the product at a 15 microgram per 0.5 ML
22 concentration. And then if more or less

1 antigen was needed, a greater or lesser volume
2 of vaccine could be injected, so just because
3 you bottled it, doesn't necessarily commit you
4 to what the dose administered, as long as the
5 range it doesn't get too far out of range.
6 But, does anybody else have a comment on that
7 one?

8 MEMBER SCANNON: Well, this is
9 Pat. I guess the question to follow-up on
10 Eric Rose, this is Pat Scannon. To follow-up
11 with Eric Rose's, on August 15th, assuming a
12 15 microgram dose, could that be forward by
13 mid-September?

14 MEMBER GRABENSTEIN: There is
15 rustling of papers in the background, so if
16 somebody could go on mute.

17 Pat, one of your last -- I think
18 the verb in your sentence got garbled, so you
19 might want to restate it.

20 MEMBER SCANNON: Yes. Just to
21 follow-up with Eric Rose's question, if you
22 assume a 15 microgram per dose, could vaccine

1 be available on that empiric basis by
2 September 15th?

3 DR. ROBINSON: John, do you want
4 me to answer that? This is Robin Robinson.

5 MEMBER GRABENSTEIN: Yes, please.

6 DR. ROBINSON: Yes. There will be
7 three to four weeks, so we give ourselves four
8 weeks for that.

9 MEMBER SCANNON: Four weeks after?

10 DR. ROBINSON: The moment that we
11 know what the formulation is, we can start
12 formulation, and then the next day we start
13 filling, and then two weeks for sterility
14 testing, QC tests, and QA release after that
15 it can go out.

16 MEMBER SCANNON: So, you'll have
17 the formulation information by August 15th, or
18 later than that?

19 DR. ROBINSON: No, if we were to
20 do it at 15 micrograms, the standard 15
21 micrograms.

22 MEMBER SCANNON: Right.

1 DR. ROBINSON: It's unlikely that
2 we will have the first immunogenicity set of
3 data to inform us on August 15th.

4 MEMBER GRABENSTEIN: So, Robin,
5 this is John. Would you be inclined to accept
6 the risk, and formulate some doses at 15
7 micrograms with a go point at August 15th, or
8 would you be leery of that, and prefer to wait
9 for the immunogenicity data for the full
10 collection that you'd have?

11 DR. ROBINSON: As I indicated
12 earlier, the FDA is considering if the vaccine
13 could be at the standard dose as a licensed
14 product based on the many years that 15
15 micrograms for a strain change, and a slightly
16 different consideration, the upcoming VRBPAC
17 meeting will probably opine quite heavily on
18 that. So, yes, as you say, we could actually
19 move forward at 15 micrograms per half ML, and
20 then it could be used in lawful ways.

21 MEMBER SCANNON: This is Pat
22 Scannon again. I guess the reason for my

1 question, and I think other people's question
2 was, there was a considerable sense of urgency
3 that came out of the June meeting, because of
4 the possibility that the new wave of H1N1
5 could come back to the United States by
6 September. So, I mean, I think that's what's
7 driving this line of questions.

8 MEMBER GRABENSTEIN: So, this is
9 John Grabenstein, again. So, it's in the
10 purview of VRBPAC, the Vaccine Related
11 Biologic Products Advisory Committee, to the
12 FDA to opine on dose and that sort of thing,
13 so I don't want this Committee to get into
14 that realm, because that's not our
15 responsibility, nor our expertise.

16 So, as the report is drafted now,
17 it would seem that if we continue with our
18 current wording, we would be encouraging the
19 Department to take the risk of assuming the
20 answer is going to be 15 micrograms, and
21 choose whether to begin the bottling so that
22 there would be some product available, even

1 before waiting for the immunogenicity data.

2 I think that's the decision that confronts us.

3 MEMBER PAVIA: I think what Robin

4 has made clear is that the FDA has not yet

5 opined that they would license vaccine at the

6 existing dose based on strain change.

7 However, it seems that it's pretty easily

8 allowed for. It could be a decision they

9 reach. I think that it would be ideal if the

10 FDA tell us where they are with the

11 deliberations, and when they expect to

12 finalize those today. If they can't, I think

13 that would be extremely important for this

14 Board to be kept up-to-date about the progress

15 and the speed of deliberations by the FDA.

16 CAPT. SAWYER: That was Andy

17 Pavia.

18 MEMBER GELLIN: This is Bruce

19 Gellin. I missed the front end of this, so if

20 I'm treading on areas you've already talked

21 about, just fast forward me. But it seems to

22 me, John, if I understood you right, the

1 question you're asking Robin is the question
2 we think is a question to the Board. Given
3 what you see, given these things, should we go
4 ahead, at risk with no known data on what a
5 dose would be. Go ahead and do what would be
6 done for seasonal. We know that there will be
7 shortly thereafter, and, again, it's hard to
8 know exactly when the information will be
9 available for clinical trials to determine
10 that, but if things aren't going to go
11 perfectly. And if you thought things were
12 going to happen the following Monday, and they
13 were two Mondays later, now you've lost two
14 weeks. So, my question really to the Board
15 is, what is their recommendation on pursuing
16 this line, knowing that you're going to go
17 ahead and formulate in the absence of data,
18 but do it on a historical basis of what you
19 would hope would be the case.

20 And then the subsequent question
21 is, how much? I mean, well, the vaccine is
22 going to be rolling in over time, and Robin

1 can tell us how much would be even available
2 on not only August 15th, which is probably a
3 Sunday now that we look at it, but how much
4 would be available. But, then what's your
5 assessment of, given all the uncertainties,
6 how much should we go ahead and bottle on
7 August 15th to be ready for something
8 September 15th? If you've already talked
9 about that -

10 MEMBER GRABENSTEIN: No, no, no.
11 That's well phrased. What does the Board
12 think?

13 MEMBER ROSE: Before we do we have
14 to wait until August 15th to make that
15 decision?

16 MEMBER GRABENSTEIN: Robin, what's
17 the earliest date on which that bottling
18 decision will be made?

19 MEMBER ROSE: I understand August
20 15th is the latest date to have it ready by
21 September 15th, but why not make a decision
22 now to have some ready for September 1,

1 instead of September 15th?

2 DR. ROBINSON: Well, there's two
3 things right now, one is the fill finish of
4 seasonal influenza is ongoing right now. They
5 will be going through a portion of August, so
6 that our intentions were not to interfere with
7 that, so they will be finishing late this
8 month, in early August. So, August 15th
9 allows them to do the changeover to
10 formulation and filling the fill sites, so the
11 15th is a reasonable date that we could
12 actually start.

13 MEMBER ROSE: Okay.

14 MEMBER PAVIA: Robin, let's just
15 understand the parameters. If we begin fill
16 and finish on August 15th, of what the current
17 lab has on hand, or expects to have on hand by
18 then, it would be available for distribution
19 roughly 30 days later. If we make the
20 decision when the immunogenicity studies are
21 in hand, the first round of this minimum data
22 set, and for argument's sake we say that's

1 September 15th, so we begin fill and finish
2 that evening, when does that become available?

3 DR. ROBINSON: October 15th.

4 MEMBER PAVIA: A 30-day lag time.

5 DR. ROBINSON: Yes. Just one
6 slight thing there. We would, again, have
7 product by September 15th if we started
8 filling on August the 15th. And it would be
9 approximately about 60 to 80 million.

10 MEMBER GRABENSTEIN: It wouldn't
11 all have to be processed.

12 MEMBER GELLIN: So, just to be
13 clear, on August 15th you have 60 million bulk
14 antigen, you potentially have to play with to
15 finish some portion or all of it. Is that
16 right?

17 DR. ROBINSON: That is correct.

18 MEMBER GELLIN: So, then given
19 that -

20 MEMBER GRABENSTEIN: Which, if I
21 remember correctly, is at least two or three
22 tiers in the prioritization scheme of the

1 nation, or the old one, anyway.

2 MEMBER GELLIN: Well, I wouldn't
3 be wedded to that. I would just think more
4 about what -- you've seen the planning
5 scenarios, I hope, from CDC about what they're
6 thinking about to envision venues. But I
7 think the question is, you can pick some of
8 the subsets. I mean, ACIP will have that
9 whole discussion about prioritization, as
10 well. But, again, I just wanted to hear sort
11 of nominally, if the idea was one that you
12 were endorsing. And then, second, how you
13 would approach what percentage of the 60
14 million available doses on that now Saturday,
15 August 15th, you would opt to put into
16 bottles?

17 MEMBER PAVIA: This is Andy. The
18 second piece that we want to understand, I
19 think, is the risk. If you bottle at 15
20 micrograms per 0.5 ML, it's certainly
21 practical and feasible to give .25 ML or 1 ML
22 of the most populations, not to the youngest

1 children. Would there be regulatory barriers
2 to doing that? Are we in that vaccine at risk
3 of being wasted, if we're within a one
4 dilution, basically.

5 MEMBER GRABENSTEIN: Anyone from
6 FDA wish to comment?

7 DR. ROBINSON: This is Robin
8 Robinson from BARDA. I just wanted to remind
9 people that in 2004, the NIH undertook studies
10 doing something similar, showing that there
11 was a sort of a dose varying effect with the
12 amount of antigen at that time.

13 MEMBER ROSE: Fine. The reason I
14 asked is my gut feeling in the absence of
15 regulatory or technical issues, things that I
16 haven't thought about, is that the risk is
17 relatively small compared to the upside of
18 committing at least a portion of that 60
19 million doses until the finish. And then the
20 second part of the question is how much? And
21 I'd love to hear other people.

22 MEMBER CANTRILL: Yes. This is

1 Steve Cantrill. Do we have an FDA opinion on
2 that in terms of if we move within the one
3 dilution range, that's still okay?

4 MEMBER GRABENSTEIN: This is John
5 Grabenstein. I'll speak from my own
6 experience, which is that it's not so much the
7 label on the vial, it's the package insert,
8 the prescribing information that accompanies
9 it, and declares the dose. You don't
10 literally have to have it on the vial, more or
11 less. I also say I'm subject to FDA
12 corrections, but it's mainly the accompanying
13 prescribing information, which can be changed.

14 MEMBER CANTRILL: So, we do have
15 some wiggle room there.

16 MEMBER GRABENSTEIN: I think.

17 MEMBER PAVIA: Yes. But
18 prescribing information could be developed
19 fairly rapidly between our nominal September
20 15th when the data package arrives. And I
21 don't know how long that needs to take, but
22 it's certainly much quicker than 30 days to do

1 the fill and finish process.

2 MEMBER CANTRILL: Steve Cantrill,
3 again. It makes sense to me that we commit
4 some amount of the vaccine to being finished
5 at the 15 microgram level. Again, since we
6 can change that based on -- if we gather
7 further immunogenicity information further
8 down the line, we can change the prescribing
9 information. And the trigger will not
10 necessarily be pulled on September 15h to
11 start the vaccination, but at least, it seems
12 to me, that gives us the most defensible
13 position in terms of risk-benefit, in terms of
14 hedging our bets.

15 MEMBER JAMES: This is Jim James.
16 I just don't see the downside to what Steve
17 just enunciated.

18 MEMBER GELLIN: This is Bruce. I
19 think the only downside, which I don't know,
20 is what Andy asked, is what's the risk? Will
21 you somehow waste this if you go ahead and use
22 it? So, I think we just need to be clear that

1 that's not the case, to be able to make this
2 equation.

3 MEMBER GRABENSTEIN: So, I'm not
4 hearing anybody saying oh, don't, stop, wait,
5 don't take this risk. So, just to crystallize
6 the conversation for the purposes of the
7 document and our vote, let me propose that we
8 do it this way; and that is, that we recommend
9 to the Department that on or about August
10 15th, they proceed to package several tens of
11 millions of doses, a precise number to be
12 determined by the Department, but we're giving
13 an order of magnitude based on what you know
14 at that point, which will be another month
15 from now.

16 MEMBER CANTRILL: Is that a
17 motion, John, because I would second that.

18 MEMBER SCANNON: Yes. This is Pat
19 Scannon. I think the only thing I would add
20 to that is that the 60 to 80 million doses
21 that Dr. Robinson talked about is what they
22 will have by that date. There will be more

1 vaccine following that, so that if you can
2 adjust dose, I don't see any reason you
3 shouldn't go ahead and bottle, and prepare the
4 available doses that are available by
5 September 15th.

6 MEMBER ROSE: This is Eric Rose.
7 Between August 15th and presumably early
8 September, when we'll have immunogenicity
9 data, how much actually can be filled and
10 finished?

11 MEMBER GELLIN: This is Bruce.
12 Let me just propose that one of the things we
13 talked about endlessly since we started all
14 this, is the importance of revisiting
15 strategies. So, I guess the question is, I
16 think what I understand is that you've got a
17 statement about what you want to do on August
18 15th. And then maybe that's up to you, but
19 then you consider whether you keep going, or
20 revisit it on date something, to see whether
21 or not that continues to make sense.

22 MEMBER ROSE: Yes, but when you

1 get the immunogenicity data, that would seem
2 to be the next decision point.

3 MEMBER SCANNON: So, the
4 prevailing sentiment appears to be to go ahead
5 with the 15 microgram dose until such time as
6 the immunogenicity data are available to see
7 if there's any dose adjustment.

8 MEMBER ROSE: I would agree with
9 that.

10 CAPT. SAWYER: Okay. I need
11 people to say their names, please. The person
12 who made the previous comments, Eric Rose.
13 Now, who agreed?

14 MEMBER CANTRILL: Steve Cantrill.

15 CAPT. SAWYER: Okay.

16 MEMBER SCANNON: Well, it was Pat
17 Scannon somewhere in there.

18 CAPT. SAWYER: Okay, Pat.

19 MEMBER GELLIN: So, this is Bruce.
20 The way that you phrase that, it implies
21 whatever you got, put it in a vial. Is that
22 what I understood? When you start, do it, and

1 then keep going until you're told not to?
2 That's different than some portion of 60, or
3 something.

4 MEMBER ROSE: Well, that's why I
5 asked the question, as to how much of this can
6 you do over that interval between the first
7 decision point and the second decision point?
8 If you can do all of it, then I think there's
9 a discussion around it.

10 MEMBER GRABENSTEIN: This is John
11 Grabenstein. I don't believe we should take
12 a finite number today, because we don't know
13 population sizes of the various cohorts. We
14 haven't heard their discussion to approach
15 that. ACIP will be considering it, Advisory
16 Committee on Immunization Practices, at the
17 end of July meeting, presumably, so that -- I
18 think our role is to decide whether or not to
19 say we want some product in mid-September, and
20 then as the other groups weigh in, then the
21 clarity of HHS action becomes clear.

22 MEMBER PAVIA: This is Andy. I

1 agree entirely with what John just said. I
2 think it's important that the number of doses
3 be informed in part by the target groups. And
4 another key element, which is the capacity
5 that the states develop to immunize with that
6 first batch of vaccine, so if only 20 million
7 doses can be administered in the first four
8 weeks after September 15th, there's not much
9 point delivering 60 or 80 million doses. So,
10 I would adopt John's wording.

11 MEMBER GRABENSTEIN: So, I have
12 the word processor, so what I've done is gone
13 to page 2 at the H1N1 vaccine section first
14 bullet. And what I have drafted at the moment
15 is based on available data, the NBSB
16 recommends that HHS set a goal of having
17 several tens of millions of doses of
18 monovalent A/H1N1 vaccine available for
19 clinical use on or about September 15th, 2009.

20 MEMBER CANTRILL: Steve Cantrill.
21 I would say September 15th, or earlier, if
22 possible.

1 MEMBER JAMES: Or no later than.

2 MEMBER CANTRILL: Yes. Because if
3 you consider the logistics of getting that
4 vaccine out into the population, and actually
5 having it administered, again, we're playing
6 against the odds here. If it shows up in
7 early September, we're still going to be in a
8 world of hurt.

9 MEMBER GRABENSTEIN: Okay.

10 MEMBER JAMES: I would agree. Jim
11 James, with what Steve said. And, secondly,
12 just a question, do we need to clarify that
13 it's non-adjuvanted vaccine that we're
14 recommending?

15 MEMBER GRABENSTEIN: I'll add that
16 adjective, yes. I'll change it to by September
17 15th, and add unadjuvanted.

18 MEMBER JAMES: That sounds good.

19 MEMBER SCANNON: Do you want to
20 add wording about modification to that,
21 subject to later clinical data?

22 MEMBER GRABENSTEIN: I've got

1 based on available data at the entrance to the
2 sentence, beginning of the sentence.

3 MEMBER SCANNON: All right. Good.

4 MEMBER GRABENSTEIN: And, I want
5 to remind you we've got two other sections of
6 the document to cover, but are there other
7 parts of the vaccine section that you want to
8 discuss?

9 MEMBER ROSE: Well, if the
10 clinical data in September confirms that the
11 15 microgram dose is effective, then the
12 balance of what's available, as soon as
13 feasible, ought to be made available.

14 MEMBER GRABENSTEIN: That was Eric
15 Rose. Right.

16 MEMBER ROSE: Yes.

17 MEMBER GRABENSTEIN: Okay. Other
18 comments on the vaccine?

19 MEMBER ROSE: And, I guess a
20 corollary to that, if not, then a dose
21 adjustment ought to be rapidly made.

22 MEMBER GRABENSTEIN: Right.

1 MEMBER SCANNON: This is Pat
2 Scannon. I think what Eric means, is that you
3 wouldn't want this recommendation to become a
4 barrier to more extensive use of the vaccine.

5 MEMBER ROSE: There's a point of
6 iteration in this process that will come when
7 the clinical data with regard to 15 microgram
8 dose becomes available.

9 MEMBER GRABENSTEIN: Right. So,
10 that's covered in the following sentence about
11 additional studies with additional supplies.
12 And we've got, according to evolving
13 epidemiology multiple places in the document.

14 MEMBER PAVIA: This is Andy. Let
15 me ask one more question for Bruce, Robin, and
16 Anne. Would it be useful for this group to
17 reconvene by telephone after the ACIP meeting,
18 say in the first few days of August, to
19 consider a target size, and perhaps we could
20 be informed by -- at that point, by some of
21 the information coming back to Jay Butler's
22 group about state capacity?

1 MEMBER GRABENSTEIN: Is that one
2 of the tasks assigned to the ACIP, to pick a
3 population size?

4 MEMBER GELLIN: No, they're going
5 to discuss about the sequencing. They're
6 going to look -- they're going to do what they
7 always do, which is look at the epidemiology
8 and trying to figure out how best to apply a
9 vaccine for the largest benefit. And, the
10 epidemiology will come to some degree with
11 sizes. If you're going to say healthcare
12 workers, somebody is going to figure out that
13 size, so there will be those numbers that come
14 from it.

15 I think, Andy, that's a good idea.
16 And I don't know - again, I apologize for
17 missing the front end of this - but I would
18 think that that gives you an opportunity to
19 revisit a bunch of discussions that have
20 happened, not only that one, but the VRBPAC
21 that's going to happen next week. So, I can't
22 speak for Nicki, but if she's not here, I

1 would suggest that you organize something
2 around that time to be able to revisit these
3 discussions in light of lots of information
4 that will flow at at least those two meetings.

5 MEMBER PAVIA: Thank you. In any
6 case, the Department seeks guidance from us
7 which you will or won't follow as to whether
8 to commit some portion, or all of those \$80
9 million to fill and finish.

10 MEMBER GELLIN: Nicki is on?

11 MEMBER CANTRILL: This is Steve
12 Cantrill. I'd like to generalize your
13 suggestion. I think that we should probably
14 schedule NBSB teleconferences once a month for
15 the next six months. Now, Leigh, you can tell
16 me if that's completely out of line, and
17 what's involved, but I would like to get that
18 in the Federal Register so we can -- and we
19 can always cancel the meeting, if we have no
20 business. Because, obviously, this is a
21 dynamic situation, and we're going to have to
22 stay on top of it.

1 MEMBER GRABENSTEIN: So, in the
2 room, the HHS folks are taking that under
3 advisement, and we'll hear from them I think
4 towards the end of the call.

5 MS. MAZANEC: Thinking about it,
6 it can be more than once a month.

7 MEMBER GRABENSTEIN: So, we have
8 on the line Admiral Schuchat from CDC, and Jay
9 Butler, as well, if they have anything else to
10 add.

11 RADM SCHUCHAT: Yes, this is Anne
12 Schuchat. I'm sorry, I just was able to join,
13 and I'm not sure if there were questions about
14 vaccine planning, but I wanted to introduce
15 people who don't know him to Jay Butler, who
16 was the Health Officer of Alaska who's
17 rejoined us at CDC to lead our Vaccine
18 Implementation Planning Task Force, that is
19 working closely with Public Health and others
20 in terms of the implementation piece of
21 things, as well as the monitoring and
22 evaluation issues.

1 MR. BUTLER: Thank you, Anne.
2 I've been a mute participant, Star One
3 wouldn't get me in, but I have been listening
4 closely.

5 MEMBER GRABENSTEIN: Thank you.
6 So, I'm going to take one more comment on
7 vaccine. We're going to go talk about
8 antivirals, then diagnostics, and come back to
9 vaccine, if we need to. Are there any Board
10 comments about the antiviral, and other
11 therapeutic agents section?

12 MEMBER ROSE: Eric Rose. Maybe as
13 a specific nuance, now that we've clarified I
14 think substantially September 15th, if we're
15 seeing a second wave that's in late August or
16 early September, it sounds like the only thing
17 that we're going to have available at that
18 point would be antivirals. And the issue of
19 whether or not they should be used for post-
20 exposure prophylaxis, or even prophylaxis in
21 high-risk groups, or certain groups, I just
22 put out on the table.

1 MEMBER PAVIA: Eric, this is Andy.
2 Let me weigh in, if I can, on that.
3 Antivirals is sort of what I do, and I think
4 getting into the weeds of antiviral strategy
5 may not be the best use of our group's
6 expertise. I wonder whether there are other
7 groups that include more people who've done
8 the resistance work, who've done the clinical
9 trials, who've modeled it, who are the
10 appropriate people to contribute. That's just
11 my thought. But I've similarly struggled with
12 prophylaxis versus treatment since April of
13 2004.

14 MEMBER SCANNON: Yes, this is Pat
15 Scannon. I think that the -- and, Andy, I
16 think your comment is one -- I think that one
17 concern that I have is particularly thinking
18 about the immuno-compromised populations, and
19 their likelihood at having less than desirable
20 vaccine response. So, I'd appreciate your
21 comments about that.

22 MEMBER PAVIA: On that, speaking

1 one way or the other on that particular issue,
2 I just think that this Board comments on broad
3 countermeasure strategy, and I think we're
4 getting down into a CDC level of clinical
5 treatment advice. And I appreciate Anne's
6 thoughts, and Bruce's, as to whether it's best
7 handled by NBSB, or other mechanisms? We
8 could spend a lot of time on this. Five years
9 later we don't have the right answer, we need
10 one now. There are missing pieces to this
11 puzzle.

12 MEMBER GELLIN: Just quickly,
13 Andy. Do you have another mechanism in mind
14 that you're aware of?

15 MEMBER PAVIA: I was actually
16 thinking that the ad hoc advisory that Lyn
17 Finelli and others have been using for their
18 antiviral guidance, as well as what Tony does
19 for ACIP are probably appropriate advice. But
20 I'm willing to entertain any other idea on
21 this.

22 MEMBER GELLIN: Yes. So, maybe

1 somebody who can speak for them, can speak for
2 them.

3 MEMBER JAMES: This is Jim James.
4 I would just like to interject. I totally
5 agree with Andy, the vaccine question is
6 complex enough, but I think that's something
7 that is much more clear in terms of what type
8 of recommendation our Board can make back to
9 try and get the advice they're looking for.

10 In terms of the antivirals, I
11 mean, weeds is being euphemistic.

12 MEMBER GRABENSTEIN: Okay. So, I
13 want to move on. So, we're at the minute that
14 we should be going into public comment. I'm
15 going to ask the public to be patient with us,
16 just another couple of minutes while I'll see
17 if there are any Board discussion points with
18 relation to the diagnostic section.

19 MS. HIGGS: Before we leave the
20 antivirals, this is Libby Higgs from NIH, one
21 update that Robin alluded to was with IV
22 Zanamivir, at the time of our meeting GSK

1 stated that they were not going to move
2 forward with data for an EUA use of their
3 intravenous product. Then they reversed that
4 decision and they said that the NBSB meeting
5 is quite helpful with regard to their decision
6 making process. So, I wanted the Board to
7 know that. I had a call from them this week
8 saying they couldn't be on this call, but
9 wanted me to convey that to you all.

10 MEMBER GRABENSTEIN: Thank you. We
11 appreciate that.

12 MEMBER ROSE: John, this is Eric
13 Rose. I don't believe -

14 (Simultaneous speech.)

15 MR. SCHOENBURGER: I wanted to
16 question whether the National Biodefense
17 Science Board's prerogative to make a
18 recommendation with regard to the changing of
19 the fill of the seasonal vaccine to the
20 pandemic vaccine now, given that it sounds as
21 if the Board has made a tentative decision to
22 just not wait for clinical data, and to accept

1 the 15 microgram dose before such data are
2 available. Is that even a possibility? I
3 know people said that the plan was for the
4 companies to continue for the next month, I
5 believe, filling vials with the seasonal
6 vaccine. Is that a fixed thing, or can the
7 National Board recommend that no, we would
8 like to have the pandemic strain earlier?

9 MEMBER JAMES: This is Jim James,
10 again. Before answering, I don't think--maybe
11 I'm wrong--I don't think that has to be an all
12 or none. Maybe one or two of the producers
13 could be so informed.

14 MEMBER GELLIN: This is Bruce
15 Gellin, and maybe Robin will weigh in. But I
16 would -- maybe this is one where we need a few
17 facts before we make any recommendations, to
18 try to find out what the implications or
19 impacts would be of such a recommendation,
20 where there may be other flexibilities in the
21 system. So, I think I would frame it that
22 way, and get back to you about what the

1 options may be, rather than pulling the
2 trigger on this.

3 MEMBER GRABENSTEIN: And I assume
4 that they are so far along that almost all the
5 work has been invested.

6 MEMBER GELLIN: Again, I think
7 that that's where we need to know where this
8 stands, and what the risks and benefits of
9 such a -- of acting on such a recommendation
10 might be.

11 MEMBER GRABENSTEIN: Robin, a
12 quick comment on this?

13 MEMBER DRETCHEN: This is Ken
14 Dretchen. Again, if we're going to be meeting
15 potentially in two weeks, you know, the
16 beginning of August -

17 (Background noise.)

18 MEMBER DRETCHEN: -- make that
19 call.

20 MEMBER GRABENSTEIN: Okay. Thank
21 you. If there are any comments about
22 diagnostics, speak now, or you're going to get

1 overwhelmed by the other contents.

2 MEMBER ROSE: Before we leave
3 antivirals, I just want to state that I do not
4 believe, maybe a minority do, but I don't
5 think the question of how to use them,
6 particularly in the absence of vaccine, in the
7 presence of a pandemic wave is an in the
8 weeds, tactical question. I think it's a
9 strategic question.

10 MEMBER GRABENSTEIN: All right.

11 MEMBER ROSE: Drugs and quarantine
12 are the only strategy you have left then.

13 MEMBER GRABENSTEIN: Well, so,
14 Robin framed it up actually at the very
15 beginning, where he talked about should we
16 limit the use of the antivirals and save them.
17 So, let me turn to all the federal officials
18 who are around me and ask, which of the
19 advisory committees is going to address that
20 question? Have you put it to any of them yet?
21 Antivirals is typically part of the ACIP
22 supplement with the MMWR. Is that going to be

1 a question for that group, or do you want us
2 to go do a work stream with this Board to get
3 you that answer?

4 MEMBER GELLIN: This is Bruce
5 Gellin. I'm not aware that that antiviral
6 question of that ilk has been asked to a
7 federal advisory committee. When there was a
8 seeming shortage of antivirals several years
9 ago, there was a -- I think it was a
10 recommendation that came out of, ultimately,
11 IDSA. I don't think CDC actually weighed in
12 on that one, about limiting home stockpiles to
13 ensure that there was enough for seasonal flu.
14 That was, I think, 2005. So, it's not clear
15 to me, and maybe Anne could talk about what
16 ACIP might be prepared to do, but I don't
17 think that something like that, of shifting
18 the clinical use of a drug like this has been
19 something that these vaccine advisory
20 committees have done before.

21 RADM SCHUCHAT: Let me make a few
22 comments, and then Tony Fiore may want to add

1 to this. The ACIP traditionally does make
2 antiviral recommendations in conjunction with
3 their annual influenza vaccine
4 recommendations. And they did deliberate
5 quite a bit about this this year for seasonal
6 influenza because, as you know, there's been
7 challenges with seasonal H1N1, also Tamavir
8 resistance, and they issued some -- and then
9 there's been need to keep clinicians updated
10 on that matter.

11 CDC has also issued interim
12 guidance about antiviral use for -- in the
13 context of the H1N1 challenge. And those, I
14 think, have probably been updated at least
15 once since they were originally issued. At
16 the ACIP meeting in June, there was discussion
17 about updating the antiviral recommendations.
18 Remember that in most people you don't know,
19 which influenza you were exposed to for post-
20 exposure prophylaxis, or for treatment, you
21 don't know what kind of influenza you have
22 when those decisions are being made. So, I

1 think this was something that we both have had
2 the -- ACIP making progress on, and then, as
3 Andy mentioned, these various ad hoc groups
4 that included clinicians and outside experts,
5 so that more real time information could be
6 incorporated.

7 The general philosophy has been
8 focusing on treatment and use of prophylaxis
9 for those who had risk factors for
10 complications of influenza, and I think
11 there's a process in place to get those
12 updated. But, Tony could probably comment
13 further on this, because he was closer to it
14 all.

15 CAPT. FIORE: Right, thanks. This
16 is Tony Fiore, Influenza Division, CDC. The
17 ACIP did propose on antiviral recommendations
18 this past June, and focus was on treatment,
19 prophylaxis recommendations are bound to be too
20 rapidly changing, and too subject to change
21 based on supply, and resistance, and so on.
22 So, ACIP suggested that CDC maintain a website

1 that keeps that updated.

2 MEMBER GRABENSTEIN: Okay. So,
3 I'm going to put this tangent of the
4 conversation on hold for a little bit, whether
5 there's some future work stream for some
6 committee or not, on hold for a minute,
7 because the public has been very patient, and
8 I would like to ask the operator to repeat the
9 instructions for how to indicate on your phone
10 line that you'd like to make a comment. We
11 have received one by email that we want to
12 address. And, operator, if you would go
13 ahead, please.

14 OPERATOR: Again, if you would
15 like to ask questions on the phone line,
16 please press Star and the number one on your
17 telephone keypad.

18 CAPT. SAWYER: Okay. While you
19 are all queuing up for the public talk, I
20 would like to read the one comment that we
21 received this morning. This says, "Dear NBSB:
22 I am not able to phone in on July 17th, but I

1 would like to put forward my deep concerns
2 about an adjuvant being used in the flu
3 vaccines being made to counteract the novel
4 H1N1 flu virus. I am a homemaker. I have two
5 sons, both with allergies, and history of
6 asthma. I am very, very worried about the
7 novel H1N1 virus, but I am even more worried
8 about the potential use of the MF59 squaline
9 vaccine adjuvant. I think MF59 could cause
10 autoimmune diseases to develop in my sons.

11 I do understand that the vaccine
12 production is challenging, and that the
13 current production system is having problems
14 getting enough antigen produced. Even so, I
15 hope people will be informed as to which
16 vaccines have adjuvants and which do not.
17 Please let us have a choice in the matter.

18 I would definitely have my sons
19 get a flu vaccine this fall, if I knew it had
20 no adjuvants. If it comes with adjuvants,
21 particularly if the adjuvant is MF59, I would
22 advise my sons to avoid the vaccine. I would

1 also advice my community about my deep
2 concerns. In these challenging times, we are
3 all hoping that the upcoming flu season is
4 mild. If may not be, but please don't have us
5 go from the frying pan to the fire by putting
6 out vaccine that harms us long-term.

7 Everything that I have read about MF59 makes
8 me think the numbers of reactions to it would
9 far out number the reactions that occurred in
10 the 1976 flu vaccination program. Please
11 protect us. Ellen Rice, Olympia, Washington."

12 MEMBER GRABENSTEIN: Thank you
13 very much. Operator, if you'll tell us what
14 calls we might have in the queue.

15 OPERATOR: Yes, sir. Your first
16 question comes from Nicholas Kelley.

17 MR. KELLEY: Hello?

18 MEMBER GRABENSTEIN: Yes. Please,
19 go ahead.

20 MR. KELLEY: My question is
21 related to -- we've heard a lot about the work
22 going into the vaccine production, and

1 antigen, what could be there, but I heard
2 nothing about whether or not there's enough
3 syringes in the FNS for the distribution of
4 these millions of doses for the fall. And I
5 was wondering if the Board could address that,
6 or provide some comment to that.

7 DR. ROBINSON: This is Robin
8 Robinson, if I could address that, please,
9 from BARDA.

10 MEMBER GRABENSTEIN: Yes, please,
11 Robin Robinson.

12 DR. ROBINSON: Yes. We have been
13 in contact with the syringe and needle
14 manufacturers, the three that will be
15 providing, and we are making arrangements with
16 the appropriations that were just made
17 available from Congress to procure those, and
18 that would be commensurate with the amount of
19 vaccine that would be going out.

20 MEMBER GRABENSTEIN: Thank you.
21 Next question, please?

22 OPERATOR: The next question comes

1 from David Schonfeld.

2 MR. SCHONFELD: Hello. I had a
3 question regarding the vaccine study update
4 that was given. And may have been said, but
5 I didn't hear any information about the issue
6 of children, specifically, given that they're
7 going to be, obviously, a high-risk
8 population.

9 MEMBER GRABENSTEIN: Dr. Robinson,
10 can you answer that?

11 DR. ROBINSON: There will be
12 pediatric studies that will be occurring for
13 each of the vaccines, both by the
14 manufacturers and NIH.

15 MR. SCHONFELD: Are those studies
16 already planned for next week, or the
17 following week, as you described, or are they
18 coming later?

19 DR. ROBINSON: It depends on the
20 manufacturer, but the guidance given by FDA
21 was that they could start either at the same
22 time, or just right after the first dose was

1 given for the adult, we'd see if anything
2 adverse would happen.

3 MEMBER GRABENSTEIN: Thank you.
4 Next, please?

5 OPERATOR: Your next question
6 comes from Erin Mullen.

7 MS. MULLEN: Hello. My question
8 is in regards to the vaccine prioritization.
9 In looking at the recommendations from the
10 NBSB, I see that they look like the focus is
11 going to be on -- it would be on an age-basis
12 rather than the previous recommendations,
13 which had included critical infrastructure and
14 healthcare workers as priority groups. Is the
15 NBSB moving away from a recommendation to
16 include priority for critical infrastructure
17 and healthcare workers?

18 MEMBER GRABENSTEIN: So, this is
19 John Grabenstein. The way our report is
20 written is focusing on those at greatest risk
21 of disease, and one of our assumptions that
22 Dr. Pavia mentioned is that there's unlikely

1 to be the social disruption, as had been
2 feared in the highest hurricane-like
3 categories of a pandemic. But I'll let
4 anybody else from HHS or the Board comment, if
5 there's something additional to say.

6 MEMBER PAVIA: Yes. This is
7 Andrew Pavia. One of the things we did was to
8 really think who makes specific
9 recommendations, and recommendations on
10 specific target groups are developed with the
11 advice of ACIP and CDC, so we are not, in
12 fact, changing recommendations or priority
13 groups. What we're doing for planning
14 purposes, we're making some assumptions about
15 what the epidemiology suggested were likely to
16 be target groups after ACIP has given it due
17 consideration.

18 MEMBER GRABENSTEIN: Great. Thank
19 you. Next question, please?

20 OPERATOR: Your next question is
21 from Jeff Bowman.

22 MR. BOWMAN: Yes, thank you.

1 First of all, recognizing the importance of
2 the human capital healthcare workers,
3 alongside the supplies of retrovirals,
4 respirators, et cetera, et cetera, my question
5 pertains to healthcare worker exposure
6 management, and the significance related to
7 vaccine, diagnostic testing, and antivirals.
8 And I'm wondering if there have been any
9 provisions for healthcare worker surveillance
10 as a part of monitoring vaccine effectiveness
11 following confirmed exposures to H1N1. And
12 the second part of that is, are there any
13 provisions for hospitals and providers in
14 order to obtain confirmatory H1N1 testing when
15 state health departments are limiting access,
16 and the private labs do not possess the
17 confirmatory test.

18 As you may be aware, the
19 significance of managing healthcare worker
20 exposures yields not only potentially sick and
21 ill healthcare workers, and contributing to
22 nosocomial spread, but it also undermines our

1 infrastructure of people. And, on top of
2 that, there's quite a bit of cost associated
3 with not only the lost time, but also the cost
4 associated with the use of a critical supply
5 of antivirals.

6 And I think with the limits on
7 testing, and limited availability, we're going
8 to see increased use of the antivirals. And
9 I'm concerned that with the limits we have on
10 diagnostic testing, it will disrupt our
11 epidemiological investigations, and increase
12 the utilization of a critical resource.

13 MEMBER GRABENSTEIN: This is John
14 Grabenstein. We do make a comment about
15 encouraging the dissemination of a bunch of
16 these laboratory tests and reagents to
17 clinical care laboratories more than just
18 public health laboratories, I think alluding
19 to one of the issues you cited. Andy, do you
20 want to make any other comments about
21 surveillance, or the like?

22 MEMBER PAVIA: I think that as far

1 as what's going on, that's really a key
2 question. I think it's pretty clear from the-
3 - our diagnostic recommendation that we
4 recognize and we're really emphasizing the
5 importance of having accurate diagnostics
6 available for a variety of reasons that have
7 to do with local epidemiologic control, as
8 well as management. The NVAC, the National
9 Vaccine Advisory Committee, which is handling
10 issues about safety monitoring
11 recommendations, the night before last in
12 discussions with CDC and a fairly complex
13 discussions about vaccine effectiveness and
14 safety monitoring amongst healthcare workers,
15 and I know that's being considered by CDC. I
16 don't know if Jay or Anne want to comment.

17 MEMBER GRABENSTEIN: Anything else
18 from CDC on that? Okay. Are there any other
19 questions or comments from the public?

20 OPERATOR: There are no further
21 questions.

22 MEMBER GRABENSTEIN: Thank you.

1 Okay. So, let's come back to the Board
2 discussion. I want to -- we have 12 minutes
3 left in the hour, so I want to focus on the
4 procedural issue of conveying a document from
5 the -- adopting a document by the Board to
6 convey to the Secretary and the Department.
7 So far, the only change that we've made to the
8 document is on page 2 in that first section
9 within the H1N1 vaccine, the first bullet of
10 the H1N1 vaccine. And I'll just read it
11 again, and I'll make it a motion this time.
12 And if somebody wants to second that, that
13 would be great. And it would be substitution,
14 as follows.

15 "Based on available data, the NBSB
16 recommends that HHS set a goal of having
17 several tens of millions of doses of
18 unadjuvanted monovalent A/H1N1 vaccine
19 available for clinical use not later than
20 September 15th, 2009. To achieve this, HHS
21 should pursue", and the balance of the bullet.

22 MEMBER CANTRILL: John, Steve

1 Cantrill. I second that.

2 MEMBER GRABENSTEIN: Okay. Let me
3 just take a vote. I'm not Chair, I'm
4 Moderator. Leigh is Chair. Leigh can call
5 for the vote.

6 CAPT. SAWYER: Okay. So, I would
7 like to have a vote. Now, do you just want to
8 vote on all -

9 MEMBER GRABENSTEIN: No, just the
10 amendment.

11 CAPT. SAWYER: Okay. I'd like to
12 hear a vote from the members who agree that we
13 should make this change that was just read by
14 John Grabenstein. Let's go around. We need
15 your name. I'm trying to find my list of names
16 here. Okay. Here we go, Patricia -

17 MEMBER ROSE: Leigh, before we do,
18 should we get some other adoption of the rest
19 of the report unamended, unless there is
20 anything we -- and include those two together,
21 so we don't have to -

22 MEMBER GRABENSTEIN: We could do

1 that. Is there a -- let me ask if there is
2 people who object vigorously to that
3 amendment, and then we can just make it one
4 master adoption.

5 MEMBER ROSE: Yes.

6 MEMBER GRABENSTEIN: Any vigorous
7 objection? Okay. We'll save it for later for
8 the full vote. Roberts is turning over in his
9 grave, but that's okay. All right. Okay.
10 So, are there other -- should we return to any
11 other points of discussion from earlier? What
12 did I table? I tabled how to address
13 antiviral use, whether to change from a
14 strategic level, as opposed to clinical level
15 in terms of reserving certain category,
16 classes of antivirals, or whatnot. Was there
17 anything else that I -- just speak up, any
18 other points that you think we need to
19 address?

20 MEMBER JAMES: The motion you
21 tabled, is that -- are we going to discuss
22 that now, or is that tabled for future

1 discussion?

2 MEMBER GRABENSTEIN: Go ahead and
3 discuss it now.

4 MEMBER JAMES: Just quickly, I
5 totally agree, it's a strategic issue, but I
6 think it's something where when we're dealing
7 with the antivirals, we already have the
8 product. The recommendations will be made as
9 this thing unfolds.

10 With regard to the vaccine, I
11 think we have the ability to potentially
12 influence how we develop a new product, or
13 intervention. And that's why I think we need
14 to focus on the vaccine, and leave the
15 recommendations on specific use to other more
16 informed bodies.

17 MEMBER GRABENSTEIN: Thank you.
18 Other comments?

19 MEMBER ROSE: This is Eric Rose.
20 My understanding of the antiviral stockpile
21 for influenza is it's intended use is for
22 therapeutic use. And that there is no, or a

1 relatively small stockpile for prophylaxis.
2 My only point here is that if there is an
3 earlier wave of H1N1 that precedes the
4 availability of vaccine, though there is
5 antiviral drug available for therapeutic use
6 that have been stockpiled with that intent, I
7 think that consideration for using a portion
8 of it for prophylactic use, or that
9 feasibility, at least, ought to be considered.
10 And to not wait until we're confronted with it
11 at the time.

12 MEMBER GRABENSTEIN: All right.

13 MEMBER PAVIA: This is Andy. I
14 totally agree that it needs to be discussed.
15 There are a lot of elements that go into that
16 discussion, how to fix Zanamivir, the speed
17 with which you burn through drugs using it for
18 prophylaxis rather than treatment.

19 MEMBER ROSE: Sure. I agree.

20 MEMBER PAVIA: So, I think that
21 whoever addresses that needs to start with --
22 needs to put a significant amount of time

1 into it, and needs to review the data that we
2 have, and the data that we need in some
3 detail. Our plate is pretty full. We can
4 certainly tackle that, if we want, but we're
5 certainly not going to be able to get to it on
6 this phone call, or in this document.

7 MEMBER GRABENSTEIN: Right.

8 MEMBER ROSE: I'll ask again, I
9 fully agree. My only point is that I just
10 want to have some comfort that somebody is
11 going to be doing it. And I haven't heard
12 that yet. The ball hasn't landed anywhere.

13 MEMBER GRABENSTEIN: All right.
14 So, even in the half-day discussion we had in
15 Bethesda, we acknowledged that we scratched
16 the surface with antivirals, so I think the
17 question is, does the Board -- does the NBSB
18 take this issue of the antivirals on in the
19 relative short term. It may mean more
20 meetings for us, or travel, potentially
21 linking up with the expertise of CDC, and
22 perhaps with ACIP given their previous work in

1 the antiviral section of the MMWRs. Should we
2 take this one? Should we defer it to another
3 board, or should we not get involved? I think
4 that's the question for us?

5 MEMBER SCANNON: This is Pat
6 Scannon. We could put wording to the extent
7 that consideration should be given to
8 addressing this, whether it's done by us, or
9 others. And, again, I think our
10 recommendations are going to be seen by other
11 advisory boards, and this could be helpful in
12 their deliberations.

13 MEMBER BERKELMAN: This is Ruth
14 Berkelman. We could wait, and have HHS take
15 it under advisement that we are recommending
16 this be considered. And if they don't have
17 the ball land somewhere, then the NBSB takes
18 it up.

19 MEMBER ROSE: I agree with that.

20 DR. ROBINSON: John, this is Robin
21 Robinson from BARDA.

22 MEMBER GRABENSTEIN: Yes.

1 DR. ROBINSON: The Department
2 deliberated on this in 2007, and came to the
3 conclusion, and then as was reasonable,
4 recently had started reopening the
5 deliberations again on the questions of
6 prophylaxis, and to whom, and how much. So,
7 any assistance you can provide would go a long
8 way with what we're already doing.

9 MEMBER GELLIN: If Tony Fiore, if
10 he's on, he might want to speak to the ACIP's
11 Influenza Working Group, which is, my guess,
12 would be the one place where there's the
13 technical expertise for this to land. If he
14 wants to speak to that, fine. Otherwise, I
15 think what you propose is this should be
16 looked at by somebody, get back to us about
17 who, and then if there's nobody else doing it,
18 then consider NBSB doing it. Tony, are you
19 on?

20 CAPT. FIORE: Yes, I'm on. As a
21 couple of the earlier subjects, Dr. Pavia and
22 Dr. Robinson mentioned planning about use of

1 antivirals for chemoprophylaxis, and the
2 scenarios that had antivirals being used
3 extremely rapidly when you opened things up
4 for chemoprophylaxis. That's important, and
5 I'm not sure that's changed. We have had a
6 wide range of views when we talked about this
7 our work group called many, for example, who
8 represent local and state public health
9 departments have been concerned about
10 widespread use and long-term use of
11 chemoprophylaxis quickly depleting antiviral
12 stockpiles. And I think that sort of also
13 speaks to the concerns that the modelers had
14 when this was discussed back in 2007 about how
15 quickly one might go through prophylaxis. We
16 can keep revisiting it, and certainly in the
17 context of changes in severity of illness or
18 particular groups that are at higher risk, a
19 view that you might be -- where
20 chemoprophylaxis might be focused on.
21 Certainly, we can take it up.

22 MEMBER GRABENSTEIN: All right.

1 So, what I've heard -- so, at a minimum, the
2 Board is offering to HHS that if they wish us
3 to address this question, or assist in
4 addressing the question, we are available to
5 assist you. If somebody from the Board wants
6 to make a stronger motion, now would be the
7 time to do it.

8 CAPT. FIORE: Sir, this is Tony
9 Fiore. I forgot to add one thing, which is
10 when Anne talked about antivirals, we
11 typically do discuss within our work group
12 with clinicians, such as Dr. Pavia, to discuss
13 them. It is a one vaccine focused work group.

14 MEMBER JAMES: Dr. James here. If
15 what John said was put forth as a motion, I
16 would second that.

17 MEMBER SCANNON: Well, coming back
18 - this is Pat Scannon. Coming back to Eric
19 Rose, what he raised, I don't want to speak
20 for Eric, but what he raised, that I heard
21 was, there's a particular issue if the H1N1
22 virus starts showing up in August before

1 vaccine is available. So, I think that it's
2 not just a matter of ongoing consideration of
3 even prophylaxis using antivirals, it's
4 particularly in the setting if there's an
5 early emergence of the virus before vaccine is
6 available, consideration needs to be given to
7 modifying the use of antivirals to accommodate
8 that until vaccines are available. Eric, do
9 you have any comment?

10 MEMBER ROSE: That's exactly my
11 point, Pat.

12 MEMBER GRABENSTEIN: All right.

13 MEMBER ROSE: That very specific
14 narrow question, a strategic question.

15 MEMBER GRABENSTEIN: All right.
16 So, the Board is making itself available to
17 the Department to assist in addressing this
18 question. All right.

19 MEMBER ROSE: I think that's fine.

20 MEMBER GRABENSTEIN: It's 1:59 by
21 my watch, so I'm going to give one more chance
22 for comments from the Board members, and then

1 we'll proceed to a vote on the report with the
2 addition of the substituted clause I read out.
3 Any last points of discussion? Hearing none,
4 all right. So, we have -- the motion is to
5 adopt the report of the Working Group with the
6 amendment of the first bullet in the H1N1
7 vaccine section, and relay it to the Secretary
8 and the Department. And we'll leave the
9 antiviral as a verbal, so we don't have to
10 quibble over the wording before we do the
11 vote.

12 CAPT. SAWYER: Okay. So, we will
13 take a vote on that now. I don't know if
14 Patty Quinlisk has joined. Ruth Berkelman, do
15 you agree with this?

16 MEMBER BERKELMAN: Yes.

17 CAPT. SAWYER: Cantrill?

18 MEMBER CANTRILL: Yes.

19 CAPT. SAWYER: Roberta Carlin?

20 MEMBER CARLIN: Yes.

21 CAPT. SAWYER: Al Di Rienzo?

22 MEMBER DI RIENZO: Yes.

1 CAPT. SAWYER: Ken Dretchen?

2 MEMBER DRETCHEN: Yes.

3 CAPT. SAWYER: John Grabenstein?

4 MEMBER GRABENSTEIN: Yes.

5 CAPT. SAWYER: Jim James?

6 MEMBER JAMES: Yes.

7 CAPT. SAWYER: Tom Mac Vittie?

8 MEMBER MAC VITTIE: Yes.

9 CAPT. SAWYER: John Parker?

10 MEMBER PARKER: Yes.

11 CAPT. SAWYER: Andy Pavia?

12 MEMBER PAVIA: Yes.

13 CAPT. SAWYER: Eric Rose?

14 MEMBER ROSE: Yes.

15 CAPT. SAWYER: Pat Scannon?

16 MEMBER SCANNON: Yes.

17 CAPT. SAWYER: Okay. So, we will

18 be sending these recommendations forward as

19 approved by the NBSB.

20 I'd like to thank everyone for

21 their participation today. Are there any

22 other questions of the Board members at this

1 moment?

2 MEMBER SCANNON: Yes. This is Pat
3 Scannon. Steve Cantrill brought up the
4 question of additional meetings. Is this time
5 to bring that up, or should that be discussed
6 on -

7 CAPT. SAWYER: Well, has Dr. Lurie
8 joined again? I know that she -- we met with
9 her briefly this morning, and I feel that I
10 can state that Dr. Lurie is very interested in
11 engaging the Board, and continuing
12 discussions, which we'd like to do on a more
13 regular basis. We will be putting a notice in
14 the Federal Register to this point. The
15 question is really how regular, if it would be
16 every two weeks, or once a month. So, we will
17 need to convene an administrative meeting of
18 the Board to learn of your availability, but
19 that is the intention, I believe, of the
20 Department, and of Dr. Lurie, to have more
21 dialogue with the Board, so that we're able to
22 have updates, and be more on top of things, so

1 that when decisions need to be made, we will
2 be prepared to do so.

3 MEMBER JAMES: This is Jim James.
4 With the rapidity that this might change over
5 the next couple of months, I really think we
6 should be looking at every two weeks, at least
7 telephonically.

8 MEMBER CANTRILL: I just wanted to
9 avoid the FACA overhead that sometimes
10 hamstring us in terms of how fast we can
11 respond. So, I would say even tentatively
12 scheduling them, and we can always cancel them
13 if there's no business.

14 MEMBER JAMES: Precisely.

15 CAPT. SAWYER: Yes. We will
16 actually do that. We will proceed with the
17 Federal Register notice indicating that we
18 will be having these regular meetings. I know
19 that this is the approach that the NVAC has
20 taken, and we will follow that as the example.

21 MEMBER PAVIA: And, Leigh, the
22 other thing we should consider maybe times

1 when we need to have informational meetings,
2 where there are space for information only, so
3 we may want to turn some of those into working
4 group meetings, if we need to.

5 CAPT. SAWYER: Yes. I think that
6 that would be very helpful. In fact, I'd like
7 to thank those, and maybe, Andy, you would
8 like to do this. I know that it was of great
9 benefit to the Working Group to have the
10 participation of the experts that were
11 invited. And I know many of them, although
12 you can't see them on our list of calling in
13 today, are on the phone today and listening to
14 this, so we greatly appreciate the
15 participation of these experts, and we look
16 forward to further opportunity to work with
17 you.

18 MEMBER CANTRILL: Steve Cantrill.
19 I'd like to thank you and Andy for the
20 marvelous job you guys did for setting up that
21 conference, which I think was really earth-
22 breaking. And I'd like to also thank John

1 Grabenstein for the fine work he's done in
2 terms of putting the finishing touches on this
3 project.

4 CAPT. SAWYER: Thank you. Okay.
5 With that, I'd like to close this meeting then
6 today, and we look forward to more
7 opportunities for this discussion in the
8 future. Thank you.

9 (Whereupon, the proceedings went
10 off the record at 2:05 p.m.)

11

12

13

14

15

16

17

18

19

20

21

22

A				
ability 9:20 26:13 112:11	acutely 15:16	adults 45:8,10 47:22 49:19	101:19 112:2	Anne's 90:5
able 5:8 10:9 13:10 19:22 22:22 23:2 23:3,7 28:19 29:17 30:19 37:4 47:2 61:19 77:1 86:2 87:12 99:22 114:5 122:21	ad 90:16 98:3	advanced 42:17 43:3 50:9	aid 48:14	announcement 5:7
absent 8:12 69:17 74:14 95:6	adamantines 52:4	advantage 24:19 40:16 47:13	Al 5:21 120:21	announcing 10:16
accelerate 17:12	adapted 40:19	adverse 104:2	Alaska 87:16	annual 97:3
accept 66:5 92:22	add 34:6,9 46:22 77:19 82:15,17,20 87:10 96:22 118:9	advice 8:22 9:21 14:16 16:3,7,8,19 17:4 22:8 25:6 90:5,19 91:9 101:1 105:11	ALBERT 1:13	answer 20:2 31:5 32:18 65:4 67:20 90:9 96:3 103:10
acceptable 46:9	addition 55:16 120:2	advise 100:22	Alignment 50:4	answering 93:10
acceptance 46:11	additional 21:10 41:9,10 48:6 63:13 84:11,11 105:5 122:4	advisement 87:3 115:15	allow 37:2 55:19	anti 53:9
access 5:3 13:1 106:15	address 11:12 34:3 51:8 95:19 99:12 102:5,8 111:12,19 118:3	advisor 14:14	allowed 68:8	antibiotic 51:5
accommodate 119:7	addressed 10:18	advisory 4:7 8:16 8:17,18 13:22 16:2 49:7 67:11 80:15 90:16 95:19 96:7,19 108:9 115:11	allows 71:9	antibiotics 43:11 55:1 58:22
accompanies 75:8	addresses 113:21	aeon 24:5	alluded 91:21	anticipate 45:4
accompanying 75:12	addressing 115:8 118:4 119:17	Aeronautics 2:14	alluding 107:18	anticipated 28:22 29:18 30:2 43:9 44:5 45:20 51:22 54:19,22 59:3
accord 36:12	Adirim 2:2 23:13 23:14	Affairs 2:6 12:16	alongside 106:3	antigen 18:6 19:18 26:2,5 28:16 41:16 64:1 72:14 74:12 100:14 102:1
accurate 57:14 108:5	adjective 82:16	affect 10:2,3	alternate 53:1 54:17	antigenicity 28:2
achievable 53:14	ADJOURN 3:21	age 47:22 49:22	alternative 29:15	antiviral 42:13,22 43:2,9 51:14 53:16 54:19 58:21 88:10 89:4 90:18 96:5 97:2,12,17 98:17 111:13 112:20 113:5 115:1 117:11 120:9
achieve 41:8 58:7 109:20	adjust 78:2	agencies 8:20 12:7	ameliorate 51:3	
acid 57:15	adjustment 79:7 83:21	Agency 2:12	amend 25:1	
ACIP 18:21 50:14 73:8 80:15 84:17 85:2 90:19 95:21 96:16 97:1,16 98:2,17,22 105:11 105:16 114:22	adjuvant 19:18 20:8 26:4 30:1 32:6 33:5 42:2 100:2,9,21	Agenda 3:9 23:20	amendment 110:10 111:3 120:6	
ACIP's 116:10	adjuvants 50:1 100:16,20,20	agents 43:10 51:22 53:3 55:1 88:11	American 16:18	
acknowledged 114:15	administered 64:4 81:7 82:5	ages 36:13	Americans 47:3	
acknowledgment 36:15	administration 2:14 50:11 53:2	age-basis 104:11	Amivir 20:16	
act 8:18 45:13	administrative 3:2 122:17	age-stratified 49:9	amount 28:15 29:8 30:4 35:22 36:9 47:17 74:12 76:4 102:18 113:22	
acting 94:9	Admiral 87:8	aggressively 33:20	amplification-ba... 57:15	
action 12:12 44:10 80:21	adopt 81:10 120:5	ago 24:4 96:9	amplifiers 45:13	
actions 16:3 21:10 55:15,16	adopted 60:14	agree 79:8 81:1 82:10 91:5 110:12 112:5 113:14,19 114:9 115:19 120:15	Andrew 1:20 105:7	
	adopting 109:5	agreed 79:13	Andy 3:13 6:10 23:2 32:14,16 38:15 39:16 60:6 68:16 73:17 76:20 80:22 84:14 85:15 89:1,15 90:13 91:5 98:3 107:19 113:13 121:11 124:7,19	
	adoption 110:18 111:4	ahead 5:7 19:5,7 63:15,15 69:4,5 69:17 70:6 76:21 78:3 79:4 99:13	and/or 53:21	
	adult 104:1		Animal 2:3	
			Anne 84:16 87:11 88:1 96:15 108:16 118:10	
			Anelli 2:3 7:4,5	
				anybody 34:5 63:1 64:6 77:4 105:4

anyway 73:1	74:14 76:20 80:5	70:7,14,19 71:5,8	background 64:15	beyond 18:8 63:6
apologize 85:16	96:6	71:8,16 72:8,13	94:17	Biodefense 1:1 3:5
apparent 8:3 9:18	asking 19:15 69:1	73:15 77:9 78:7	balance 19:11	3:18 4:5,13 11:7
apparently 26:11	ASO3 32:7	78:17 84:18 88:15	83:12 109:21	12:1 39:4,19
appear 10:2 42:6	aspects 15:12	94:16 118:22	ball 114:12 115:17	92:16
53:8	ASPR 12:10	Authority 50:10	BARDA 24:6 47:1	Biologic 67:11
appears 79:4	Assays 43:17 57:12	authorization	74:8 102:9 115:21	Biomedical 50:9
applicable 48:1	assess 9:18	20:10 37:8	barrier 84:4	bit 16:5,16 17:10
apply 85:8	assessment 70:5	autoimmune	barriers 53:13	26:13 97:5 99:4
applying 46:13	assigned 85:2	100:10	54:10 58:5,8 74:1	107:2
appreciate 5:11	assist 118:3,5	availability 41:12	based 20:3 21:11	black 14:5
59:9 89:20 90:5	119:17	41:18 44:7 58:20	27:6 48:21 66:14	board 1:1 3:5,18
92:11 124:14	assistance 116:7	59:4 107:7 113:4	68:6 76:6 77:13	4:6,14 8:17 9:6,7
approach 41:21	Assistant 3:8 11:20	122:18	81:15 83:1 98:21	9:12,15,21,22
73:13 80:14	12:4,20 14:12	available 11:12	109:15	10:18 11:2,7,13
123:19	25:3 39:12	19:1,22 28:1 29:8	basically 28:15	11:15 12:1 13:6,6
approaches 52:22	associated 107:2,4	29:11 30:8 31:19	37:3 74:4	16:2 22:5,18,22
53:16,17	assume 31:17	32:1 37:15,20	basis 15:18 19:14	24:22,22 25:14,16
appropriate 35:3	44:19 45:16 64:22	41:5 42:3,11,22	41:15 46:17 54:21	31:9 32:9 33:18
41:10 44:10,11	94:3	43:4 46:18,20	65:1 69:18 122:13	39:5,19 59:11,17
47:4 54:11 55:17	assuming 31:12	47:11,16 50:17	batch 81:6	68:14 69:2,14
58:22 89:10 90:19	64:11 67:19	53:17 57:16 60:2	bear 63:14	70:11 88:9 90:2
appropriations	assumption 47:1	60:3 63:12 65:1	beginning 27:8	91:8,17 92:6,21
102:16	assumptions 40:14	67:22 69:9 70:1,4	83:2 94:16 95:15	93:7 96:2 102:5
approval 53:14	44:14,17 45:6	71:18 72:2 73:14	behalf 12:2	105:4 109:1,5
54:7	51:1 55:6 104:21	78:4,4 79:6 81:15	believe 22:21 23:4	114:17 115:3
approved 42:21	105:14	81:18 83:1,12,13	35:2 38:11 48:2	118:2,5 119:16,22
43:9 54:19 121:19	assure 4:15	84:8 88:17 93:2	63:18 80:11 92:13	121:22 122:11,18
approves 25:2	asthma 100:6	102:17 108:6	93:5 95:4 122:19	122:21
approximately	asymptomatic	109:15,19 113:5	benefit 42:20 46:5	boards 115:11
31:22 72:9	42:10	118:4 119:1,6,8	46:11 51:15 85:9	Board's 92:17
April 24:16 89:12	attack 45:7	119:16	124:9	bodies 112:16
area 8:5 55:5	attempt 28:20	avoid 100:22 123:9	benefits 51:11,20	Bonnie 7:13
areas 12:22 35:14	attend 61:19	aware 15:16 90:14	94:8	Boris 7:14
39:22 48:19 60:12	attention 16:13	96:5 106:18	Berkelman 1:12	bottle 70:6 73:19
62:11 68:20	24:18 38:3	A/H1N1 41:14	5:17 115:13,14	78:3
arena 50:19 56:13	attentive 9:22	81:18 109:18	120:14,16	bottled 64:3
57:3	attenuated 28:18	A/H3N2 52:5	Berry 2:4 7:15,16	bottles 73:16
argument's 71:22	29:18 31:3 41:20		Besser 2:6 7:13	bottling 67:21
arm 30:13	49:4	B	best 18:19 44:21	70:17
Army 2:17	attractive 53:7,9	B 52:5	52:12 85:8 89:5	bound 98:19
arrangements	Auchincloss 7:14	back 14:3 18:4	90:6	Bowman 105:21,22
102:15	augmented 57:10	33:10 52:19 59:6	Bethesda 24:8	Branch 9:11
array 20:4	August 30:11 31:17	67:5 84:21 88:8	39:21 114:15	breaking 124:22
arrives 75:20	34:19 36:1 60:2	91:8 93:22 109:1	bets 76:14	brief 41:1
articulated 48:21	63:10,16 64:11	116:16 117:14	better 27:17,18,22	briefly 122:9
asked 8:10 10:4	65:17 66:3,7 70:2	118:17,18	44:3	Brigadier 1:15

bring 57:2 122:5	81:20,20 82:2	96:11 97:11 98:16	choice 100:17	COL 2:17 7:11
broad 90:2	86:11,12 109:22	98:22 105:11	choices 55:18 61:15	collection 66:10
brought 63:14	110:1 120:17,18	108:12,15,18	choose 67:21	collective 46:13
122:3	122:3 123:8	114:21	chooses 14:18	Colonel 7:10
browser 38:19,22	124:18,18	celecoxib 53:12	chose 31:20	combination 53:3
Bruce 2:9 7:14	capacity 37:1 47:4	Center 2:12	circulate 44:20	come 18:6 35:21
68:18 76:18 78:11	55:20 56:6,13	Centers 2:8 50:8	circulation 55:9	52:19 67:5 84:6
79:19 84:15 93:14	57:2,9,11,18 58:1	certain 88:21	circumstances 8:19	85:10,13 88:8
96:4	58:5 81:4 84:22	111:15	40:20	109:1
Bruce's 90:6	capital 106:2	certainly 25:19	cited 107:19	comes 100:20
bulk 26:3,4 29:11	Capt 3:4,19,22 4:3	29:19 30:12,19	Clare 15:13	101:16 102:22
31:19 72:13	5:16,19,21 6:1,3,5	62:10 73:20 75:22	clarified 88:13	104:6
bullet 62:20 81:14	6:7,10,12,14,16	114:4,5 117:16,21	clarify 40:13 59:16	comfort 114:10
109:9,21 120:6	6:21 7:3,6,9,12,17	cetera 106:4,4	61:3 82:12	coming 15:19
bunch 19:17 85:19	7:20 8:1 22:21	Chair 3:14 8:3,8,12	clarifying 60:7	18:16 24:21 84:21
107:15	23:5,15,18 62:3,9	11:22 38:7 110:3	clarity 80:21	103:18 118:17,18
burn 113:17	68:16 79:10,15,18	110:4	classes 53:4,4	Commander 2:17
business 86:20	98:15 99:18 110:6	Chairing 15:13	111:16	commensurate
123:13	110:11 116:20	challenge 97:13	Claudia 7:20	102:18
Butler 87:9,15 88:1	118:8 120:12,17	challenges 40:8	clause 120:2	comment 3:15
Butler's 84:21	120:19,21 121:1,3	97:7	clear 14:9 68:4	10:11 11:3 30:18
button 23:1,3 39:9	121:5,7,9,11,13	challenging 100:12	72:13 76:22 80:21	62:2 64:6 74:6
buy 19:21	121:15,17 122:7	101:2	91:7 96:14 108:2	88:6 89:16 91:14
buying 37:3	123:15 124:5	chance 119:21	clearly 48:21 60:11	94:12 98:12 99:10
	125:4	change 27:21 36:16	click 39:3,9	99:20 102:6 105:4
C	Captain 2:22 15:12	66:15 68:6 76:6,8	clinical 30:20 32:11	107:14 108:16
C 4:1	care 13:1,1 15:10	82:16 98:20 109:7	32:19 34:2 37:9	119:9
calculations 46:11	56:15 57:13 59:5	110:13 111:13	37:12,18 43:16,18	comments 4:9,17
California 24:17	107:17	123:4	43:22 53:6 55:7	10:7,17,20 52:18
28:3	Carlin 1:13 5:19,20	changed 46:19	55:15,21 56:12,13	59:10,15,22 63:3
call 3:3 5:13,15	120:19,20	75:13 117:5	56:15,18 57:3,12	79:12 83:18 88:10
6:17,20 8:6,12,14	Carol 7:14	changeover 71:9	57:13 59:4 63:11	89:21 90:2 94:21
17:1 23:11 24:13	cascade 53:6	changes 30:3 60:11	69:9 81:19 82:21	96:22 107:20
38:18 87:4 92:7,8	case 69:19 77:1	60:14 117:17	83:10 84:7 89:8	108:19 112:18
94:19 110:4 114:6	86:6	changing 92:18	90:4 92:22 96:18	119:22
called 37:11 117:7	cases 24:17 45:18	98:20 105:12	107:17 109:19	Commerce 2:16
calling 124:12	catastrophic 45:19	Characterization	111:14	commercial 26:1
calls 101:14	catch 32:4	2:5	clinical-care 43:19	commercial-scale
campaign 18:1	categories 105:3	chemoprophylaxis	44:7	28:20
27:15	category 111:15	117:1,4,11,20	clinicians 97:9 98:4	commit 64:3 76:3
cancel 86:19	caught 24:17	Chief 2:4,13	118:12	86:8
123:12	causal 48:13	children 36:11	close 18:11 50:6	committee 4:7 8:16
candidates 53:9	cause 100:9	41:21 45:8,10,12	125:5	8:18 49:7 67:11
Cantrill 1:12 5:17	CDC 17:15 27:19	47:22 48:18 49:15	closely 87:19 88:4	67:13 80:16 96:7
5:18 74:22 75:1	48:4 58:11 61:9	49:17 53:20 54:2	closer 98:13	99:6 108:9
75:14 76:2,2	61:13 62:1,4 73:5	61:10 62:22 74:1	clues 56:18	committees 8:21
77:16 79:14,14	87:8,17 90:4	103:6	cohorts 48:6 80:13	13:22 95:19 96:20

committing 74:18	confronts 68:2	18:8,9 50:8 55:17	critically 19:3	decisions 15:17,18
communication	Congress 102:17	58:20 108:7	cross 19:4 58:4	19:9 40:12 46:16
48:15	conjunction 97:2	controls 8:19	cross-agency 15:3	49:6 50:16 52:6
communications	consensus 51:13	convene 122:17	crystallize 77:5	97:22 123:1
15:11	consider 25:1 47:9	convened 1:8 4:8	current 40:21 43:8	declares 75:9
community 15:10	48:16 62:20 78:19	4:15 11:8 39:19	44:5 45:17 48:1	decrease 51:4
45:13 55:10,14,16	82:3 84:19 116:18	conversation 77:6	54:18,22 57:10	deep 100:1 101:1
101:1	123:22	99:4	59:3 67:18 71:16	defensible 76:12
companies 32:20	considerable 67:2	convey 92:9 109:6	100:13	defer 115:2
93:4	consideration 36:5	conveying 109:4	currently 28:3	define 56:17
compared 74:17	37:7,14 54:16	coordinated 12:13		definitely 100:18
compile 22:1	61:13 66:16	Coordinating 2:6	D	degree 85:10
completely 86:16	105:17 113:7	coordination 14:16	D 2:15 3:1 4:1	delay 50:2
complex 91:6	115:7 119:2,6	50:6	daily 15:5,18 21:5	delayed 41:22
108:12	considerations	corollary 83:20	Dan 6:21	51:19
complicate 52:6	40:8	correct 31:14 34:21	data 19:9 33:10,16	deliberate 30:17
complications	considered 42:14	62:7,8 63:19	42:19 46:18,19,21	97:4
98:10	53:1 108:15 113:9	72:17	47:20 49:6,11	deliberated 116:2
compromise 9:19	115:16	corrections 75:12	50:12,16 56:15	deliberations 4:16
computer 5:3	considering 30:14	correctly 72:21	63:11 66:3,9 68:1	21:12 25:16 41:2
computers 4:21	66:12 80:15	cost 107:2,3	69:4,17 71:21	68:11,15 115:12
concentrate 26:3	consistent 51:11,12	costs 46:4	75:20 78:9 79:1,6	116:5
concentrated 45:9	consultant 14:21	Counsel 2:10,10	81:15 82:21 83:1	delivering 29:15
concentration	contact 102:13	counteract 100:3	83:10 84:7 92:2	81:9
63:22	contacts 55:20	countermeasure	92:22 93:1 109:15	delivery 48:17
concern 26:6 89:17	containing 52:3	90:3	114:1,2	62:21
concerned 107:9	containment 57:20	countermeasures	date 70:17,20 71:11	demand 43:12 55:3
117:9	contemporary	2:5 4:11 40:3	77:22 78:20	department 2:2,6
concerns 100:1	40:16	counting 14:15	David 103:1	2:10,16,19 12:11
101:2 117:13	contents 95:1	country 15:21	day 65:12	12:15 24:9 25:7
conclusion 60:16	context 97:13	couple 14:21 21:4	days 15:1 21:4	30:13 40:1 67:19
116:3	117:17	23:10 31:8 32:22	71:19 75:22 84:18	77:9,12 86:6
conditions 20:7	continual 54:21	91:16 116:21	dealing 112:6	109:6 116:1
45:11	continuation 43:7	123:5	Dear 99:21	119:17 120:8
Conduct 9:10	continue 12:11	course 11:14 24:5	deaths 45:9	122:20
confer 51:20	44:20 45:7,9,13	49:18 56:9	decades 41:14	departments 12:17
conference 42:15	45:16 67:17 93:4	courses 35:10,16	47:13 56:10	106:15 117:9
124:21	continues 78:21	cover 83:6	decide 21:9 80:18	depends 103:19
confirmatory	continuing 122:11	covered 84:10	deciding 19:5	depleting 117:11
106:14,17	continuous 16:19	co-circulation 52:2	46:14	deployed 44:4
confirmed 12:3	contracted 26:1	56:2	decision 3:13 4:11	56:22
14:22 106:11	28:14 30:4	criteria 44:1	30:10 34:19 40:2	deployment 46:6
confirming 58:12	contribute 89:10	criterion 41:13	40:11 41:13 46:20	Deputy 2:11 12:20
confirms 83:10	contributes 57:18	critical 12:10 40:13	48:19 63:10,15,20	describe 25:4
conflict 3:3 9:9,14	contributing	47:10 57:3 58:4	68:2,8 70:15,18	described 103:17
conflicts 9:19	106:21	104:13,16 107:4	70:21 71:20 79:2	Designated 2:21
confronted 113:10	control 2:8 8:21	107:12	80:7,7 92:4,5,21	4:6 8:7

designed 49:11 51:11	27:21 66:16 80:2	document 9:11 38:17 50:20 59:15 77:7 83:6 84:13 109:4,5,8 114:6	122:7,10,20	effectiveness 42:16 106:10 108:13
designee 2:1 6:18	difficult 26:14	documents 4:19 5:1,9 10:22 39:10 48:3	draft 30:9 54:3	effects 49:22
desirable 89:19	dilution 74:4 75:3	doing 14:6 17:4,11 24:2 61:14 74:2 74:10 105:13 114:11 116:8,17 116:18	drafted 67:16 81:14	efficacy 56:19
desire 58:7	direct 4:21	dominant 41:12	drafting 9:4	efficiency 56:7
desperate 37:16	directly 9:7 33:17	dosages 36:9	dramatically 58:2	efficient 57:20
detail 114:3	Director 2:4,6,9,11 2:18,22 3:5 4:5	dose 31:2,13 33:12 33:13,14 34:14,16 47:15 49:13,16,21 64:4,12,22 66:13 67:12 68:6 69:5 74:11 75:9 78:2 79:5,7 83:11,20 84:8 93:1 103:22	Dretchen 1:14 6:1 6:2 61:6,7 62:8 94:13,14,18 121:1 121:2	efforts 40:17 62:6 62:13
detailed 49:20	discuss 4:9 13:16 17:6 24:14 38:5 59:22 83:8 85:5 111:21 112:3 118:11,12	doses 19:21 20:1 26:15 27:1,3 28:12,14 29:7 30:5 31:19,22 32:6 49:22 53:2 66:6 73:14 74:19 77:11,20 78:4 81:2,7,9,17 102:4 109:17	driven 47:19	egg-grown 49:3
details 58:17	discussed 42:15 113:14 117:14 122:5	download 39:11	driving 67:7	either 20:15 103:21
detect 48:13 55:8 55:11,11 56:17	discussing 24:21 63:12	downside 76:16,19	drug 37:8,11,13 50:11 52:15,18 55:11 96:18 113:5	element 81:4
detection 56:20	discussion 3:11,15 10:6 21:7 30:15 38:14 59:10,14 73:9 80:9,14 91:17 97:16 109:2 111:11 112:1 113:16 114:14 120:3 125:7	Dr 8:3,10 11:21 12:5,14 13:5,7,9 22:4,11 25:4,9,13 31:14,21 32:6,16 34:16,21 35:4,4,6 38:4,8,8 59:22 65:3,6,10,19 66:1 66:11 71:2 72:3,5 72:17 74:7 77:21 102:7,12 103:9,11 103:19 104:22 115:20 116:1,21 116:22 118:12,14	drugs 42:13 43:2 51:14 53:2 95:11 113:17	elements 113:15
determine 48:13 49:20 69:9	discussions 11:15 25:18 30:17 55:5 85:19 86:3 108:12 108:13 122:12	Dr.PH 1:17	drunk 16:10	eliminated 58:9
determined 77:12	disease 2:8 42:9,12 42:17 43:3 50:8 51:7,16,18,19 53:19 54:8 104:21	due 105:16	Dr.V.M 3:4,19,22	Ellen 101:11
develop 12:12 81:5 100:10 112:12	diseases 2:18 100:10	DVM 3:4,19,22	dynamic 86:21	email 5:1 10:19 99:11
developed 43:5 44:4 53:17 54:9 54:12,14 56:22 75:18 105:10	disparities 13:4	dynamic 86:21	D.V.M 2:3,17,22	emailed 5:2
developer 53:15	disrupt 107:10	E		Emanuel 6:22
developing 47:4	disruption 45:19 105:1	E 3:1 4:1,1		emergence 20:13 51:21 119:5
development 9:4 50:10 52:15,18 53:11 54:2,3,4,17	dissemination 107:15	earlier 18:20 29:19 66:12 81:21 93:8 111:11 113:3 116:21		emergency 2:8 20:10 37:7
Deyton 7:21	distributed 11:2 35:13 43:19 57:13	earliest 70:17		emphasizing 108:4
DHS 23:14	distribution 71:18 102:3	early 17:1 36:1 41:7 42:9,12 45:5 46:6 47:11 49:6 49:17 50:2,13 51:17 54:2 71:8 78:7 82:7 88:16 119:5		empiric 65:1
Di 1:13 5:21,22 120:21,22	Division 62:4 98:16	effective 34:15 42:8 43:2 83:11		employees 9:2,10 9:13
diagnostic 11:9 40:6 43:16,20 44:1,3 56:13 57:17 58:3,19 91:18 106:7 107:10 108:3	divulging 58:13			encourage 62:10
diagnostics 43:14 55:6 56:8 57:14 59:14 88:8 94:22 108:5				encouraged 11:14
dial 38:21				encouraging 67:18 107:15
dialogue 122:21				endlessly 78:13
Diane 2:4,15 7:7,9 7:15				endorsing 73:12
difference 13:21 14:9				endpoints 54:11
different 26:10				Energy 2:19

47:20 108:7	53:2,3 58:15 68:6	109:7	finished 76:4 78:10	64:21
epidemiological	expansion 57:11	fast 38:3 68:21	finishing 71:7	Food 50:11
107:11	expect 68:11	123:10	125:2	force 15:3,13 21:6
epidemiology	expected 42:1 45:2	FDA 30:14,17 34:7	finite 80:12	21:8 87:18
40:20 50:12 84:13	expects 71:17	34:8 54:3 66:12	Fiore 62:3,4,9	foremost 13:20
85:7,10 105:15	experience 12:10	67:12 68:4,10,15	96:22 98:15,16	forgot 118:9
equation 77:2	14:17 41:14 47:14	74:6 75:1,11	116:9,20 118:8,9	formal 62:13
equipment 15:9	58:10 75:6	103:20	fire 101:5	formed 24:15
equipped 43:16	experiences 16:16	feared 105:2	first 13:20 14:10	forms 29:17 37:17
Eric 1:21 6:12	expert 22:8 51:14	feasibility 113:9	18:6 25:20 28:19	formulate 66:6
34:12 63:5 64:10	expertise 67:15	feasible 73:21	31:8 32:19 33:13	69:17
64:11,21 78:6	89:6 114:21	83:13	34:16 54:5 59:11	formulated 30:22
79:12 83:14 84:2	116:13	federal 2:21 4:6,7	60:22 66:2 71:21	formulation 42:21
88:12 89:1 92:12	experts 11:9,10	8:7,16,18,20 9:2	80:6 81:6,7,13	46:17 65:11,12,17
112:19 118:18,20	16:19 39:20 40:6	10:15 24:19,20	84:18 101:15	71:10
119:8 121:13	98:4 124:10,15	36:2,11 86:18	103:22 106:1	formulations 33:4
Erin 104:6	explicit 49:15	95:17 96:7 122:14	109:8,9 120:6	36:8
essential 47:9 56:6	exposed 42:10	123:17	five 25:22 27:13	forth 27:18 28:7
56:16	97:19	feedback 19:10	40:18 45:21 90:8	118:15
establish 8:21	exposure 88:20	20:19,21	fix 113:16	Forum 3:13 4:12
estimated 26:22	97:20 106:5	feel 16:1 60:17	fixed 93:6	forward 13:7,12
estimates 44:22	exposures 106:11	122:9	Fletcher 6:21	15:15 17:7 20:22
et 106:4,4	106:20	feeling 74:14	flexibilities 93:20	22:10,13 33:16,19
Ethical 9:10	expressing 13:14	felt 40:13	flexible 48:20	33:20 34:4 36:7,9
EUA 92:2	extensive 84:4	fewer 26:11	flow 86:4	61:16 64:12 66:19
euphemistic 91:11	extensively 42:15	field 12:22	flu 29:15 96:13	68:21 92:2 100:1
evaluation 87:22	extent 24:3 47:19	figure 18:13 85:8	100:2,4,19 101:3	121:18 124:16
evening 60:10 72:2	115:6	85:12	101:10	125:6
evidence 42:16,18	extremely 68:13	fill 29:12,14 71:3	flu-mist-like 29:3	found 38:18
48:22 50:13 51:2	117:3	71:10,15 72:1	FNS 102:3	foundation 40:17
51:6	ex-officios 6:17	76:1 86:9 92:19	focus 17:13 40:2	four 27:13 28:6
evolving 50:18	e.g 49:8 55:1 57:15	filled 78:9	98:18 104:10	45:21 59:11 65:7
84:12		filling 30:11 65:13	109:3 112:14	65:7,9 81:7
ex 2:1 11:14 59:18	F	71:10 72:8 93:5	focused 62:6	frame 93:21
exactly 27:2 69:8	FACA 8:18 123:9	finalize 68:12	117:20 118:13	framed 95:14
119:10	fact 27:6 32:21	finally 59:14	focusing 47:21 98:8	Frank 7:4
example 22:17	46:2 105:12 124:6	financial 9:17	104:20	frankly 15:21
117:7 123:20	factors 48:1 49:8	find 93:18 110:15	fog 16:16	19:13
examples 58:9,18	98:9	finding 27:11 48:3	folks 87:2	FRIDAY 1:5
exception 53:11	facts 93:17	findings 4:10 13:16	follow 47:5 86:7	front 20:11 26:5
exclude 49:18	fairly 75:19 108:12	41:1	123:20	30:1 50:21 68:19
Executive 2:22 3:5	fall 17:3,21 20:9,17	fine 74:13 116:14	following 18:17	85:17
3:12 4:4 9:11	43:1 44:3,21 46:2	119:19 125:1	21:6 41:3 69:12	frying 101:5
38:10	100:19 102:4	Finelli 90:17	78:1 84:10 103:17	fulfill 22:7
exist 53:13	far 20:4 28:10,15	finish 71:3,16 72:1	106:11	full 9:6 20:4 24:22
existing 40:21 43:4	30:5 64:5 94:4	72:15 74:19 76:1	follows 109:14	24:22 66:9 111:8
43:20 51:10,22	101:9 107:22	86:9	follow-up 64:9,10	114:3

Fultz 7:21
function 45:19
 56:12
fund 59:1
fundamental 54:6
further 37:18
 38:13 54:14 59:1
 76:7,7 98:13
 108:20 124:16
future 43:6 52:15
 52:18 57:4 99:5
 111:22 125:8

G

G 3:1 4:1
galvanized 24:18
garbled 64:18
gather 76:6
gathered 24:8
gathering 9:3 24:3
 25:9
Gellin 2:9 7:14
 68:18,19 72:12,18
 73:2 76:18 78:11
 79:19 85:4 86:10
 90:12,22 93:14,15
 94:6 96:4,5 116:9
general 1:15,19
 59:15 98:7
generalize 86:12
generated 60:8
getting 16:8 29:5
 82:3 89:4 90:4
 100:14
give 24:7,10 25:20
 35:18 36:10 54:15
 62:17 65:7 73:21
 119:21
given 4:15 10:12
 38:16 69:2,3 70:5
 72:18 92:20 103:4
 103:6,20 104:1
 105:16 114:22
 115:7 119:6
gives 76:12 85:18
giving 9:20 61:9
 77:12

global 15:22
globe 29:22
go 5:4,6 17:2,6 19:5
 19:7 27:10,14,16
 30:21 31:20 32:1
 33:8 36:6 37:12
 39:15 44:18 58:17
 62:13 63:15,15
 64:16 65:15 66:7
 69:3,5,10,16 70:6
 76:21 78:3 79:4
 88:7 96:2 99:12
 101:5,19 110:14
 110:16 112:2
 113:15 116:7
 117:15
goal 25:5 41:9,17
 47:1,4,6,13 81:16
 109:16
goals 3:9 23:20
 40:15 44:14 47:8
 47:16 48:8 50:4
 52:21 56:5
goes 32:21
going 4:21 14:5
 15:19,20 18:6
 19:8,13 21:15
 22:13,15 23:19
 24:20 29:11 33:16
 34:3 36:9 44:12
 52:17,19 63:11
 67:20 69:10,12,16
 69:22 71:5 78:19
 80:1 82:7 85:4,6,6
 85:11,12,21 86:21
 88:6,7,17 91:14
 91:15 92:1 94:14
 94:22 95:19,22
 99:3 101:22
 102:19 103:7
 104:11 107:7
 108:1 111:21
 114:5,11 115:10
 119:21
good 16:18 22:11
 23:5 29:19 39:17
 47:18 61:4,18

62:11 82:18 83:3
 85:15
Google 5:6
governed 8:17
government 8:21
 9:13 12:8 24:9
 39:20 40:5 41:4
 50:6 54:15
Grabenstein 1:9,14
 3:10 6:3,4 8:11
 22:3,4 23:21,22
 31:7,8,16 32:3,8
 32:14 34:5,10
 35:1 38:1,15 59:8
 60:15 61:1,4,18
 62:18 63:17 64:14
 65:5 66:4 67:8,9
 70:10,16 72:10,20
 74:5 75:4,5,16
 77:3 80:10,11
 81:11 82:9,15,22
 83:4,14,17,22
 84:9 85:1 87:1,7
 88:5 91:12 92:10
 94:3,11,20 95:10
 95:13 99:2 101:12
 101:18 102:10,20
 103:9 104:3,18,19
 105:18 107:13,14
 108:17,22 110:2,9
 110:14,22 111:6
 112:2,17 113:12
 114:7,13 115:22
 117:22 119:12,15
 119:20 121:3,4
 125:1
grateful 13:15
grave 111:9
great 22:17 105:18
 109:13 124:8
greater 45:17 57:2
 64:1
greatest 24:2
 104:20
greatly 8:13 124:14
group 3:12 4:13 9:1
 11:6,8 13:17 17:1

21:9 22:19 24:15
 24:15,22 39:18,19
 40:13 44:8 47:17
 47:18 84:16,22
 96:1 116:11 117:7
 118:11,13 120:5
 124:4,9
groups 8:22 9:6
 15:6 17:14,17
 80:20 81:3 88:21
 88:21 89:7 98:3
 104:14 105:10,13
 105:16 117:18
group's 89:5
grow 26:8
grows 26:8
GSK 91:22
guess 18:19 27:5
 64:9 66:22 78:15
 83:19 116:11
guessed 27:5
guidance 54:4 86:6
 90:18 97:12
 103:20
guide 56:14
gut 74:14
guys 124:20

H

half 28:11 66:19
half-day 114:14
hamstrings 123:10
hand 71:17,17,21
handled 90:7
handling 108:9
happen 10:4 22:15
 27:14 37:2 69:12
 85:21 104:2
happened 85:20
happens 14:1
happy 21:14
hard 22:12 69:7
harder 27:12
harms 101:6
Hart 2:10 7:18,19
Haseltine 7:17
Hatchett 23:16,17

head 26:16 27:1,3
health 2:4,5,13,19
 12:6,17,18,20,21
 13:2,2,3 15:20
 25:7 39:2,14 40:1
 43:15 46:5,12
 50:11 55:7,13
 56:11,17 57:1,9
 57:19,21 87:16,19
 106:15 107:18
 117:8
healthcare 52:9
 85:11 104:14,17
 106:2,5,9,19,21
 108:14
hear 4:16 14:3
 16:14 23:1 73:10
 74:21 87:3 103:5
 110:12
heard 25:4 26:6
 40:4 60:10 63:7
 80:14 101:21
 102:1 114:11
 118:1,20
hearing 11:5 21:1
 28:6 60:21 77:4
 120:3
heavily 66:17
hedging 76:14
held 24:4
hello 13:13 101:17
 103:2 104:7
Helminiak 15:13
help 15:2 29:21
helped 17:9,10
helpful 25:19 92:5
 115:11 124:6
hemagglutinins
 26:11
Hey 60:5
HHS 12:15,21 15:4
 24:9 43:8 44:4
 48:16 54:18,21
 59:2 62:1,20
 80:21 81:16 87:2
 105:4 109:16,20
 115:14 118:2

hhs.gov/aspr 39:12	40:3 41:4 42:6,11	impacts 15:22 53:6	50:18 66:11	inhibitor-resistant
Hi 23:18 62:3	43:21 44:19 47:10	93:19	indicating 5:12	57:5
Higgs 91:19,20	47:14 48:2,11	imperfect 19:9	123:17	initial 17:15 41:16
high 53:13,15	52:3,4,7,14 56:2	implement 12:12	individual 43:22	46:20
higher 29:5 45:1	57:7 58:12 59:12	implementation	56:14	injected 64:2
117:18	59:20 62:14 63:3	87:18,20	individuals 37:16	input 19:3,16 22:8
highest 45:7 105:2	67:4 81:13 97:7	implications 44:15	46:14	22:9,19
high-quality 56:7	97:13 100:4,7	49:2 57:8 93:18	industry 40:5	insert 75:7
high-risk 88:21	106:11,14 109:9	implies 79:20	IND-type 33:6	Inspection 2:4
103:7	109:10 113:3	importance 78:14	infants 47:21 49:15	Institute 2:15,17
high-throughput	118:21 120:6	106:1 108:5	49:17 53:20	Institutes 50:10
58:12	H274Y 52:3	important 13:18	infection 43:22	instructions 10:12
historical 69:18	H5N1 27:6	15:20 19:3 40:10	44:22 49:9 55:17	38:17 99:9
history 12:21 100:5		45:12 46:22 50:1	58:20	insure 53:22
hit 38:12	I	54:5 55:8 68:13	Infectious 2:18	intended 112:21
hoc 90:16 98:3	idea 33:19 61:8,10	81:2 117:4	inflammatory	intense 19:6 30:16
hold 21:22 99:4,6	73:11 85:15 90:20	improve 40:10 57:1	53:10	intent 21:2 113:6
hole 14:6	ideal 68:9	improved 50:5	influence 112:12	intention 122:19
home 96:12	ideally 47:12	53:22 56:20 58:19	influenza 3:12 4:12	intentions 71:6
Homeland 2:2,6,12	identified 40:7 49:5	improvements 56:9	11:6 12:9,17	interest 3:3 9:9,14
homemaker 100:4	49:8 58:8	improves 57:20	24:14 26:18 37:10	9:19 10:3 20:5
honestly 16:4 17:8	identify 39:22	Improving 57:17	39:18 40:4 41:15	38:9
hope 20:20 22:14	40:14 55:10	inactivated 28:5,7	42:21 43:11 44:8	interested 122:10
22:15 69:19 73:5	identifying 40:11	31:1	45:2 51:3,13 52:5	interests 9:17
100:15	IDSA 96:11	incentives 53:21	52:5,7 53:7 54:4	interfere 48:8 71:6
hopefully 5:8	II 37:9	incidents 36:17	55:2 56:3,21 57:5	interim 97:11
hoping 18:15 101:3	III 37:13	inclined 66:5	58:11 62:4 71:4	interject 91:4
hospitalizations	ilk 96:6	include 18:17 41:3	97:3,6,19,21	internationally
45:8 51:5	ill 37:10 52:14	49:12,14 56:5	98:10,16 112:21	12:5
hospitalized 51:9	106:21	58:9 89:7 104:16	116:11	internet 5:4 38:19
52:14 57:17,18	illness 56:18	110:20	inform 33:4 50:14	interval 80:6
hospitals 106:13	117:17	included 98:4	55:14,15,17 66:3	intervals 33:13
host 15:6	immediately 5:2	104:13	information 4:22	intervention
hosted 4:12	immunization 19:5	includes 52:21	9:3,15,17 24:3,10	112:13
hour 109:3	19:7 48:17 49:7	including 9:3 17:22	25:8 42:3 58:14	intranasal 41:20
Hugh 7:13	62:21 80:16	30:13 53:1,13	58:14 63:13 65:17	intravenous 37:13
human 25:7 40:2	immunize 81:5	incomplete 46:21	69:8 75:8,13,18	52:12 54:13 92:3
106:2	immunogenicity	incorporated 98:6	76:7,9 84:21 86:3	introduce 87:14
humans 37:9	33:3,7,12 49:9,12	increase 56:6	98:5 103:5 124:2	introducing 11:19
hurricane-like	50:14 66:2,9 68:1	107:11	informational	introduction 38:9
105:2	71:20 76:7 78:8	increased 52:11	124:1	inventory 35:8
hurt 82:8	79:1,6	58:2 107:8	informed 61:22	invested 94:5
hyperlink 39:4,7	immunologic 53:6	increasing 58:5	81:3 84:20 93:13	investigations
H1N1 3:12 4:10	53:9	incurs 46:3	100:15 112:16	107:11
12:13 14:17 15:5	immuno-compro...	index 45:21	infrastructure 13:3	invite 24:8
21:5 25:21 26:2	89:18	indicate 6:19 99:9	104:13,16 107:1	invited 11:10 40:5
26:10 36:16,18	impact 15:20 58:19	indicated 30:8 34:1	inhibitors 42:7	124:11

involved 8:13 61:20 86:17 115:3	John's 81:10	80:12 85:16 87:15	left 39:1 95:12 109:3	26:13 99:4
involves 15:4	join 10:9 11:15 87:12	92:7 93:3 94:7,15	Legal 2:10	live 28:18 29:18 31:2 41:20 49:4
isolated 36:17	joined 23:10 120:14 122:8	97:6,18,21 108:15	Leigh 2:22 3:4,19 3:22 4:4 16:21	local 12:16 35:14 108:7 117:8
issue 10:2 18:7 19:3 88:18 90:1 103:5 109:4 112:5 114:18 118:21	JOSEPH 2:3	122:8 123:18 124:8,11	86:15 110:4,4,17 123:21	logistical 48:18 62:22
issued 97:8,11,15	July 1:6 10:16,21 12:3 39:8 80:17 99:22	knowing 69:16	lesser 64:1	logistics 82:3
issues 12:18 14:14 15:7 16:6,12 34:3 54:6 74:15 87:22 107:19 108:10	June 4:10 13:16 17:8 35:15 39:21 56:2 60:8 67:3 97:16 98:18	knowledge 12:9 50:18	let's 38:4 59:19 71:14 109:1 110:14	logs 29:5
iteration 84:6	Justice 2:10	known 13:5 69:4	level 12:8 55:14,16 76:5 90:4 111:14 111:14	long 12:21 64:4 75:21 116:7
IV 37:16 42:21 91:21	Jutro 2:11 7:21,22		levels 57:10	longer 33:6
	J.D 1:13	L	Libby 91:20	long-term 101:6 117:10
J	K	lab 71:17	license 30:20 68:5	look 13:12 17:3,6 18:11 20:22 22:9 29:14 70:3 85:6,7 104:10 124:15 125:6
J 1:13	keep 78:19 80:1 97:9 117:16	label 75:7	licensed 20:9 26:18 46:7,8 58:6,15 66:13	looked 18:4 116:16
James 1:15,15 6:5 6:6 76:15,15 82:1 82:10,11,18 91:3 91:3 93:9,9 111:20 112:4 118:14,14 121:5,6 123:3,3,14	keeps 99:1	laboratories 43:15 43:19 44:7 55:8 55:13,15 56:11,16 57:2,9,14,22 59:5 107:17,18	licensing 49:3	looking 13:7 16:10 26:22 29:12 34:17 91:9 104:9 123:6
Jay 84:21 87:8,15 108:16	Kelley 101:16,17 101:20	laboratory 44:6 55:20 59:3 107:16	licensure 30:21 50:2 58:7,16	lost 69:13 107:3
Jeff 105:21	Ken 6:1 61:6 94:13 121:1	laborious 44:16	light 86:3	lot 13:21 19:9 24:18,19 62:16 63:7 90:8 101:21 113:15
Jim 6:5 76:15 82:10 91:3 93:9 121:5 123:3	KENNETH 1:14	lags 72:4	likelihood 89:19	lots 86:3
job 16:18 124:20	kept 68:14	lamp 16:11	limit 20:15,15 95:16	love 74:21
Joe 7:4	Kerr 6:22	land 115:17 116:13	limited 18:17 28:21 29:8 55:18,22 107:7	low 27:9 43:21
John 1:9,14,19 2:17 3:10 6:3,7 8:10 22:3 23:20 25:13 31:7 38:7 59:7 60:5 61:6,7 63:5 65:3 66:5 67:9 68:22 75:4 77:17 80:10 81:1 92:12 104:19 107:13 109:22 110:14 115:20 118:15 121:3,9 124:22	key 38:13 39:22 40:11,14 41:1 42:5 43:14 44:13 51:1 55:6 81:4 108:1	landed 114:12	limiting 96:12 106:15	lower 26:19 51:7
	keypad 21:19,22 99:17	larger 45:18	limits 107:6,9	Lurie 3:7 11:21 12:5,14 13:5,9 22:4,11 25:4 38:8 122:7,10,20
	keys 16:10,11	largest 85:9	Linden 7:14	Lushniak 7:15
	kind 19:6 23:8 97:21	Larry 6:22	line 10:13 11:13 34:13 50:22 67:7 69:16 76:8 86:16 87:8 99:10,15	Lyn 90:16
	kinds 17:17 20:18	late 4:19 37:20 53:10 71:7 88:15	lines 17:12 18:5,12	M
	knew 100:19	latest 70:20	linking 114:21	Mac 121:7,8
	know 13:6 14:3,4 14:22 17:5,15,19 18:2,18 19:8 20:3 22:13 23:12 30:7 34:14,18 35:7 36:4 65:11 69:6,8 75:21 76:19 77:13	Laurie 13:8	list 110:15 124:12	MacVITTIE 1:18 6:7
		lawful 66:20	listed 48:9	magnitude 77:13
		laws 9:14	listen 21:15	maintain 98:22
		lead 52:11 60:3 87:17	listening 88:3 124:13	Major 1:19
		leader 12:6	literally 75:10	majority 9:2
		leaders 50:7	little 16:4 17:10	
		learn 122:18		
		learned 4:18		
		leave 91:19 95:2 112:14 120:8		
		leaving 10:7		
		leery 66:8		

making 3:13 4:11 10:6 13:21 14:9 15:16 40:3 41:13 46:20 48:19 92:6 98:2 102:15 105:14 119:16	8:9 10:1,17,19,22 11:8,11 13:13,15 17:9 24:3 25:17 30:16 33:18 39:8 41:2 61:8,20 66:17 67:3 80:17 84:17 86:19 91:22 92:4 94:14 97:16 122:17 125:5	93:9,14 94:3,6,11 94:13,18,20 95:2 95:10,11,13 96:4 99:2 101:12,18 102:10,20 103:9 104:3,18 105:6,18 107:13,22 108:17 108:22 109:22 110:2,9,17,22 111:5,6,20 112:2 112:4,17,19 113:12,13,19,20 114:7,8,13 115:5 115:13,19,22 116:9 117:22 118:14,17 119:10 119:12,13,15,19 119:20 120:16,18 120:20,22 121:2,4 121:6,8,10,12,14 121:16 122:2 123:3,8,14,21 124:18	65:20,21 66:7,15 66:19 67:20 73:20 mid-September 47:12 64:13 80:19 migrating 58:10 mild 101:4 Milligan 8:1 million 20:1 28:12 28:14 30:5 31:11 31:12,22 32:4 35:10,16,18,19,20 35:22 36:2,3 47:3 72:9,13 73:14 74:19 77:20 81:6 81:9 86:9 millions 31:19 77:11 81:17 102:4 109:17 mind 90:13 minimum 49:5 71:21 118:1 minority 95:4 minute 91:13 99:6 minutes 5:9 24:12 44:13 91:16 109:2 missed 68:19 missing 85:17 90:10 mist-like 29:16 mitigation 15:10 mix-and-match 42:1 ML 63:21 66:19 73:20,21,21 MMWR 95:22 MMWRs 115:1 modeled 89:9 modelers 117:13 modeling 50:12 moderator 1:9 8:11 110:4 modification 82:20 Modifications 50:17 modify 53:5 modifying 119:7 molecular 57:14	moment 8:15 21:22 65:10 81:14 122:1 Monday 69:12 Mondays 69:13 monitoring 48:10 87:21 106:10 108:10,14 monovalent 47:10 81:18 109:18 month 24:4,11 25:12 71:8 77:14 86:14 87:6 93:4 122:16 months 35:15 41:11 52:9 86:15 123:5 morbidity 52:11 morning 11:1,2 99:21 122:9 mortality 51:6,10 52:11 motion 77:17 109:11 111:20 118:6,15 120:4 move 14:17 15:15 31:6 33:19,20 35:3 36:19 38:3 50:19 61:16 66:19 75:2 91:13 92:1 moved 30:16 moving 33:21 36:21 104:15 MPH 3:4,19,22 MSPH 3:7 Mullen 104:6,7 multiple 49:22 84:13 mutation 52:3 mute 64:16 88:2 M.D 1:12,12,15,19 1:20,21,22 2:2,6,9 2:13 M.H.A 1:17 M.P.H 2:2,9,13,22 M.S 1:13
managed 13:1 management 57:16 106:6 108:8 managing 106:19 manner 48:14 manufacturer 27:17 28:4 29:13 33:21 54:14 103:20 manufacturers 18:9 25:22 102:14 103:14 manufacturing 26:17 28:1 48:5 markers 54:11 marvelous 124:20 Mary 16:21 Maryland 39:21 mass 17:22 master 111:4 matter 97:10 100:17 119:2 MATTERS 3:2 MAZANEC 87:5 McMurray 7:20 MD 3:7,13 mean 16:15 18:7 60:16 67:6 69:21 73:8 91:11 114:19 meaningful 25:17 means 29:10 47:21 84:2 mechanism 90:13 mechanisms 59:1 90:7 medical 2:13,17 15:10 45:11 Medicine 39:2,13 meet 15:5 43:16 meeting 1:3,8 4:8 4:18,22 5:7,10 8:7	meetings 9:21 39:7 39:8,15 86:4 114:20 122:4 123:18 124:1,4 member 1:9 5:18 5:20,22 6:2,4,6,9 6:11,13,15 7:1,5,7 7:16,19,22 10:5 22:3 23:4,13,16 23:22 31:7,16 32:3,8,10,14 34:5 34:10,12,18,22 35:1 38:1,6,15 39:17 59:8 60:5 60:15,20 61:1,2,4 61:6,18 62:8,18 63:5,17 64:8,14 64:20 65:5,9,16 65:22 66:4,21 67:8 68:3,18 70:10,13,16,19 71:13,14 72:4,10 72:12,18,20 73:2 73:17 74:5,13,22 75:4,14,16,17 76:2,15,18 77:3 77:16,18 78:6,11 78:22 79:3,8,14 79:16,19 80:4,10 80:22 81:11,20 82:1,2,9,10,15,18 82:19,22 83:3,4,9 83:14,16,17,19,22 84:1,5,9,14 85:1,4 86:5,10,11 87:1,7 88:5,12 89:1,14 89:22 90:12,15,22 91:3,12 92:10,12	members 1:10 2:1 9:1,12,15,22 10:9 11:2,14 13:6 22:22 23:10 32:9 59:17 110:12 119:22 121:22 Member's 9:20 mental 13:2 mentioned 98:3 104:22 116:22 messages 42:5 met 28:20 122:8 methodologic 54:9 methods 11:9 40:6 Mexico 24:17 MF59 32:7 100:8,9 100:21 101:7 Michaud 2:13 7:1,1 microgram 31:12 34:14 41:19 47:15 49:13 63:21 64:12 64:22 76:5 79:5 83:11 84:7 93:1 micrograms 30:22	65:20,21 66:7,15 66:19 67:20 73:20 mid-September 47:12 64:13 80:19 migrating 58:10 mild 101:4 Milligan 8:1 million 20:1 28:12 28:14 30:5 31:11 31:12,22 32:4 35:10,16,18,19,20 35:22 36:2,3 47:3 72:9,13 73:14 74:19 77:20 81:6 81:9 86:9 millions 31:19 77:11 81:17 102:4 109:17 mind 90:13 minimum 49:5 71:21 118:1 minority 95:4 minute 91:13 99:6 minutes 5:9 24:12 44:13 91:16 109:2 missed 68:19 missing 85:17 90:10 mist-like 29:16 mitigation 15:10 mix-and-match 42:1 ML 63:21 66:19 73:20,21,21 MMWR 95:22 MMWRs 115:1 modeled 89:9 modelers 117:13 modeling 50:12 moderator 1:9 8:11 110:4 modification 82:20 Modifications 50:17 modify 53:5 modifying 119:7 molecular 57:14	moment 8:15 21:22 65:10 81:14 122:1 Monday 69:12 Mondays 69:13 monitoring 48:10 87:21 106:10 108:10,14 monovalent 47:10 81:18 109:18 month 24:4,11 25:12 71:8 77:14 86:14 87:6 93:4 122:16 months 35:15 41:11 52:9 86:15 123:5 morbidity 52:11 morning 11:1,2 99:21 122:9 mortality 51:6,10 52:11 motion 77:17 109:11 111:20 118:6,15 120:4 move 14:17 15:15 31:6 33:19,20 35:3 36:19 38:3 50:19 61:16 66:19 75:2 91:13 92:1 moved 30:16 moving 33:21 36:21 104:15 MPH 3:4,19,22 MSPH 3:7 Mullen 104:6,7 multiple 49:22 84:13 mutation 52:3 mute 64:16 88:2 M.D 1:12,12,15,19 1:20,21,22 2:2,6,9 2:13 M.H.A 1:17 M.P.H 2:2,9,13,22 M.S 1:13
N				

N 3:1 4:1	56:14 57:11 58:2	O	ongoing 14:16 71:4	overwhelmed 56:1
NAI-resistant 57:6	63:10 75:21	O 4:1	119:2	95:1
name 5:12 11:18	113:14,21,22	object 111:2	onward 18:11	
110:15	114:1 119:6	objection 111:7	open 10:14 19:19	P
names 6:17 23:12	neuraminidase	objective 9:20	opened 117:3	P 4:1
79:11 110:15	42:7 57:4	observational	OPENING 3:6	package 75:7,20
narrow 119:14	new 11:20 24:7	51:10	operator 10:12	77:10
nation 73:1	53:3,4 67:4	obtain 8:22 106:14	21:17 99:8,12,14	page 39:1,6,6 62:19
national 1:1 2:9,11	112:12	obviously 14:12	101:13,15 102:22	81:13 109:8
2:14,15 3:5,18 4:5	news 26:6 29:19	60:19 86:20 103:7	104:5 105:20	pan 101:5
4:13 11:7,22	Nicholas 101:16	occur 41:7 44:21	108:20	page 39:1,6,6 62:19
12:13 19:20 23:17	Nicki 85:22 86:10	56:4	opine 66:17 67:12	81:13 109:8
35:12 39:4,19	Nicole 3:7 11:21	occurred 101:9	opined 68:5	pan 101:5
50:7,10 92:16	night 108:11	occurring 103:12	opinion 51:14 75:1	pandemic 3:11
93:7 108:8	NIH 32:17,18	October 18:19 45:4	opportunities	4:12 11:6 12:8,17
NBSB 5:6,14 8:16	33:21 34:1,6 74:9	72:3	125:7	24:5,14 39:18
9:3 10:16,19	91:20 103:14	odds 82:6	opportunity 4:16	40:22 41:6 43:5
23:10 39:5,7,14	noise 94:17	offer 51:15	17:5 85:18 124:16	43:17 44:8,11
44:9 81:15 86:14	nominal 75:19	offered 24:6	opposed 111:14	47:7 48:20 56:8
90:7 92:4 99:21	nominally 73:11	offering 118:2	opt 73:15	92:20 93:8 95:7
104:10,15 109:15	non-adjuvanted	Office 2:5,7,9,10,13	optimal 49:21	105:3
114:17 115:17	82:13	2:18 39:1 50:8	58:20	pandemics 43:6
116:18 121:19	non-vaccine 20:11	Officer 2:13 87:16	opined 111:14	45:21
NBSB@HHS.gov	normal 26:9 43:13	officers 8:20	opt 73:15	papers 28:6 64:15
5:1	55:4	Official 2:21 4:7	optimal 49:21	parallel 33:9
necessarily 64:3	normally 29:6	8:8	58:20	parameters 71:15
76:10	nosocomial 106:22	officials 46:12	optimally 18:22	parenthetically
necessary 18:12	note 33:17	95:17	option 30:19 52:12	41:5 48:3
50:15	notice 10:15 122:13	officio 2:1 11:14	options 52:10 94:1	Parker 1:19 6:8,9
need 15:18 16:2,7	123:17	59:18	order 3:3 18:1	121:9,10
16:13,14 20:21	novel 40:3 41:4	oh 14:1 35:4 77:4	77:13 106:14	part 15:4 74:20
21:10 22:18 37:16	43:2 44:19 47:10	okay 23:5,18,22	organize 86:1	81:3 95:21 106:10
49:18,21 53:14	48:1,11 52:4,7,13	26:9 34:10,22	originally 97:15	106:12
54:10,12 57:16	53:16 56:2 57:7	38:21 39:16 59:16	Oseltamivir 20:14	participant 34:8
58:8 60:18 63:1	58:12 62:14 100:3	63:3 71:13 75:3	36:18 52:1,8	88:2
76:22 79:10 82:12	100:7	79:10,15,18 82:9	Oseltamivir-resi...	participate 11:11
88:9 90:9 93:16	nuance 88:13	83:17 91:12 94:20	52:2,13 53:18	participation
94:7 97:9 110:14	nucleic 57:15	99:2,18 108:18	ought 19:21 63:13	121:21 124:10,15
111:18 112:13	number 18:4 21:19	109:1 110:2,6,11	83:13,21 113:9	particles 31:2
114:2 122:17	21:21 26:15 29:7	110:16 111:7,9,9	outbreak 44:3	particular 90:1
123:1 124:1,4	34:2 45:18 77:11	120:12 121:17	outbreaks 55:10	117:18 118:21
needed 18:13 19:19	80:12 81:2 99:16	125:4	56:17	particularly 52:1
25:1 47:12 49:6	101:9	old 73:1	outdated 60:13	89:17 95:6 100:21
49:17 59:2 64:1	numbers 26:20	Olympia 101:11	outside 16:2 98:4	119:4
needing 20:19	28:9 85:13 101:8	once 18:22 21:3	overall 59:11	parts 83:7
needle 102:13	NVAC 108:8	39:2 61:15 86:14	overcome 54:10	passages 27:13
needs 43:16 56:12	123:19	87:6 97:15 122:16	overhead 123:9	passaging 27:10
			Overview 3:9 8:16	Pat 6:14 23:2 64:9
			23:20	64:10,17 66:21
			overwhelm 43:13	77:18 79:16,18
			55:3	

84:1 89:14 115:5 118:18 119:11 121:15 122:2 pathogenesis 51:13 pathway 31:20 49:3 53:15 54:7 54:18 pathways 53:14 patient 91:15 99:7 patients 37:10 42:10 43:22 51:9 51:16,18 52:15 57:17,18 Patricia 2:18 8:1,4 110:16 PATRICK 1:22 Patty 5:16 7:12 120:14 Pavia 1:20 3:13 6:10,11 23:4 32:10,15 35:4 38:4,6 39:17 60:5 60:20 61:2 68:3 68:17 71:14 72:4 73:17 75:17 80:22 84:14 86:5 89:1 89:22 90:15 104:22 105:6,7 107:22 113:13,20 116:21 118:12 121:11,12 123:21 paying 16:13 38:3 PDF 39:10 peak 45:4 46:1 pediatric 36:8,9 103:12 people 13:22 14:6 16:18 18:14 20:1 22:19 24:10 27:4 52:20 59:18 60:21 61:21 62:1 74:9 74:21 79:11 87:15 89:7,10 93:3 97:18 100:15 107:1 111:2 people's 20:5 67:1 Peramivir 37:11	perceived 46:10 percent 36:10 percentage 73:13 perfectly 69:11 perform 49:19 58:4 performed 9:5 period 10:11 11:4 person 13:12,13,13 79:11 personal 9:16 15:9 persons 53:19 perspective 46:13 pertains 106:5 Peter 2:11 6:21 7:21 PFUs 31:2 Ph 2:15 pharmacokinetic 54:1 Phase 37:9,13,18 PHD 3:10 philosophy 98:7 phone 8:4 10:13 21:16 23:11 99:9 99:15,22 114:6 124:13 phrase 79:20 phrased 70:11 Ph.D 1:14,14,18,22 2:4,11,17,18 pick 73:7 85:2 piece 73:18 87:20 pieces 90:10 pipeline 18:7 place 38:20 48:10 62:11 98:11 116:12 places 84:13 plan 12:12 93:3 planned 103:16 planning 17:16 24:19,20 45:15,20 73:4 87:14,18 105:13 116:22 Plant 2:3 plate 114:3 platforms 56:20	58:13,15 play 55:8 72:14 playing 82:5 please 5:4 6:18 11:17 21:18,21 23:12 63:1 65:5 79:11 99:13,16 100:17 101:4,10 101:18 102:8,10 102:21 104:4 105:19 pleasure 11:19 pledge 22:7 plus 42:2 pneumococcal 43:12 55:2 pneumonia 51:4 point 18:10,19 30:9 31:17 33:22 34:20 44:16 62:2 63:9 63:14 66:7 77:14 79:2 80:7,7 81:9 84:5,20 88:18 113:2 114:9 119:11 122:14 points 38:13 40:11 43:14 91:17 111:11,18 120:3 policy 14:16 16:3 34:2,3 48:14 poorer 28:22 29:1 population 36:13 42:20 48:6 80:13 82:4 85:3 103:8 populations 73:22 89:18 portion 71:5 72:15 74:18 80:2 86:8 113:7 portions 59:20 posed 43:17 position 76:13 possess 106:16 possibility 10:1 67:4 93:2 possible 33:15 47:11,19 53:11	81:22 possibly 57:6 post 16:11 88:19 97:19 posted 4:19 10:16 Poster 2:15 7:7,7 post-exposure 42:9 42:13 potential 9:18 17:22 46:5 49:21 100:8 potentially 17:13 20:16 72:14 94:15 106:20 112:11 114:20 power 48:12 practical 73:21 Practices 49:7 80:16 precedes 113:3 precise 77:11 Precisely 123:14 prefer 66:8 pregnant 47:22 49:16 53:20 54:1 preparation 17:21 prepare 17:21 78:3 prepared 96:16 123:2 preparedness 2:7 3:8 11:20 12:9,18 13:3 14:13 39:13 40:17 preparing 17:18 40:12 prerogative 92:17 prescribing 75:8 75:13,18 76:8 presence 95:7 present 1:10 2:1 5:18,20,22 6:2,4,9 6:11,13,15 7:5,11 7:19,22 43:17 53:7 presentations 40:4 presiding 1:9 press 21:18,21	99:16 pressing 23:1,3 presumably 78:7 80:17 pretty 16:1 68:7 108:2 114:3 prevailing 79:4 prevention 2:8 13:2 50:9 51:9 previous 36:14 58:10 79:12 104:12 114:22 Previously 12:19 primarily 12:22 primary 44:1 48:8 49:10 55:14 principal 12:20 14:14 principles 40:15 44:14 47:9 48:21 52:21 56:5 prior 10:19 24:18 24:20 prioritization 72:22 73:9 104:8 priority 104:14,16 105:12 private 106:16 privilege 13:10 probably 20:8 26:5 27:16 36:1 37:19 66:17 70:2 86:13 90:19 97:14 98:12 problems 100:13 procedural 109:4 procedures 61:17 proceed 15:17 48:7 77:10 120:1 123:16 proceedings 125:9 process 22:9 27:10 40:11 50:5 54:3 76:1 84:6 92:6 98:11 processed 72:11 processes 26:17 processor 81:12
--	---	---	--	---

procure 102:17	protective 15:9	puzzle 90:11	R 4:1	54:18,21 59:2
procurement 36:21	protocol 58:11	p.m 1:9 4:2 125:10	radar 16:14	receive 21:3 27:2
procuring 28:15	provide 4:17 9:15		RADM 87:11 96:21	received 9:12 10:20
produce 27:12 37:4	14:16 17:4 25:5	Q	raised 118:19,20	10:21 11:1 99:11
47:2 63:20	25:10 49:11 55:10	QA 65:14	randomized 51:8	99:21
produced 30:4	56:18 102:6 116:7	QC 65:14	range 64:5,5 75:3	receiving 21:4
58:15 100:14	providers 52:9	quality 13:1 42:18	117:6	recognize 108:4
producers 93:12	106:13	51:6,7	rapid 43:20	recognized 12:6
producing 26:1	provides 41:15	quantify 55:9	rapidity 123:4	recognizing 106:1
27:8 30:2	providing 18:21	quantity 41:16	rapidly 33:22	recommend 77:8
product 29:3,11,16	22:7 27:20 62:13	quarantine 95:11	46:17 56:1,22	93:7
30:8,12,22 37:15	102:15	question 19:19	75:19 83:21 98:20	recommendation
50:3 63:21 66:14	provisions 106:9	21:18,20 61:19	117:3	69:15 84:3 91:8
67:22 72:7 80:19	106:13	62:5 64:9,21 67:1	rates 44:22 45:7	92:18 93:19 94:9
92:3 112:8,12	public 3:15 4:14,15	67:1 69:1,1,2,14	rational 41:21	96:10 104:15
production 25:22	10:9,10,17,17	69:20 73:7 74:20	reach 68:9	108:3
26:20,21 27:15	11:3 12:6,18 13:2	78:15 80:5 82:12	reactions 101:8,9	recommendations
28:10,12,17,20	24:17 39:2,14	84:15 91:5 92:16	read 11:3 38:10,12	8:22 9:5 14:1,2
37:2 41:22 60:1	43:15 46:5,12	95:5,8,9,20 96:1,6	44:13,16 52:19	17:16 18:21 21:3
63:8 100:12,13	55:7,13,21 56:11	101:16,20 102:21	99:20 101:7	44:18 50:15 60:12
101:22	56:16 57:1,9,19	102:22 103:3	109:10 110:13	93:17 97:2,4,17
productive 25:18	57:21 87:19 91:14	104:5,7 105:19,20	120:2	98:17 104:9,12
products 26:4	91:15 99:7,19	106:4 108:2	readiness 57:19	105:9,9,12 108:11
29:14 43:10 46:8	107:18 108:19	114:17 115:4	reading 50:21	112:8,15 115:10
54:20 67:11	117:8	118:3,4 119:14,14	ready 61:11 70:7	121:18
professional 9:16	public's 22:9	119:18 122:4,15	70:20,22	recommended 36:6
program 2:9 19:6,7	pulled 35:11 76:10	questions 11:12	reagents 44:6 58:3	recommending
41:8 50:7 101:10	pulling 94:1	21:14 22:2 31:5,9	59:4 107:16	14:5 48:16 62:20
Programs 58:3	purchase 36:7	31:10 32:9 35:2	real 9:18 46:10	82:14 115:15
progress 32:11	purchased 19:17	52:20 67:7 87:13	98:5	recommends 44:9
40:8 63:8 68:14	purchasing 54:16	99:15 108:19,21	realizing 20:8	81:16 109:16
98:2	purify 26:13	116:5 121:22	really 13:10,18,20	reconvene 84:17
progression 42:8	purpose 24:13	queue 10:13 101:14	14:6,8,10,15 15:3	record 125:10
project 125:3	purposes 8:6 17:16	queuing 99:19	15:19 16:18 17:9	recordations 98:19
projections 40:9	45:6,15 62:19	quibble 120:10	17:10 18:11 20:22	recuse 10:5
prophylactic 113:8	77:6 105:14	quick 94:12	29:1,4 30:16 60:9	reducing 42:8
prophylaxis 42:10	pursue 41:8 109:21	quicker 75:22	69:14 105:8 108:1	reference 27:20
42:14 55:19 88:20	pursuing 54:17	quickly 18:13	108:4 122:15	refraining 10:6
88:20 89:12 97:20	69:15	90:12 112:4	123:5 124:21	regard 84:7 92:5
98:8,19 113:1,18	purview 67:10	117:11,15	realm 67:14	92:18 112:10
116:6 117:15	put 15:2 17:15 29:9	Quinlisk 5:16 8:4	reason 27:4 36:13	regarding 19:3
119:3	73:15 79:21 88:22	120:14	66:22 74:13 78:2	103:3
propose 63:18 77:7	95:20 99:3 100:1	quite 16:4 17:8	reasonable 54:7	regards 104:8
78:12 98:17	113:22 115:6	66:17 92:5 97:5	71:11 116:3	Register 10:15
116:15	118:15	107:2	reasons 19:15	86:18 122:14
protect 101:11	putting 101:5	Q&A 22:1	108:6	123:17
Protection 2:12	122:13 125:2		reassess 43:8 44:5	regular 19:14
		R		

122:13,15 123:18	require 38:13 50:6	Richard 2:6 6:22	115:20,21 116:1	salute 25:15
regularly 19:16	requirement 23:8	7:2,13 23:16,18	116:22	sample 58:17
regulations 9:14	requires 58:22	Richter 7:13	Robinson's 59:22	samples 55:10
53:21	research 2:12,17	Rienzo 1:13 5:21	robust 42:17	Saturday 73:14
regulatory 30:13	12:22 50:9	5:22 120:21,22	role 14:12 22:7	save 20:16 95:16
74:1,15	reserving 111:15	right 16:6,6 18:19	38:7 55:8,14	111:7
rejoined 87:17	resistance 20:14	19:17 20:1,12	80:18	saw 27:9 48:2
related 15:8 67:10	36:18 51:21 55:12	27:3 31:13,15	roll 5:13,15 6:20	Sawyer 2:22 3:4,19
101:21 106:6	58:1,21 89:8 97:8	35:1,2 36:5 38:1	23:11	3:22 4:3,4 5:16,19
relation 91:18	98:21	39:6 59:19 62:9	rolling 69:22	5:21 6:1,3,5,7,10
relations 48:13	resistant 43:3 52:4	65:22 68:22 71:3	room 75:15 87:2	6:12,14,16,21 7:3
relative 114:19	52:8	71:4 72:16 83:3	Rose 1:21 6:12,13	7:6,9,12,17,20 8:1
relatively 74:17	resolved 54:7 58:9	83:15,22 84:9	34:12,12,18,22	22:21 23:5,15,18
113:1	resource 107:12	90:9 95:10 98:15	63:5,6 64:10	38:8 68:16 79:10
relay 25:2 44:9	resources 40:21	103:22 111:9	70:13,19 71:13	79:15,18 99:18
120:7	55:19,20 57:21	113:12 114:7,13	74:13 78:6,6,22	110:6,11 120:12
release 65:14	respirators 106:4	117:22 119:12,15	79:8,12 80:4 83:9	120:17,19,21
released 48:4	respiratory 56:4	119:18 120:4	83:15,16,19 84:5	121:1,3,5,7,9,11
Relenza 35:11	respond 123:11	rights 54:16	88:12,12 92:12,13	121:13,15,17
37:17	response 2:8 3:8	risk 46:10 48:1	95:2,11 110:17	122:7 123:15
relevant 40:7	11:21 12:13 14:13	49:8 51:16 66:6	111:5 112:19,19	124:5 125:4
rely 16:19	39:13 40:15 45:5	67:19 69:4 73:19	113:19 114:8	saying 14:5 22:5
remain 48:20 54:6	48:20 49:10 56:8	74:2,16 76:20	115:19 118:19	62:20 77:4 92:8
remains 52:16	60:9 89:20	77:5 98:9 104:20	119:10,13,19	says 99:21
remarks 3:6 22:5	responses 40:16,19	117:18	121:13,14	scale 26:2
25:15	responsibility	risks 46:4 94:8	Rosemary 2:10	Scannon 1:22 6:14
remember 26:16	67:15	risk-benefit 76:13	7:18	6:15 64:8,10,20
35:9 72:21 97:18	rest 21:16 110:18	Roberta 1:13 5:19	Rose's 64:11,21	65:9,16,22 66:21
remind 11:16 74:8	restate 64:19	120:19	roster 22:1	66:22 77:18,19
83:5	restating 46:16	Roberts 111:8	roughly 71:19	79:3,16,17 82:19
remote 8:5	60:7	Robin 18:3 24:6	round 71:21	83:3 84:1,2 89:14
remove 60:18	Restriction 58:16	32:10,17 60:10	routes 53:1	89:15 115:5,6
reopening 116:4	restrictions 58:6,10	65:4 66:4 68:3	RPH 3:10	118:17,18 121:15
repeat 99:8	58:13	69:1,22 70:16	rule 43:21	121:16 122:2,3
replenishing 35:20	Retired 1:15,19	71:14 74:7 84:15	RULES 3:4	scenarios 20:4
report 9:7 24:14,21	retrovirals 106:3	91:21 93:15 94:11	rustling 64:15	45:20 73:5 117:2
28:19 30:9 38:5	return 51:4 111:10	95:14 102:7,11	Ruth 1:12 5:17	schedule 26:21,22
38:11,12 44:9,18	reversed 92:3	115:20	115:13 120:14	30:3 86:14
59:21 60:8,18,21	review 3:11 21:6	Robinson 18:3 24:6	R.Ph 1:14	scheduled 10:11
62:19 63:4,6	38:4 59:9 114:1	25:10,13 31:14,21		scheduling 123:12
67:16 104:19	reviewing 24:2	32:6,16 34:16,21	S	scheme 72:22
110:19 120:1,5	revise 63:1	35:4,6 65:3,4,6,10	S 4:1	SCHOENBURG...
reports 9:4 26:7	revisit 19:14 78:20	65:19 66:1,11	safety 2:19 33:7	92:15
represent 117:8	85:19 86:2	71:2 72:3,5,17	46:9 48:10 49:12	Schonfeld 103:1,2
representative 6:18	revisiting 78:14	74:7,8 77:21	50:13 54:1 108:10	103:15
representatives	117:16	102:7,8,11,12	108:14	school 47:21 61:15
40:5	Rice 101:11	103:9,11,19	sake 71:22	61:22 62:10,14,16

schools 62:7	27:22 29:6 33:14	services 12:22 25:7	Simultaneous	91:1,1 94:22
school-age 61:10	36:17 39:3,8	40:2	92:14	111:17 116:10,14
school-based 48:17	50:21 69:3 76:16	serving 16:18	simultaneously	118:19
62:21	78:2,20 79:6	session 25:9	15:12	speaker 21:16
Schuchat 87:8,11	91:16 104:1,10	set 16:3,21 17:15	sir 101:15 118:8	speakers 59:10,18
87:12 96:21	107:8 124:12	49:6 66:2 71:22	sit 13:22	speaking 89:22
Science 1:1 3:5,18	seed 27:11 29:2,4	81:16 109:16	sites 29:13 71:10	speaks 117:13
4:5,13 11:7 12:1	seeds 27:18	sets 33:2	situation 9:8 20:17	special 2:10 9:13
39:2,5,14 92:17	seeing 88:15	setting 61:15,22	22:17 44:11 86:21	11:19
scientific 48:22	seeking 22:8	119:4 124:20	six 12:7 86:15	specific 10:3 40:14
54:9	seeks 86:6	settings 44:2 62:10	size 84:19 85:3,13	40:16,20 47:7
Scientist 2:4	seen 20:13 73:4	62:14,16	sizes 80:13 85:11	88:13 105:8,10
scientists 39:20	115:10	severe 51:7,16,19	skip 52:17	112:15 119:13
Scioli 7:4	sees 63:1	53:19 54:8	Skvorak 2:17 7:10	specifically 53:18
scratched 114:15	segment 59:17	severely 37:10	7:11	59:20 103:6
screen 16:14	segments 59:11,12	52:14	slight 72:6	speech 92:14
season 37:20 52:2	63:4	severity 45:16,21	slightly 66:15	speed 18:6 24:4
101:3	select 39:1	117:17	slow 26:8,8	48:12 51:3 68:15
seasonal 26:17	selecting 41:16	shake 16:4 17:9	slower 41:22	113:16
43:11 45:2 55:2	selectively 44:13	shape 46:10	slowing 58:21	spend 90:8
56:3 57:5 61:11	Senate 12:3	share 13:19 58:3	small 47:16 74:17	spent 12:7,14
61:14 62:5,15,17	sending 121:18	sharpen 17:13	113:1	split 36:20
69:6 71:4 92:19	sense 34:13 67:2	Shawn 7:21	smaller 33:4,11	sponsor 52:16
93:5 96:13 97:5,7	76:3 78:21	shelf 41:18	47:18	sprayer 29:16
second 29:2 33:13	sensitive 42:6	shifting 96:17	social 105:1	sprayers 29:9
33:14 41:6,22	sensitivity 43:21	short 14:8,19 20:2	societal 45:19	spread 45:14
44:20 45:1,3	48:12	52:13 114:19	somebody 63:19	106:22
73:12,18 74:20	sent 10:18,22	shortage 96:8	64:16 85:12 91:1	squaline 100:8
77:17 80:7 88:15	sentence 64:18	shortly 69:7	109:12 114:10	staff 15:2
106:12 109:12	83:2,2 84:10	show 51:11	116:16 118:5	stage 42:9 53:10
110:1 118:16	sentiment 79:4	showing 74:10	somewhat 45:17	stakeholders 39:21
secondary 51:4	separate 42:2	118:22	sons 100:5,10,18,22	stand 32:13
secondly 82:11	September 28:16	shows 82:6	soon 32:19 83:12	standard 65:20
Secretary 3:8	30:9,12 32:1	sick 106:20	sooner 33:11	66:13
11:20 12:4,20	34:17 41:5,7,18	side 39:1,6	sorry 13:11 24:1	Standards 2:15
14:13,15 21:8,9	45:5 49:5 60:4	sign 22:13,14	35:4,5 44:2 87:12	9:10
25:3,4,6 36:6	65:2 67:6 70:8,21	signals 48:13	sort 15:6 19:11	stands 94:8
39:12 44:10 61:20	70:22 71:1 72:1,7	significance 106:6	62:12 67:12 73:10	Star 88:2 99:16
109:6 120:7	75:19 76:10 78:5	106:19	74:11 89:3 117:12	start 13:14 30:10
section 81:13 83:7	78:8 81:8,19,21	significant 113:22	sound 47:20	32:19,22 65:11,12
88:11 91:18 109:8	82:7,16 83:10	similar 45:16 46:8	sounds 63:6,9	71:12 76:11 79:22
115:1 120:7	88:14,16 109:20	74:10	82:18 88:16 92:20	103:21 113:21
sections 83:5	sequencing 85:5	similarly 89:11	space 2:14 124:2	started 27:7 36:16
sector 55:21,22	seriously 30:14	simple 5:5	speak 5:11 10:14	36:17 72:7 78:13
Security 2:2,6,12	serve 4:6 8:8,11	simplicity 48:18	11:18 22:4,22	116:4
23:17	served 12:19	62:22	23:2,3,7 28:13	starting 32:20 33:9
see 13:11 26:9	Service 2:4	simplified 41:8	63:2 75:5 85:22	starts 118:22

state 11:18 12:16 84:22 95:3 106:15 117:8 122:10	strong 54:15 stronger 118:6 strongly 16:1	supply 42:4 43:9,13 44:6 54:19,22 55:4 59:3 98:21 107:4	70:8 77:21 78:13 95:15 117:6 118:10	58:2 65:14 106:7 106:14 107:7,10
stated 10:17 46:15 60:6 92:1	structure 16:22	supporting 42:19	Tamavir 97:7	tests 32:12 43:20 44:4 57:15 58:6 65:14 107:16
statement 78:17	struggled 89:11	sure 11:17 16:5,6,9 20:20 23:6 38:16 61:1 87:13 113:19 117:5	Tamiflu 35:11 36:8 37:17	thank 4:3 7:3,9 8:2 22:5 23:15,19,21 24:1 25:13,14 38:2,8 39:16 59:8 61:4 86:5 88:1,5 92:10 94:20 101:12 102:20 104:3 105:18,22 108:22 112:17 121:20 124:7,19 124:22 125:4,8
states 17:18,20 26:19 29:14,20 35:12,13,17,20 36:3 37:4 40:1 41:3 67:5 81:5	studies 30:20 32:12 32:18,20 33:2,3,4 33:7,11 34:1 37:12,18 41:9 42:1 49:10,14,16 49:20 50:2 51:10 59:2 71:20 74:9 84:11 103:12,15	surface 114:16	tangent 99:3	target 17:13,17 19:20 28:9 81:3 84:19 105:10,16
status 60:1	study 59:1 103:3	surge 43:12 55:3	targeting 47:16	task 15:3,13 21:5,8 87:18
statute 8:19	sub 58:13	surrogate 54:11	task 15:3,13 21:5,8 87:18	tasks 85:2
stay 86:22	subgroups 15:7	surveillance 15:8 57:4 106:9 107:21	tasks 85:2	technical 74:15 116:13
step 54:5	subject 9:13 75:11 82:21 98:20	sustain 56:9	Technology 2:15	telecon 10:7
STEPHEN 1:12	subjects 116:21	sustained 57:11	teleconference 4:9 4:14 10:10 39:9	teleconferences 86:14
sterility 65:13	subsequent 41:2,11 69:20	sworn 12:4	teleconferences 86:14	therapeutic 43:10 55:1 88:11 112:22 113:5
Steve 5:17 75:1 76:2,16 79:14 81:20 82:11 86:11 109:22 122:3 124:18	subsets 73:8	symptoms 42:8 51:3	telephone 21:19,22 84:17 99:17	therapeutics 59:13
stockpile 35:12,17 35:21 36:11 112:20 113:1	substantial 42:19 51:2,15	syringe 102:13	TELEPHONIC 1:3	therapy 53:3
stockpiled 113:6	substantially 88:14	syringes 102:3	telephonically 1:9 123:7	thing 14:10 18:2 23:9 35:3 37:6 67:12 72:6 77:19 88:16 93:6 112:9 118:9 123:22
stockpiles 58:21 96:12 117:12	substituted 120:2	system 93:21 100:13	tell 14:7 21:2 32:11 33:8,11 68:10 70:1 86:15 101:13	things 16:4,6,7 18:15 19:11 20:19 20:20 22:14 27:14 33:8,15 38:2 60:17 61:7 69:3 69:10,11 71:3 74:15 78:12 87:21 105:7 117:3 122:22
stop 21:13 31:4 38:16 59:6 77:4	substitution 109:13	table 36:5 88:22 111:12	tens 31:18 77:10 81:17 109:17	think 13:19,21 15:15 16:12,14,15 16:17 17:11,14,19 19:12,19 20:21 25:9,18 44:15 61:12 62:5,12 63:12 64:17 67:1 67:6 68:2,3,9,12 69:2 70:12 73:3,7
story 28:6	subunit 41:19 47:14 49:3	tabled 111:12,21 111:22	tentative 92:21	
strain 27:22 28:3 66:15 68:6 93:8	sub-studies 49:15	tables 26:7	tentatively 123:11	
strains 26:12,14 27:20 42:6 43:3	sub-typing 58:14	tackle 114:4	term 33:6 114:19 61:16 63:8 75:2 76:13,13 87:20 91:7,10 111:15 123:10 125:2	
strata 49:22	success 28:21	tactical 95:8	terms 9:9 42:18 61:16 63:8 75:2 76:13,13 87:20 91:7,10 111:15 123:10 125:2	
strategic 35:12 47:1,6 50:4 95:9 111:14 112:5 119:14	Sue 7:17	take 5:13 8:15 17:3 18:16 21:5,7,11 21:14 33:17,18 39:5 40:16 44:12 47:13 59:9 67:19 75:21 77:5 80:11 88:6 110:3 114:18 115:2,14 117:21 120:13	term 33:6 114:19 61:16 63:8 75:2 76:13,13 87:20 91:7,10 111:15 123:10 125:2	
strategies 46:18 78:15	suggest 44:22 86:1 86:1	taken 21:11 35:21 123:20	terrific 13:18	
strategy 3:12 4:11 89:4 90:3 95:12	suggested 98:22 105:15	takes 27:13 115:17	Terrorism 2:7	
stream 96:2 99:5	suggestion 86:13	talk 59:19 88:7 96:15 99:19	Terry 2:2 23:14	
strengthened 56:14	Summary 3:12 38:10	talked 61:8 68:20	test 106:17	
stretch 42:3	summer 17:2		tested 37:9	
	summit 17:20 61:19		testing 41:8 54:1	
	Sunday 70:3			
	super 29:4			
	supplement 95:22			
	supplies 41:10 84:11 106:3			

73:19 75:16 76:19 76:22 77:19 78:16 80:8,18 81:2 84:2 85:15,18 86:13 87:3 88:14 89:3 89:15,16,16 90:2 90:3 91:6 93:10 93:11,21 94:6 95:5,8 96:9,11,14 96:17 97:14 98:1 98:10 100:9 101:8 105:8 107:6,18,22 108:2 111:18 112:6,11,13 113:7 113:20 114:16 115:3,9 116:15 117:12 119:1,19 123:5 124:5,21	113:11,22 118:7 122:4 timely 25:6 48:14 times 45:1 101:2 123:22 timing 44:10 45:3 titer 29:6 today 9:8 10:10 11:7,11 13:11,15 21:3 24:2 39:15 63:7 68:12 80:12 121:21 124:13,13 125:6 today's 39:8 toddlers 47:21 told 80:1 tolerance 20:6 Tom 6:7 121:7 Tony 62:3 90:18 96:22 98:12,16 116:9,18 118:8 tool 44:2 top 86:22 107:1 122:22 total 35:22 totally 91:4 112:5 113:14 touches 125:2 to-date 21:12 22:12 track 30:6 traditional 33:6 traditionally 97:1 traditional-process 50:3 transcribed 5:10 transcriber 11:17 transparent 49:1 transpired 24:11 25:11 travel 114:20 treading 68:20 treatment 35:10,16 51:19 52:6,10,22 53:10,16 55:18 89:12 90:5 97:20 98:8,18 113:18 Treatments 53:5	tremendous 15:2 trials 34:3 37:10 51:8 69:9 89:9 trigger 76:9 94:2 triggers 19:12 true 46:12 60:15 63:18 try 8:6 16:21 91:9 93:18 trying 20:14 85:8 110:15 turn 9:7 23:20 38:4 59:6 95:17 124:3 turning 111:8 turns 14:18 18:1 27:1 twists 14:18 two 10:19 15:1 20:1 28:11 29:5 33:2 45:1 49:16 65:13 69:13,13 71:2 72:21 83:5 86:4 93:12 94:15 100:4 110:20 122:16 123:6 type 34:2 38:22 58:17 91:7 typically 47:15 95:21 118:11 typing 56:21 58:11 58:14	51:18 undergoing 37:18 underlying 45:11 47:8 undermines 106:22 underneath 39:3 understand 23:9 27:17 44:17 70:19 71:15 73:18 78:16 100:11 understanding 51:12 112:20 understood 23:6 68:22 79:22 undertook 74:9 underway 40:18 60:14 unfold 20:5 unfolds 112:9 unfortunate 58:18 United 26:19 29:14 29:20 37:4 40:1 41:3 67:5 unknown 45:3 upcoming 39:7 44:3 66:16 101:3 update 24:7 25:10 25:21 35:6 38:2 91:21 103:3 updated 97:9,14 98:12 99:1 updates 15:5 24:10 122:22 updating 97:17 upside 74:17 upstairs 21:16 up-to-date 68:14 urgency 67:2 use 18:22 20:7,10 20:15 37:7 42:13 51:5 53:19,19 55:18 57:20 58:20 58:22 76:21 81:19 84:4 89:5 92:2 95:5,16 96:18 97:12 98:8 100:8 107:4,8 109:19	111:13 112:15,21 112:22 113:5,8 116:22 117:10,10 119:7 useful 25:5 84:16 uses 20:15 37:13 USPHS 2:22 utility 43:18 57:12 utilization 107:12 U.S 2:15,17,19 41:17 48:6 54:15
V				
vacation 8:5 vaccinate 19:22 62:11 vaccinated 46:14 vaccination 17:14 17:22 47:6 49:10 62:14 76:11 101:10 vaccinations 20:6 48:11 vaccine 2:9 17:17 18:14,18,22 19:18 19:21 25:21 26:2 28:13,16,18 29:18 30:20 31:1 41:4 41:13,17,19,20 42:2,4,11 43:11 43:12 46:1,3 47:2 47:11,17 48:5 49:4,4,14 50:7,13 55:2 59:13,20 60:1 61:10,11,14 62:6,15,17 63:4,8 64:2,22 66:12 67:10 68:5 69:21 74:2 76:4 78:1 81:6,13,18 82:4 82:13 83:7,18 84:4 85:9 87:14 87:17 88:7,9 89:20 91:5 92:19 92:20 93:6 95:6 96:19 97:3 100:9 100:11,19,22				

101:6,22 102:19 103:3 104:8 106:7 106:10 108:9,13 109:9,10,18 112:10,14 113:4 118:13 119:1,5 120:7	volume 64:1 vote 3:18 77:7 110:3,5,7,8,12 111:8 120:1,11,13 VOTING 1:10 VRBPAC 66:16 67:10 85:20	ways 29:15 66:20 website 4:20 98:22 wedded 73:3 weeds 89:4 91:11 95:8 week 17:15,19 32:21 48:4 85:21 92:7 103:16,17 weeks 14:21 18:16 28:11 33:1 65:7,8 65:9,13 69:14 81:8 94:15 122:16 123:6 weigh 80:20 89:2 93:15 weighed 96:11 welcome 10:8 19:2 19:13 welcoming 12:1 went 18:4 29:2 36:14 125:9 we'll 17:5 19:15 20:19 33:10 37:3 38:11 78:8 87:3 111:7 120:1,8 we're 15:11 16:8,12 17:3 18:11 19:8 19:13 22:17 24:20 29:12 34:17 37:3 52:19 74:3 77:12 82:5,7,13 86:21 88:7,14,17 90:3 91:13 94:14 105:13,14 107:7 108:4 112:6 113:10 114:4 116:8 122:21 we've 15:2 19:17 20:13 38:16 83:5 84:12 88:13 101:21 109:7 whatnot 111:16 who've 89:7,8,9 wide 117:6 widely 43:18 52:8 57:13 widespread 117:10	wiggle 75:15 Williams 6:22 7:2 Willie 7:6,8 willing 16:22 90:20 willingness 20:5 22:6 window 28:17 winds 18:10 wish 62:1 74:6 118:2 wishes 25:10 women 47:22 49:16 53:20 54:2 wonder 89:6 wondering 60:22 102:5 106:8 word 81:12 wording 67:18 81:10 82:20 115:6 120:10 work 9:2 16:9 22:6 22:12 24:15,15,22 31:19 44:8 51:4 60:8,9 89:8 94:5 96:2 99:5 101:21 114:22 117:7 118:11,13 124:16 125:1 worker 106:5,9,19 workers 38:5 85:12 104:14,17 106:2 106:21 108:14 working 3:12 4:12 9:6 11:6,8 12:7,15 13:7,17 14:20 15:6,11 16:15,20 17:1 20:22 22:10 22:18 39:18 40:13 87:19 116:11 120:5 124:3,9 works 27:22 world 48:7 82:8 worried 100:6,7 worse 22:16 46:2 worsening 20:16 worth 46:16 60:7 63:12	Worthington 2:18 7:12 worthy 60:17 wouldn't 72:10 73:2 84:3 88:3 WRAP 3:21 written 10:20 104:20 wrong 63:19 93:11 www.hhs.gov/aspr 38:22 WWW.HHS.gov... 5:5
vaccines 11:9 15:9 26:18 27:7 28:5 31:5 32:12 40:6 46:7,7,9 47:14 55:3 56:19 100:3 100:16 103:13 119:8	<hr/> W <hr/> wait 66:8 70:14 77:4 92:22 113:10 115:14 waiting 68:1 want 5:3 11:16 13:14,19 14:7,10 17:18 25:14,15 27:21 38:7,15 50:19 64:19 65:3 67:13 73:18 78:17 80:19 82:19 83:4 83:7 84:3 91:13 95:3 96:1,22 99:11 107:20 108:16 109:2,3 110:7 114:4,10 116:10 118:19 124:3 wanted 23:6 30:7 36:19 61:2 73:10 74:8 87:14 92:6,9 92:15 123:8 wants 41:4 109:12 116:14 118:5 war 16:17 Washington 101:11 waste 76:21 wasted 74:3 watch 119:21 wave 41:6,22 42:12 44:20 45:1,3,5,17 46:2 67:4 88:15 95:7 113:3 way 5:5 10:3 16:17 32:2 38:21 77:8 79:20 90:1 93:22 104:19 116:8	validation 58:4 variety 61:21 108:6 various 80:13 98:3 varying 74:11 venues 73:6 verb 64:18 verbal 120:9 versions 39:10 versus 89:12 Veterans 12:16 vial 75:7,10 79:21 vials 93:5 view 117:19 views 117:6 vigorous 111:6 vigorously 43:6 111:2 Vince 7:1,3 VINCENT 2:13 viral 55:9,11 virion 26:12 virus 12:13 18:10 26:3,7,8,11 27:7 27:11,15,20 28:21 29:4,6 31:1 36:15 40:4 45:14 48:2 52:3,7 53:18 57:7 100:4,7 118:22 119:5 viruses 27:11 36:19 41:15 44:19 56:3 56:4,21 57:6 Vittie 121:7,8	<hr/> Y <hr/> year 36:22 37:21 62:15 97:5 years 12:7,15 40:18 66:14 90:8 96:8 yesterday 12:4 yield 27:16 42:2 yields 27:9 28:7,22 106:20 young 45:8 53:20 younger 45:10 youngest 73:22	
			<hr/> Z <hr/> Zanamivir 36:7,14 52:12 54:13 91:22 113:16	
			<hr/> \$ <hr/> \$80 86:8	
			<hr/> 0 <hr/> 0.5 63:21 73:20	
			<hr/> 1 <hr/> 1 70:22 73:21 1.4 27:1,3 1.5 27:3 1:30 10:11 1:50 10:11 1:59 119:20 10 31:1 10th 10:21 12:3 101 3:15	

11 35:10,18,20 119 30:5 32:4 12 109:2 12:00 1:9 12:02 4:2 120 3:18 125 3:21 13 3:6 15 30:22 31:12 34:14 41:19 47:15 49:13 63:21 64:12 64:22 65:20,20 66:6,14,19 67:20 73:19 76:5 79:5 83:11 84:7 93:1 15h 76:10 15th 18:20 30:11 30:12 31:17 34:19 60:2,4 63:10,16 64:11 65:2,17 66:3,7 70:2,7,8,14 70:20,21 71:1,8 71:11,16 72:1,3,7 72:8,13 73:15 75:20 77:10 78:5 78:7,18 81:8,19 81:21 82:17 88:14 109:20 17 1:6 17th 10:16 39:9 99:22 18 28:12 31:11 18th 60:8 18th-19th 39:22 18-19 4:10 18-19th 13:16 19th 60:9 193 28:14 31:11 1976 101:10 <hr/> 2 <hr/> 2 81:13 109:8 2:05 125:10 20 36:10 81:6 2004 27:8 74:9 89:13 2005 96:14	2007 116:2 117:14 2009 1:6 4:10 24:16 26:10 36:18 39:22 41:5,18 43:1 44:21 56:2 81:19 109:20 22 3:9 24.5 35:16 25 73:21 <hr/> 3 <hr/> 30 71:19 75:22 30th 28:16 30-day 72:4 300 47:3 35 35:19 36:2 38 3:13 <hr/> 4 <hr/> 4 3:4 409 28:3 44 35:22 36:2 <hr/> 5 <hr/> 5 62:19 50-50 36:20 <hr/> 6 <hr/> 60 72:9,13 73:13 74:18 77:20 80:2 81:9 60-80 31:22 600 20:1 <hr/> 7 <hr/> 7th 31:1 <hr/> 8 <hr/> 80 72:9 77:20 81:9 80-20 36:20			
--	--	--	--	--