1 MEMBER MICHAUD: Vince Michaud for
2 Richard Williams.
3 CAPT. SAWYER: Thank you, Vince.
4 Frank Scioli, Joe Annelli.
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 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 recordations 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 hamstrings 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.)
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