

Science Board to the
U.S. Food and Drug Administration

Advisory Committee Meeting

October 21, 1998

Washington Plaza Hotel
Washingtonian Room
10 Thomas Circle, NW
Washington, D.C.

Members of the Board in attendance:

David M. Kipnis, M.D., Chair

Robert Langer, Sc.D.

Leslie Z. Benet, Ph.D.

Gilbert A. Leveille, Ph.D.

Richard B. Setlow, Ph.D.

Pedro Cuatrecasas, M.D.

Marion Nestle, Ph.D., M.P.H.

Rita Colwell, Ph.D.

FDA participants:

Elkan R. Blout, Ph.D., Senior Advisor for
Science, FDA

Michael A. Friedman, M.D., Lead Deputy
Commissioner, FDA

Bernard A. Schwetz, D.V.M., Ph.D., Interim Chief
Scientist, FDA

Linda A. Suydam, D.P.A., Associate Commissioner
for Strategic Planning

Susan K. Meadows, M.S., Executive Secretary, FDA
Science Board

Susan Homire, D.V.M., Office of Science.

Neil Wilcox, D.V.M., M.P.H., Office of Science

Brenda Gomez, Office of Science

Agenda

Closed Session

1997 FDA Scientific Achievement Awards

Budget Implications, Science and Research

Programs [Not transcribed]

Open Session [10:30 a.m.]

Introductions

Elkan R. Blout, Ph.D. 5

Opening Remarks

David M. Kipnis, M.D., Chair 5

Chief Scientist Position: Status 11

David M. Kipnis, M.D.

Michael A. Friedman, M.D.

FDA Research Coordination Plan 16

Bernard A. Schwetz, D.V.M., Ph.D.

Anita O'Connor, Ph.D.

Science Board Issues 55

Science Board Expertise

Elkan R. Blout, Ph.D.

Stakeholder comments - FDA Science

Bernard A. Schwetz, D.V.M., Ph.D.

CBER Review report	4
David M. Kipnis, M.D.	
CFSAN Research Review	66
Alan M. Rulis, Ph.D.	
Bernard A. Schwetz, D.V.M., Ph.D.	
Public Comment	96
Science Board Summary and Recommendations	106
Adjourn	109

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23

P R O C E E D I N G S

DR. KIPNIS: I will call this meeting of the Science Committee to order. This is now an open Science Committee. I don't see any sunshine coming through, but we do follow sunshine requests and requirements.

I wonder if the members of the Board would introduce themselves. I'm Chairman of the Board, my name is David Kipnis, I'm Professor of Medicine, Washington University.

DR. BENET: I'm Les Benet, Professor of Biopharmaceutical Sciences, University of California, San Francisco.

DR. LEVEILLE: I'm Gil Leveille, formerly with Nabisco Company; I'm currently retired from that, and I'm consulting.

DR. COLWELL: Rita Colwell, -- it was the University of Maryland; as of two months ago I became Director of the National Science Foundation. You may wonder why I'm here, because I certainly have enough things to do over there; but I believe very strongly in working, partnering with agencies, and I

1 thought it was very important to stay on the
2 Science Board as a link between the National
3 Science Foundation and the FDA; and I don't
4 think there's been much link in the past and
5 there should be more in the future. So that's
6 why I'm here.

7 DR. BLOUT: We're grateful for your
8 saying that.

9 DR. CUATRECASAS: I'm Pedro
10 Cuatrecasas, I'm retired as president of Parke-
11 Davis, Warner-Lambert. And I'm an independent
12 consultant on the faculty of USSC in the
13 Department of Medicine in San Diego.

14 DR. SETLOW: I'm Richard Setlow, I'm a
15 senior biophysicist at the Brookhaven National
16 Laboratory.

17 DR. BLOUT: I'm Elkan Blout, and I'm
18 still the Senior Advisor for Science at this
19 agency. And I'm happy that we have so many
20 interesting subjects to talk about today. And
21 also, Dr. Kipnis had a hand in rearranging the
22 program. So we'll get to it.

23 DR. LANGER: Bob Langer, from M.I.T.

1 DR. NESTLE: Marian Nestle from New
2 York University.

3 DR. KIPNIS: Please notice that the
4 program for today, the agenda has been somewhat
5 changed; there will be comments on the chief
6 scientist position, the FDA Research
7 Coordination Plan, Science Board issues and
8 then CFSAN Research Review. Then subsequently,
9 public comments at 12:30, with the Science
10 Board Summary with recommendations at 1:00.

11 I'd like to open this session by
12 pointing out that approximately a month and a
13 half or two months ago, the subcommittee that
14 reviewed CBER submitted its report; they then
15 submitted it to this committee. Modifications
16 were made, some just sent out within the last
17 few days. Dr. Benet, who chaired that
18 committee and did a superb job has modified
19 those -- modifications that I had made subject
20 to comments by others, and I thought they were
21 excellent. He agrees to have them. I think
22 Pedro, who was one of the other individuals
23 intimately involved -- and I'd like to move to

1 finally submit that report to the FDA for
2 CBER's use.

3 Any comments on that? Les, did you
4 have any comments?

5 DR. BENET: Well, yes, let me make a
6 comment. I'm not sure everyone is aware that
7 one of my committee members was MaryLou
8 Clemens, and MaryLou was in the Swissair
9 accident with Dr. Mann. Dr. Mann got all the
10 publicity, Marylou was a very fine scientist in
11 the area of biologicals.

12 MaryLou had written me an Email when
13 we got the final approval of the committee in
14 May that said, you know, "We've now done our
15 work. This is a great report. It's now our
16 responsibility" -- she's talking about members
17 of the committee -- to go out and make sure
18 that this happens; because it's something
19 that's really important to CBER and to the
20 agency.

21 In my sense, I'm happy that we're
22 going to move forward, somewhat disappointed
23 that we couldn't get this out earlier, because

1 it would have been nice to have that as part of
2 the present budget process. I do think it's
3 important that we get it out, and it will have
4 its impact. And from MaryLou's position, I
5 think it's dedicated; she put a lot of effort
6 into this, and I'm hopeful it can have the
7 effort that she wanted it to have.

8 DR. KIPNIS: Appreciate those
9 comments.

10 DR. BLOUT: It's the first of the
11 reviews we're going to make of the various
12 centers; as you know, Les, this sets a model
13 for the future of views, and we'll be talking a
14 little about the next one that's coming up
15 today.

16 DR. KIPNIS: I'd like to second Dr.
17 Blout's comments. That was that the
18 modifications did not alter the substance of
19 the report, which is directed to CBER to help
20 them internally change, modification, add to or
21 do whatever was in accord with the
22 recommendations. It in essence sort of set the
23 mode by which the introductions would be

1 written, so that we recognize we have
2 responsibility to total all the centers, rather
3 than any one report just focusing exclusively
4 on that activity.

5 Pedro, did you have any additional
6 comments?

7 DR. CUATRECASAS: I thought it really
8 was an excellent report, and hopefully the very
9 minor changes, and with the delay perhaps --
10 could be even larger.

11 DR. KIPNIS: I know that CBER is
12 anxiously awaiting the report. Is there a move
13 to submit the report to the FDA?

14 [Moved and seconded.]

15 DR. BLOUT: All in favor?

16 [Voice vote.]

17 DR. KIPNIS: Fine. So we'll submit
18 the report.

19 The next issue, for Dr. Blout.

20 Do you have any introductory comments
21 you'd like to make; particularly with respect
22 to the chief scientist position?

23

1 Chief Scientist Position

2 DR. BLOUT: Yes. I'd like to simply
3 say that I consider this new position could be
4 one of the most influential scientific
5 positions in Washington, and certainly among
6 the regulatory agencies. And we have been
7 talking with the FDA administrative people the
8 last couple of months to try and set the
9 groundwork for this position.

10 I think we all agree on its
11 importance, but the relationship to the agency
12 is not yet completely agreed on; and Dr.
13 Friedman has rightfully suggested that the new
14 commissioner, whoever that may be, should be
15 satisfied about these points.

16 I don't know how many of you read the
17 New York Times, that scientific journal; but
18 today there an article which said that the
19 nominee for the position of commissioner to the
20 FDA is likely to be approved today, in the
21 Senate.

22 If that occurs, Jane Haney will be the
23 new commissioner. The Senator who had

1 questioned her has now withdrawn his
2 questionings and so it is likely, according to
3 the New York Times, that we'll have a
4 commissioner sometime soon, very soon. If that
5 occurs we can proceed, I hope, rather
6 expeditiously with getting the chief scientist
7 search underway.

8 DR. KIPNIS: The evolution of that
9 position of chief scientist was a consequence
10 of the subcommittee report. That subcommittee
11 submitted to us a report which really carefully
12 defined both the strengths, weaknesses, and
13 hopes for the future for science within the
14 FDA.

15 The report focused, importantly, on
16 the position of a chief scientist who in
17 essence be a center -- that office would
18 represent a center, not in the sense of a
19 Center of the FDA, but a focus for research
20 development, not only in terms of the quality
21 of the research, but the spec research, the
22 training programs within the system to sustain
23 high quality research.

1 And it would have a major effect; but
2 critical in that report was the focus on making
3 that an office that carried with it not only
4 responsibility but sufficient authority to
5 carry out that function.

6 In that context, it was recommended
7 that that individual report directly to the
8 commissioner, and occupy a position in which
9 all science would be focused through that
10 position.

11 I would have to say personally that --
12 also a search committee was appointed with some
13 members from this committee and other members
14 from the scientific community at large to seek
15 an appropriate list of candidates to be
16 considered.

17 I would like to say that I found that
18 Dr. Friedman and other members of the FDA have
19 been extremely cordial and supportive in these
20 discussions. They've been very frank and
21 candid discussions; and I think uniformly
22 support with the development of this kind of
23 office, but in the context of both what are the

1 responsibilities of the FDA and its current
2 organizational structure. So that there are
3 both internal problems as well as external
4 problems with respect to how this has
5 eventually evolved.

6 One of the limiting factors was that
7 there was no commissioner in office, because
8 the commissioner in office is going to have to
9 approve the organizational structure that is
10 needed to accommodate the anticipated goals,
11 both of this committee and their subcommittee's
12 report. I found our conversation with Dr.
13 Friedman very supportive in attempting to
14 arrive at a generic conclusion, and appointment
15 of a commissioner would greatly facilitate
16 that.

17 Dr. Friedman, do you have any comments
18 that you'd like to make?

19 DR. FRIEDMAN: Only just a couple, if
20 I may. I would like to underscore the comments
21 that both you and Elkan have made. I think
22 there's tremendous agreement on the
23 characteristics of the position. This has to

1 be an individual who really moves science
2 forward within the agency, who serves to focus
3 the best science, who is both an ambassador
4 outside but also a coordinator of things
5 inside. It's got to be an enormously effective
6 person, this is a hugely important mandate
7 right now.

8 The characteristics of what we want, I
9 think we all agree on. As you correctly point
10 out, there are a lot of different ways of doing
11 that. What sorts of budget authorities should
12 or should not be under consideration, what sort
13 of appointment authority should or should not,
14 what's the location, what's the reporting and
15 so forth.

16 Those are topics that I think we can
17 have very useful discussions about, and I quite
18 agree that Jane's appointment will very much
19 facilitate focusing exactly how to achieve
20 that. But in terms of having a vision of what
21 we want, I think there's a lot of unanimity.
22 And I've appreciated the seriousness and really
23 the energy that all the advisors have focused

1 on this, because it's taken a lot of time; not
2 only of this committee but of others, David,
3 that you've engaged in this task on the search
4 committee, and it would be appropriate for me
5 to recognize and thank all those individuals
6 here.

7 DR. KIPNIS: Pedro, did you have any
8 comments you want to make?

9 I think that progress is being made,
10 and I think now with the commissioner's
11 position potentially being finally decided
12 upon, we'll be able to move ahead, much more
13 rapidly and effectively.

14 The next element on the program is an
15 FDA Research Coordination Report by Dr. Schwetz
16 and Dr. O'Connor.

17 FDA Research Coordination Plan

18 DR. SCHWETZ: Thank you, Dr. Kipnis.

19 We have talked to you in earlier
20 meetings about plans that we are working on
21 within the Office of Science to continue to
22 change the culture of science within the
23 Agency, to be more responsive to high priority

1 issues, to get the various factions of the
2 Agency coordinated and integrated to be able to
3 respond to the high priority issues of the
4 agency, and to develop further support through
5 a variety of mechanisms.

6 [Overhead: Proposed Model for Support
7 of FDA Research & Science]

8 You may recall that this was the
9 transparency that I used to present those kinds
10 of ideas, and the role of the Office of Science
11 in integrating these activities that relate to
12 generating new sources of revenue and how those
13 sources of revenue can be used to support
14 ideas; how will we bring together priorities
15 and advice on how the resources of the agency
16 that related to science and research should be
17 focused, and how we might implement those
18 ideas.

19 So we want to update you on pieces of
20 this, and the numbers that we have up on this
21 transparency this time are keyed to the page in
22 your document that is behind this chart.

23 I would start first by commenting on

1 the research coordination, the overall process
2 that we're looking at, and some specific things
3 we're doing from the Office of Science that
4 have to do with facilities. We realize that
5 we've got some major research facilities within
6 the FDA; and if you look for example at the
7 animal research part of it, we have a major
8 laboratory in Arkansas, the National Center for
9 Toxicological Research; we've got facilities
10 here in the Washington area, the Beltsville
11 area.

12 We have multiple centers using these
13 facilities and at this time when we're trying
14 to improve our efficiency, one of the things
15 that we realize is that by having all these
16 disjointed laboratories for doing the work and
17 competition for the resources, there can be
18 some efficiency gained by hopefully providing
19 some additional coordination type of leadership
20 from the Office of Science about how these
21 resources can be managed and used. Not to set
22 the priorities specifically for research that
23 comes out of the individual centers, but to be

1 sure that we've got the right people working on
2 proposals, and that when we have high priority
3 work that needs to be done, we've got somebody
4 who can help to identify the resources that we
5 have throughout the agency to get that work
6 done.

7 So we are working on a plan right now
8 that will very soon be presented to the Center
9 Directors that helps to provide some focus for
10 our research capabilities that would help to be
11 administered through the Office of Science, to
12 assist the Centers in using our resources to
13 the best that we can. And as this undergoes
14 further review, we'll bring this back for
15 further information to you, to let you
16 understand how we're really going to implement
17 this coordination of using our research
18 facilities.

19 The second one has to do with
20 programmatic reviews. We've had the discussion
21 already this morning about the CBER review;
22 you're going to hear discussion later on this
23 morning about the next center that's in line

1 for a programmatic review, the review of the
2 bigger picture of what the research program is
3 and the one that's up next is the Center for
4 Food Safety and Applied Nutrition; and Alan
5 Rulis will join us later to talk about that.

6 What we have in mind is that we will
7 continue to play these out, once center at a
8 time, and eventually make the rounds of all the
9 centers so that we have this process through;
10 and hopefully as we move through, there's
11 something learned in each center that applies
12 to other centers as well.

13 So by the time we get to the last one,
14 this should be a relatively stressless process,
15 compared to the first one or two down the
16 chute.

17 But the plan is to continue, as you
18 have recommended, to go through the various
19 centers with this kind of a review of the high
20 level look at the center. And when we get done
21 with that, we ought to be able to look at how
22 these fit together -- these do constitute the
23 research program for the whole agency, so we

1 need to look at each of these and see how we're
2 using the center research activities to meet
3 the needs of the agency.

4 If there are questions or comments on
5 any of these as we go, we would welcome input
6 and questions.

7 DR. KIPNIS: Bern, one of the comments
8 I would make, I would like to hear what other
9 Board members think, is that the effectiveness
10 of the NIH in presenting its case to Congress
11 was the issue of external peer review, which
12 resulted in substantial changes that Varmus
13 able to introduce, both with respect to
14 structure as well as individuals; and I would
15 think that the collective center reviews could
16 very well constitute a way of also
17 demonstrating similar attempts to have external
18 review to improve the quality and
19 organizational structure.

20 DR. FRIEDMAN: That's exactly right,
21 David. I was very much influenced by my
22 experience at NIH, when I propose we do this.
23 Because I think it does add credibility, and it

1 does introduce a quality assurance that large,
2 complex organizations like FDA don't
3 necessarily have built in.

4 The advantage for the individual
5 programs I think is obvious.

6 The point that Bern is making is a
7 more subtle one, but I think actually it may
8 ultimately be more important. Which is that to
9 even inventory and link effectively the
10 scientists in different parts of the agency,
11 you have to know what's actually going on. We
12 have not done as good a job of linking across
13 the agency as we need to in the future. This
14 is an extremely important step.

15 So we're not only talking about
16 reviewing CBER or CFSAN or CDER; we're then
17 getting a sense of the overall agency
18 abilities. And if I were to try to envision
19 what the next set of peer reviews would be, for
20 the next cycle, I might not repeat center by
21 center, I might take themes and review them
22 throughout the agency. In other words, cut it
23 vertically and then cut it horizontally.

1 Now we're talking ten years from now
2 before we get all that done, but ultimately
3 that's where I think we should be looking.

4 DR. KIPNIS: Dr. Cuatrecasas.

5 DR. CUATRECASAS: I think the
6 objective, the purpose in what we do with the
7 findings of the report to be carefully thought
8 through. The main value, I think was intended
9 and is intended, in my opinion, yet to be a
10 value to that particular center or division to
11 help identify strengths and weaknesses and to
12 support it in its mission of research.

13 It is not intended, in my opinion, to
14 be used for promotional purposes or for
15 advertising or for raising money or for showing
16 off what a great job it's doing.

17 If the purpose is to show what
18 research is being done, I think it will be
19 counterproductive. Again, the main value, we
20 have a lot of scientists reviewing and
21 critiquing things, is not to find criticisms or
22 to find great scientists; but to help them to
23 improve a -- it can be used, of course,

1 properly to inform -- and it should be, of
2 course -- inform management, and to help
3 provide more resources.

4 DR. KIPNIS: Dr. Cuatrecasas, my
5 comments were not directed to releasing these
6 reports to Congress per se, but the fact that
7 external review groups have carefully reviewed
8 and made suggestions. It's the very thing
9 that, after all, NIH did not release its
10 reports, either. They're confidential for
11 individual scientists.

12 The setting up of a precedent of this
13 nature is really what's important.

14 DR. CUATRECASAS: Oh, yes, I agree.
15 The system. I agree.

16 DR. KIPNIS: Dr. Blout.

17 DR. BLOUT: I think one of the
18 by-products, maybe even a main objective, is to
19 identify lacunae in our system, where there are
20 holes that should be and can be plugged. And I
21 think we should take that into account because
22 certainly what we're moving towards is an
23 agency-wide system rather than a center-

1 directed system.

2 DR. SCHWETZ: Well to expand, Elkan,
3 on what you're saying, and speaking as a center
4 director, our -- and I'm not alone, I think,
5 with this reality. As a center director we are
6 primarily and foremost responsible for what
7 goes on in our center. And it is only
8 secondarily or tertiary that we would look at
9 other centers to meet our needs. And the kind
10 of review that we will go through now I think
11 will help raise the level of attention to the
12 other centers of what actually is available in
13 the centers, and where are the high quality
14 programs that we can link to to make us more
15 efficient. And I think that will help to
16 decrease the silos that we have between the
17 centers and to increase cooperation.

18 To the extent that there are specific
19 functions within our centers that aren't as
20 good as they are in some other center, is a
21 good message to look there as well for help.

22 I think as we go through this series
23 of reviews of the Centers, I think, David, we

1 don't have to wait until the end to pick
2 generalizations that reinforce that reinforce,
3 because there will be some things that I think
4 are common in every one of the reviews that
5 become the basis for comments that we would
6 make that reinforce that there is an effort to
7 improve the quality, and to look broadly
8 throughout the agency to see how we can better
9 the lot.

10 DR. KIPNIS: Can I ask one other
11 question? In terms of assuring interactions
12 with the centers, is the informational base,
13 the computer base, the interactive base also
14 being given consideration? Or is that --

15 DR. SCHWETZ: That's coming up next.

16 DR. KIPNIS: Okay.

17 DR. SCHWETZ: And if no other
18 questions, we can move to that.

19 Anita, if you would cover the research
20 priorities and the database.

21 DR. O'CONNOR: We've been doing
22 actually quite a bit in that regard. About six
23 months ago, we got all of the research projects

1 in from all the centers, and it was about 700
2 different projects. We actually sat down and
3 looked, read every project and put them into
4 some very broad categories.

5 One of the things we learned was that
6 40 percent of the projects in the agency can be
7 linked directly to method development; and
8 other projects fit very easily into
9 manufacturing, safety assessment, standards
10 development. We're doing some work in the area
11 of knowledge base, generating computer
12 databases, too, based on all the data that
13 we've had in the agency for years. We're
14 starting to look very seriously at that: How
15 can that help us make decisions in the future?

16 So this was the first step. We
17 actually put those all on line and made them
18 searchable for everyone in the agency within,
19 on our intranet system first. That was the
20 first step. The second step was to actually
21 create a formal database, and we've done this;
22 it's an Oracle database, and we're in the
23 process now of just finishing up the search

1 screens and populating the database. We have
2 all the projects in from CVM and Center for
3 Drugs, and we're in the process of getting all
4 the projects from the other centers.

5 So what this gives us is, helps us
6 with our long term plan of prioritizing
7 research; what are we doing now? What do we
8 want to do in the future? Where do we want to
9 put our resources? So we're making an
10 investment in this regard.

11 DR. SCHWETZ: What this also helps is,
12 if new questions come up within a center, and
13 for example the need to do further work on BSE.
14 While it's easy to get into the database now
15 and find out who has any projects in any of the
16 other centers that relate either to BSE or the
17 related technologies; so hopefully there will
18 be less of an excuse for groups of individuals
19 to reinvent things, because the information
20 will be there to see who else is working on
21 something.

22 But it also retrospectively gives us a
23 tool to look at what we're doing and see

1 whether that's what we want this resource to be
2 doing. Because now if, for example, we feel
3 that 40 percent of our overall budget for
4 research, if we're not happy with the fact that
5 that's related to methods development at the 40
6 percent level gives us an opportunity to say
7 "Well, it should be 60 percent" or "it should
8 be 30 percent" or something other than what it
9 is.

10 So this was one way to discover what
11 we're doing as the basis for developing
12 prospectively research plans for next year.

13 Anything else on those two, Anita?

14 Well, one of the tools that we realize
15 that would allow the Office of Science to again
16 help affect the culture of the science and
17 provide leadership, one of those tools is
18 always money. And if all we can do is talk
19 about what the priorities of the agency should
20 be and we never have the leverage that it takes
21 to get people's real attention: money, then all
22 we can do is continue to work with people and
23 provide advice and guidance.

1 Dr. Friedman was very helpful to us
2 this year, at the end of '98, by providing us
3 with \$300,000 for our budget in the Office of
4 Science to support research through a
5 competitive process within the agency. And we
6 had gone through an activity earlier to
7 identify the highest priorities of underfunded
8 research within the agency, and reached
9 agreement that these fell in categories of the
10 development of more predictive animal and non-
11 animal models for safety and efficacy
12 evaluation as one category, and the second one
13 was the development of improved methods for
14 postmarket surveillance, and a third one, the
15 detection and assessment of infectious agents
16 and intoxicants -- the food borne pathogen kind
17 of a question -- better methods for doing that;
18 and better ways to identify mechanisms of
19 disease pathogenesis in evaluating new and long
20 term therapies.

21 So these were areas of research that
22 we agreed were important to us, and higher
23 priority than a lot of other things that we

1 have going on. So as we put out for
2 competition for projects, we asked people to
3 respond with proposals in those four
4 categories.

5 We have now gotten proposals in, we
6 have reviewed them, selected ones that we think
7 represent about a million dollars' worth of
8 work because they estimated the cost, \$1
9 million to be narrowed down now through an
10 additional competitive process, to spend that
11 \$300,000 on the work that's the highest quality
12 of science, that represents inter-center
13 projects throughout the Agency, and matches up
14 with these priorities.

15 So within the next few weeks, we will
16 be distributing this money out to research
17 groups within the centers to conduct this work.
18 The \$300,000 is important, to get this work
19 done, but what I'm also hoping is that this
20 will be the seed to go back in to the
21 commissioner in the future and say "Here's what
22 we got for this kind of an investment. We
23 would sure like to see this continue on an

1 annual basis, that there would be money that
2 the Office of Science could use to support
3 research that's high priority within the
4 Agency."

5 So that has been a boost for everybody
6 this year at a time when money to support
7 research is tight; and while \$300,000 in some
8 people's minds is a huge amount of money, when
9 it comes to doing the kind of work we do, we're
10 trying to get as much out of it as we can,
11 primarily as a seed for future activities.

12 DR. FRIEDMAN: If I could add, Bern, I
13 recognize there really is a disparity between
14 the number of needs and the smallness of this
15 amount of money. But it was very hard, even to
16 carve this amount out of the budget. I thought
17 it was a very important symbol.

18 I can't represent to you all or to
19 others that I think the chief scientist
20 position should have authorities and
21 opportunities to actually leverage things
22 without carving out some resources, minimal
23 though they are, and I accept that criticism,

1 but it was all that we could scrape together.
2 I agree with Bern, it's a very good precedent;
3 and we'll have to see what we can do with it in
4 the future.

5 DR. KIPNIS: Would it be possible to
6 distribute to members of the Science Committee
7 the topics, just the topics that were submitted
8 as potential research projects, and those that
9 were selected? To get a feel for what the
10 response would be?

11 DR. SCHWETZ: Yes. We will get a copy
12 of that to you. I don't think we have extra
13 copies here today, but we'll get it to you in
14 the mail, or electronically.

15 DR. KIPNIS: I think that's an
16 excellent way of starting out, encouraging
17 scientists to think seriously about projects.

18 DR. SCHWETZ: I think it's also a
19 moralizing effect, because we now have
20 identified -- beyond those who will be funded,
21 we have identified a number of other
22 researchers and their projects that we consider
23 to be high priority, with the hopes that it

1 will provide the encouragement to get that work
2 supported within the centers and give these
3 people a pat on the back for the work that they
4 have done.

5 We'll be happy to get you that list of
6 projects.

7 One of the things that we would
8 benefit from you in this arena is that your
9 experience in the most efficient way to go
10 through this kind of a competitive process,
11 because we have tried to get outside reviewer
12 input, outside the FDA, as well as internal
13 input; but one of the things that we've found
14 in some of the other programs in the agency
15 where you've got a million dollars or so that
16 can be distributed competitively, it seems like
17 you use an inordinate amount of people's time
18 to write people's projects that don't get
19 funded and go through reviews, and distribute a
20 very small amount of money at the end.

21 To the extent that others of you have
22 experience in how to go through the competition
23 for money in this size and have it really be an

1 uplifting effect in the agency as opposed to
2 dashing people's hopes because they wrote a
3 proposal and it wasn't funded, we would sure
4 benefit from your input. We would receive
5 things by Email or --

6 DR. KIPNIS: What percentage of
7 applicants were funded?

8 DR. SCHWETZ: At this point we have
9 ten proposals, and what we're anticipating is
10 that we will fund either three or four of
11 those. So that's a relatively high percent.

12 DR. KIPNIS: I was about to say, in
13 the real world, that's a pretty good yield.

14 DR. SCHWETZ: Yes, it is. But in the
15 past the ratios have been much higher than
16 that. And we intentionally have narrowed it
17 down this time so that we ask people -- we only
18 asked ten people to write a full proposal for
19 review as opposed to 30 or 40 or 60. We
20 narrowed it down from 60 to these 10. And we
21 narrowed it down from 60 to 10 on the basis of
22 just a one-page summary of what the proposal
23 would be; and then we picked ten knowing that

1 three or four of those will get money.

2 DR. LEVEILLE: Sounds to me, just as
3 you've described it briefly, it's a pretty
4 efficient process as these things go. If you
5 can use that first approach, of a one-page
6 submission to narrow it down to three times of
7 what would be funded, or some ratio of that
8 sort, I think that's a very efficient initial
9 step. And that means subsequent review is
10 inevitable; you just have to go through that
11 time and effort. My reaction is that that's a
12 pretty efficient system, as you've set it up.

13 DR. SCHWETZ: One of the questions
14 that we have also dealt with in this and other
15 programs like in the Office of Womens Health is
16 how broad the category should be for soliciting
17 proposals. Because if you make that terribly
18 broad, then you end up needing an awfully wide
19 range of reviewers to just narrow it down to
20 something that you would select from. And if
21 you make it a real narrow cut, then you're
22 maybe talking to only 10 percent of the
23 researchers in the agency, telling them that

1 "We're not interested in the rest of you
2 submitting, just this very narrow cut."

3 So someplace in between -- and that's
4 why this year we had these four categories, and
5 it seemed appropriate to use them for this
6 purpose -- and with those four categories, we
7 got about 63 or 64 proposals, whatever it was.

8 Thanks for the input.

9 [Chart]

10 In the past we have talked about
11 foundations, and on this chart I refer to it as
12 an FDA alliance, where that number 6 is on the
13 left hand side in two places. We have begun
14 some additional discussions within the Agency
15 about using foundations as a basis for getting
16 additional support of one kind or another, and
17 what we have done is to get the groups of
18 people together from General Counsel through
19 the Center experiences, and through others who
20 have experience with foundations by virtue of,
21 for example, being on the boards of foundations
22 that others use.

23 We are currently looking at four or

1 five as models that could be used either by the
2 FDA or that we would tie in cooperatively with
3 foundations that exist for CDC or for NIH,
4 trying to learn from their experiences; so
5 we're just collecting -- we have just recently
6 collected all of the bylaws and the charters
7 for four or five foundations that do exist,
8 trying to see what we can learn from that to
9 construct a foundation mechanism that we might
10 use within the FDA, that would hopefully be
11 able to attract resources that could be used
12 for training, for educational activities, for
13 maybe -- to support what we've referred to as
14 an "FDA College" that could be a grounds where
15 the scientists of the agency would be able to
16 converse and exchange ideas and help plan
17 priorities and have input on the overall
18 resources of the agency.

19 So we'll come back to you in the
20 future and tell you how these discussions on
21 the development of a foundation within the FDA
22 have evolved.

23 The next category has to do with

1 partnership opportunities. Anita?

2 DR. O'CONNOR: We've been doing a
3 couple of things in this area. You can see,
4 under Sources of Funds in the far left hand
5 corner, one of the things we've been doing is
6 trying to solicit ideas from the Centers for
7 advertisement on the Internet. There are a
8 couple things up there already; we have a
9 partnership page on the FDA Internet site, and
10 as I understand it there's been a very good
11 response to one of the items; at least it's
12 been on that page for a couple months.

13 We're trying to get more ideas from
14 the Centers so that we can advertise for
15 partners, for CRADAs and other creative ways to
16 establish partnerships with the external
17 organizations in industry. And we're still
18 participating in grants with other outside
19 institutions; NIH and other organizations.

20 The other thing we've done is that
21 we've made available two funding databases to
22 our scientists, and through the community of
23 science, has a lot of traffic on it.

1 So I think we're making inroads in
2 this area, but we still have a long ways to go.

3 DR. SCHWETZ: An example of where
4 there's a lot of interest and activity right
5 now in the Cooperative Research and Development
6 Agreements, CRADAs, is in the area of chip
7 technology. Where we have researchers who have
8 knowledge that would be useful to put into a
9 DNA microchip technology platform, and might
10 have to do with enzymatic activity, varies p450
11 in identifying a subset of susceptibility. Or
12 another example in which there's an awful lot
13 of interest is developing chip technology to
14 identify pathogens in various substrates;
15 everything from food to whatever. And of
16 course that's a technology that the U.S.D.A.
17 and the FDA have developed very intensively.
18 So now there's a lot of interest from companies
19 to use that technology to pay us to continue to
20 extend that to a DNA chip technology. Where
21 that will end up remains to be seen, but there
22 sure is a flurry of activity in the CRADAs
23 right now around those couple of things.

1 DR. KIPNIS: Certainly we all hear
2 about a tremendous amount of activity in that
3 area.

4 Are there restricted limits by law as
5 to how you can interact with this group?

6 DR. SCHWETZ: No, not -- for example,
7 the two topics that I'm talking about are
8 unrelated to a product per se; it's a new
9 technology. So in that case, that's something
10 that will flow through the approval systems
11 without an awful lot of problem.

12 DR. KIPNIS: But new technologies are
13 new products.

14 DR. SCHWETZ: If it related to new
15 products that come back to the FDA for
16 approval, like in the Center for Devices, where
17 we will see technologies of one kind or
18 another, then it becomes a problem if we're
19 helping a company develop a technology and we
20 become one of the inventors, coming into CDRH
21 for approval.

22 So you're right, there are significant
23 limits for us to be involved in this.

1 DR. NESTLE: Could you tell us a
2 little bit more about the kinds of partnerships
3 that you're seeking, because I'm very concerned
4 about the potential for conflict of interest
5 here.

6 I just can't think of anything that
7 wouldn't be a conflict of interest.

8 DR. SCHWETZ: I can give you an
9 example of a couple that we're using at the
10 National Center for Toxicological Research.
11 These are partners through interagency
12 agreements with NIEHS; where under the umbrella
13 of the National Toxicology Program where
14 chemicals can be nominated for research and
15 testing through the NTP, we have had for
16 several years an interagency agreement with
17 NIEHS to provide money directly to NCTR to work
18 on those chemicals that are nominated to the
19 NTP that are of FDA origin. So we're working
20 on chlorohydrate {ph}, fumonicin B, urethane
21 and alcohol, a number of chemicals that are of
22 concern to the FDA.

23 So through a transfer mechanism, we've

1 developed this partnership with NIEHS where
2 they provide the money and we do the research
3 that's needed for the FDA.

4 DR. KIPNIS: Conflict of interest has
5 been discussed at this committee meeting on
6 numerous occasions, and one of the
7 recommendations which I think was accepted by
8 the FDA was disclosure. One of the best things
9 you can recommend is that full disclosure of
10 any investigator problem.

11 But it turns out that conflict of
12 interest is not always economic.

13 DR. FRIEDMAN: That's right; exactly
14 right. There are intellectual and other kinds
15 of conflict of interest that are just as
16 difficult.

17 DR. KIPNIS: Very difficult.

18 DR. BLOUT: I think it's important
19 that we work on these relationships, Marion,
20 because one way the Agency will go forward is
21 having some of those relationships.

22 DR. NESTLE: We discussed this last
23 time. The difficulty, it seems to me, is in

1 the difference between FDA and the other
2 federal agencies; the research agencies like
3 CDC or NIH for example. This is a regulatory
4 agency, and it's just hard to imagine a
5 situation in which FDA is engaged in a
6 partnership with a company whose products the
7 agency is going to need to regulate. I don't
8 know; I just have cognitive difficulties with
9 this, conceptual difficulties.

10 DR. SCHWETZ: There are partnering
11 opportunities between the federal agencies that
12 we need to explore even before we get into ones
13 that are more contentious.

14 DR. NESTLE: Such as the one that Rita
15 suggested which, I think deserves attention.

16 DR. SCHWETZ: Yes. And one of the
17 things that I am working on now and have it
18 developed to the stage where we have our first
19 meeting planned is to get the directors of
20 several federal laboratories that have common
21 interests to sit down and talk with each other
22 about how we can interact better.

23 So I have gotten the director of

1 NIOSH, the director of the ARS part of
2 U.S.D.A., the EPA laboratories, us in the FDA,
3 and the director of NIEHS as a toxicology-kind
4 of an organization. We're going to meet for a
5 day and a half to talk about how it is we can
6 work together more effectively, and how can we
7 partner between us where there are no
8 constraints? And how can we be more mutually
9 supportive of each other's needs? Communicate
10 better on what capabilities we have; how do we
11 leverage our resources.

12 So there are some partnering
13 opportunities that haven't been maximized yet,
14 for which there is little concern about
15 conflict.

16 DR. BENET: I can think of other areas
17 that don't relate -- that do eventually relate
18 to projects, but the funding has nothing to do
19 with it. That has to do with what we've talked
20 about in terms of analytical aspects that are
21 required within the agency to develop
22 techniques that allow the agency to more
23 efficiently monitor particular techniques for

1 adventitious agents or things like that.

2 So those are kinds of interactive
3 natures within the industry and the agency that
4 really relate to no product, relate to the
5 techniques that will be developed, that I think
6 can be funded. And at least in the CBER review
7 committee, we heard the industry saying these
8 would be good interactive measures that could
9 be funded interactively to make the agency more
10 efficient.

11 There are areas that I think do not
12 relate to specific products.

13 DR. CUATRECASAS: I think there are
14 also a number of other very close
15 relationships, personal, that have worked very
16 well. An example is the sabbaticals which,
17 chemists from the Center for Drug Research has
18 had a program for chemists, will spend
19 sabbaticals at the companies. Short
20 sabbaticals; three months, to learn something
21 about how the science is conducted, to look at
22 the laboratories. There are certain unique
23 aspects of the chemistry that goes on in

1 industry. Those scientists from FDA do not
2 review, of course, applications from that
3 company. But it's an ongoing program which is
4 educational and gives the chemists also a much
5 better sense of what they're reviewing when
6 they get applications. Thus it's not something
7 that just comes through thin air.

8 A lot of people are proposing that
9 that kind of sabbatical where people spend
10 time, for example in a toxicology laboratory or
11 analytical laboratory or anywhere, could be
12 valuable to scientists. People proposing that
13 people from industry also spend a little bit of
14 time in the FDA sometimes; that that could be
15 very valuable, I would agree with that..

16 DR. FRIEDMAN: Certainly as a threat I
17 think it's very effective.

18 (Laughter)

19 DR. CUATRECASAS: Then also I know of
20 research projects that have resulted as a
21 consequence of a review of a drug. For
22 example, some very important work resulted from
23 collaborative research on the mechanism of

1 action of retroviruses as a consequence of
2 interaction of the scientists in the review of
3 drugs in this area. And also acyclovir. I was
4 personally involved with that, in Zovirax,
5 where the "regulators" the people who were
6 doing the evaluation, had some excellent ideas
7 on how to further pursue the science.

8 Those things were done openly;
9 everybody knew it was happening. I don't think
10 anyone thought that those activities
11 compromised the review of the application, that
12 in any way there was any prejudicial judgment.
13 And it left a very good sense of collaboration
14 and cooperation, both sides.

15 DR. KIPNIS: I suspect that many of
16 those relationships will be one-on-one
17 relationships that initiate them, rather than
18 institutionalizing them.

19 DR. CUATRECASAS: Yes, they are one-
20 on-one relationships.

21 And usually it is very difficult for
22 an individual like that to influence -- it is
23 so inappropriate that it's just purely

1 something theoretical.

2 DR. SCHWETZ: We really appreciate
3 your input and your thoughts. Even in times
4 where money is not an issue, of how to leverage
5 output by virtue of tapping into other
6 resources, partnering is still important in
7 reaching out for technology.

8 I think we will -- my intent is that
9 we will continue to explore this, to use it in
10 ways where we're not wasting our time on the
11 issues that we've talked about that can limit
12 this, from a conflict standpoint but to
13 continue to try to develop it where we can
14 benefit either in output or in technology ideas
15 to maximize this as we can.

16 Anita, on the Expertise database.

17 DR. O'CONNOR: Let me just say a
18 couple words. We've had a scientific expertise
19 and equipment database on line for at least
20 half a year, possibly a year, and it's
21 available to all our scientists. We have about
22 400 people that have actually gone on line and
23 entered their expertise.

1 We're having some challenges
2 convincing people to actually take the time to
3 do this, and I don't think it's unique to the
4 FDA. I think we see the same situation in
5 universities; at least I've heard this.

6 But it's very simple. You can request
7 a password on line. If you've got your c.v.
8 together, you ought to be able to just cut and
9 past your c.v. in on line. The interesting
10 thing about this database is that we get a lot
11 of searches on it; we get anywhere from 100 to
12 200 searches of people actually using it. So
13 we're still plugging away, trying to convince
14 people that this is important.

15 DR. SCHWETZ: An area of new technical
16 committees. One of the things that we've
17 actually been fairly successful at throughout
18 the agency and getting people to communicate
19 more effectively across institutional barriers
20 is by getting groups within a certain area of
21 expertise to get together, to organize, to
22 begin to talk to each other.

23 So we have groups of statisticians,

1 immunologists, toxicologists, a lot of other
2 disciplines throughout the agency where they
3 are meeting on a regular basis. They have
4 electronic means of communicating with each
5 other and finding out where they can get help,
6 where they can get input on protocols, where
7 they can get expertise to try to help solve
8 problems, what not.

9 We have several of those to go yet
10 that we're still trying to organize; but for
11 example in response to the announcement that we
12 have \$3 00,000, several of the respondees were
13 these groups who had already themselves around
14 an issue like BSE or TSE, or a discipline of
15 neurotoxicology, for example, that was already
16 in the stage of identifying priorities; and
17 they simply put their thoughts together and
18 submitted a proposal.

19 So we see part of the benefit of those
20 discipline-oriented groups across the Agency.
21 Another thing that we are now starting is the
22 development of mechanism-based discussion
23 groups across the agency so that those people

1 who are either interested in the research mode
2 or from the standpoint of what kinds of
3 proposals they are seeing that for example have
4 to do with angiogenesis or with cox inhibitors,
5 or with apoptosis.

6 All of these different groups of
7 people who are probably more knowledgeable than
8 others in the agency about specific mechanisms
9 as it relates to a disease or a new product
10 area, to not only get them talking more to each
11 other within the agency but to introduce some
12 people from outside who are the experts in
13 these areas, and begin discussions of these
14 very specific topics to have us up the learning
15 curve more quickly as we need that kind of
16 information to make internal decisions.

17 Mike has been a big champion of th is,
18 and I know he wants to say more.

19 DR. FRIEDMAN: I think this is
20 potentially one of the most important new
21 approaches that we're trying to take.

22 To me, it seems like the next way in
23 which we should be organizing some of our

1 approaches -- if you think about products that
2 come to us that exploit mechanisms that aren't
3 related to disease, to a particular disease,
4 that aren't related to a particular center,
5 suddenly you realize that we've got to orient
6 ourselves in an entirely different way.

7 I agree with Bern very much. If you
8 look at RAS modulators or NO modulators, or COX
9 inhibitors, you're not talking about just joint
10 disease, you're talking about many other
11 systems. You're not just talking about
12 treatment, you're also talking about
13 prevention. And you're not just talking about
14 humans, but also animal treatments as well.

15 For us to take advantage of these new
16 mechanisms, what we need to do is have a
17 coordinated approach across the agency. So
18 you're not having the GI division proposing one
19 set of studies and the Arthritis division
20 proposing a different set of studies, and not
21 talking to each other but asking, "As an
22 Agency, how can we learn the most about these
23 strikingly novel and powerful new products?"

1 Bern is right; I'm just enormously
2 keen to try this. I'm very excited about this
3 as a way in which we can proceed. We've spoken
4 to some scientists from industry, and they've
5 been very supportive; they think this is a very
6 important way to do things as well. So I'm
7 just really optimistic about this as an
8 opportunity for us.

9 DR. SCHWETZ: That's the end of the
10 list that we had as an update. If there are
11 other specific points of discussion you want to
12 raise, we can deal with it.

13 Otherwise, thank you for your
14 thoughts.

15 DR. KIPNIS: I found this really very
16 informative. It's very encouraging to see the
17 interactions that are going on. So nature's
18 laws are working here. I congratulate you. I
19 think it's remarkable progress.

20 Why don't we go on to the next
21 section. Thank you very much. Ann, thank you;
22 and thank you very much, Bern.

23 The next section deals with Science

1 Board issues. Specifically two of them:
2 Science Board expertise, and stakeholder's
3 comments.

4 Elkan, do you want to --

5 Science Board Issues

6 DR. BLOUT: Let me just start the
7 discussion of the Science Board.

8 Now all the members of the Science
9 Board know that there is a rotation among the
10 membership, mandated by the existence of the
11 Board. So we're going to lose some members
12 probably at the end of this year; that's one
13 thing. The second thing is, we have to be
14 prepared to have scientific expertise in areas
15 we may not be expert in now.

16 So having said that, I'd like to get
17 the Board involved in suggesting two things:
18 expertise needed on the Board and secondly,
19 possible members of the Board.

20 I'll throw out some ideas on expertise
21 needed. I think we're going to need increasing
22 expertise in some aspects of food science. I
23 think we're going to need increasing expertise

1 in biotechnology and bioengineering. And if we
2 think of those areas, much of the expertise
3 arises from industry. Should we have an
4 industry-related person in those areas?

5 I think we're going to need additional
6 expertise in toxicology and carcinogenesis. I
7 think we're going to need the expertise in
8 genetic engineering, the broad area.

9 So with that background, I'd like to
10 ask the current Science Board members, what
11 areas do you see that we should be looking at
12 for the future?

13 Rita.

14 DR. COLWELL: I think you're going to
15 need bioinformatics and genomics. It's moving
16 very, very fast, and it's an area where you're
17 going to have to deal with a lot of processes,
18 methods, machines, and so forth, devices.

19 DR. BLOUT: I agree.

20 DR. KIPNIS: Other comments?

21 DR. CUATRECASAS: Only other one; I
22 think it's fairly obvious, good old-fashioned
23 chemistry, organic chemists. It permeates

1 everything, almost everything. I don't see
2 anyone here, so it's a possibility.

3 DR. BENET: Is the only way you get
4 off this committee is finally finding somebody
5 to replace you? Is that it?

6 (Laughter)

7 DR. BLOUT: Sometimes it seems that
8 way.

9 DR. BENET: Well, I'm going to come up
10 with some suggestions, because I think it's
11 been a while.

12 DR. BLOUT: All right.

13 DR. KIPNIS: You know, old-fashioned
14 chemistry, you might talk about old-fashioned
15 pharmacology.

16 I think that whoever you recommend
17 ought to be top-notch. That's one. Somebody
18 also willing to put in some time to the
19 activity. And I wouldn't care what their
20 association is; industry, individual
21 consultant, academe. I think any of those
22 backgrounds are quite appropriate.

23 DR. BLOUT: What we really need at

1 this point are some names. It will focus the
2 internal discussions if we have some names.

3 DR. COLWELL: I'd suggest, if you can
4 get him, try to get Leroy Hood to join the
5 Board. He's at the forefront, or at least he's
6 amongst those who are at the forefront.

7 DR. KIPNIS: Many of us know him. If
8 you could send a plane out to pick him up in
9 the morning, bring him here and take him back,
10 you'd be sure of getting him.

11 DR. COLWELL: You'll have to send the
12 FDA private plane out for him.

13 DR. KIPNIS: I don't know if they have
14 a private plane --

15 (Laughter)

16 DR. FRIEDMAN: We do, it's in my
17 office. But it's a model.

18 DR. COLWELL: Maybe you could borrow
19 Dan Golden's NASA plane.

20 DR. FRIEDMAN: That's right. But in
21 addition to making suggestions, we really need
22 your help in sort of talking to these people
23 and explaining the importance, the value, the

1 comraderie, the good times, all the good stuff.

2 DR. CUATRECASAS: Could we send the --
3 Elkan, E-mail is okay?

4 DR. BLOUT: Fine, or to Susan Meadows.

5 DR. KIPNIS: Correspondingly, by the
6 way, if you can come up with names for chief
7 scientist, that would also be extremely
8 helpful.

9 DR. BLOUT: Right.

10 DR. COLWELL: Another expertise area
11 would be computers, and data processing. It's
12 the kind of thing that you really need, I
13 think; and someone from one of the software
14 companies or from one of the companies that
15 produced the work stations. They're going to
16 be very helpful.

17 You do get into conflict of interest
18 because you use their equipment, but still, I
19 think it's --.

20 DR. BLOUT: Well, one thing I've been
21 thinking; there are people now making the
22 change from industry back to academia. I can
23 think of a few excellent people who've made

1 that change in the last few years. Those types
2 of people would be ideal candidates for the
3 Science Board.

4 DR. COLWELL: You raise another point
5 here, Michael. I don't know whether you had a
6 representative on Dr. Varmus's committee that's
7 been sent out to look at computation throughout
8 the NIH, but I think because there is the
9 President's Advisory Committee on Information
10 Technology, that's making a major
11 recommendation for investment in computers and
12 computation over the next five years, I can't
13 think of any agency than would need very
14 advanced computation than the FDA.

15 Now you don't need the high end
16 computing, but you certainly need data
17 management and that kind of expertise.

18 DR. FRIEDMAN: I'll certainly look at
19 that; I don't know the answer.

20 DR. COLWELL: I would suggest that if
21 you could be represented on Varmus's planning
22 committee, which is going to give him an
23 interim report in December and a final report

1 in June, you really should try to get somebody
2 on that.

3 DR. KIPNIS: Any other comments?

4 Thank you, Elkan.

5 Stakeholder comments.

6 Bern?

7 Stakeholder Comments

8 DR. SCHWETZ: This was touched on
9 already this morning by Dr. Friedman in his
10 earlier comments, so I'm not going to say much
11 more; except to bring to your attention there
12 is a section in there that summarizes what this
13 FDA Modernization Act is, and what it is we
14 have done as we've gone out to the various
15 stakeholders.

16 Behind that is a list of comments we
17 have received in the various Center stakeholder
18 meetings, and they summarize what people said
19 about science and the need for research and how
20 it ties together with the priorities for review
21 and so on. To the extent that this becomes an
22 issue for one reason or another that we would
23 bring back to the Science Board in the future,

1 we'll try to formulate that into something
2 beyond just information for you; but at this
3 stage, it's there for information to give you a
4 feel for what the people are saying about the
5 agency.

6 DR. FRIEDMAN: This will be an ongoing
7 activity, so even though we're in the process
8 of writing the report for the November 21st
9 deadline, it will be a continuous project so
10 you and others can make comments that will be
11 incorporated next year.

12 DR. LEVEILLE: What are the numbers?

13 DR. SCHWETZ: Those are all the keys
14 to the long list of comments. These are
15 extracted from a long list of comments.

16 They're of no significance otherwise.

17 DR. LEVEILLE: I presume you hold out
18 here for this list those that are related to
19 science issues.

20 DR. SCHWETZ: These are the ones that
21 are. The broader list has to do with all kinds
22 of other recommendations to the Centers. So
23 these are the ones that relate more

1 specifically to science and research than all
2 of the others. All these have been aggregated
3 -- they are being aggregated now into a report
4 that will go to Congress, and this is the basis
5 for the science comments that are in there.

6 DR. FRIEDMAN: This is one
7 distillation of it.

8 DR. LEVEILLE: I saw a lack of some
9 very important issues I'm sure would have come
10 out in stakeholders meetings.

11 DR. FRIEDMAN: Right. Oh, this is
12 from a much more extensive list. There are
13 just hundreds and hundreds of comments, and
14 long letters to the docket. Really thoughtful.
15 All sorts of thoughtful commentaries.

16 DR. KIPNIS: Any other comments?

17 DR. FRIEDMAN: Let me just make one
18 observation if I may, David. That is, there
19 are a lot of interesting features of this
20 exercise, and one of the most interesting is,
21 when we ask at these various meetings -- there
22 were hundreds of people at these meetings; some
23 were industry, some were specialty

1 organizations, some were consumers and so forth
2 -- when we asked people what we should do,
3 there were a lot of good comments offered about
4 what we should do.

5 When we then asked them to please tell
6 us what we should deemphasize or cease doing,
7 because obviously we can't do everything, and
8 we really wanted to hear from people, you know,
9 "help us set national priorities" people were
10 reluctant; that is, they refused to tell us to
11 stop doing anything, even when given free reign
12 to poach on somebody else's territory.

13 So you would say, for example, to the
14 makers of one kind of product: "Please feel
15 free to tell us to stop doing something with
16 another kind of product." And their response
17 was, "Well, no, because we use that product in
18 our day-to-day lives, even this is of
19 importance to my industry." As consumers, they
20 were incapable of telling us to deemphasize
21 something.

22 I just found that very interesting.

23 DR. KIPNIS: It sounds like asking

1 people: "What don't you ___ in health care
2 delivery?" Tell us what not to do.

3 DR. FRIEDMAN: It's one thing for us
4 to say we think we're doing all these important
5 things; but there's always the chance that
6 maybe we're wrong. It's very important to ask
7 the consumers, the citizens what they think is
8 important. So I found that very valuable,
9 actually.

10 DR. KIPNIS: What would you like us to
11 do with the stakeholder comments?

12 That's not a provocative question.

13 (Laughter)

14 DR. SCHWETZ: That they are provided
15 for information. And to the extent that as you
16 look at them, you see that there is something
17 there that strikes you that you would like to
18 reinforce to us as being an important part of
19 the document that we're providing for Congress,
20 we can take those comments.

21 DR. KIPNIS: Just as a casual review,
22 there's a lot of, a few generic topics would
23 cover a large number of these.

1 DR. SCHWETZ: Yes.

2 DR. KIPNIS: Any other comments with
3 respect this?

4 If not, I suggest we take a break for
5 a few minutes and reconvene in about 15
6 minutes, to go on to the CFSAN Research Review.

7 [Recess; 11:40 a.m. to 12 noon.]

8 DR. KIPNIS: I'd like to start the
9 Board's activities now. This deals with the
10 CFSAN Research Review.

11 The presentation on the CFSAN Research
12 Review will be initiated by Dr. Schwetz, who
13 will then introduce Dr. Rulis.

14 CFSAN Research Review

15 DR. SCHWETZ: I just want to open this
16 piece again. I mentioned earlier, Alan, that
17 there would be a review of the CFSAN, of the
18 bigger picture research program, and this is
19 timely for several reasons. Partly because of
20 the food safety initiative and all of the
21 emphasis being given to research within a lot
22 of other activities within the Food Safety
23 Initiative and how it is that we connect to

1 U.S.D.A. and to other federal agencies that are
2 part of this larger food safety initiative; so
3 because we're in the process of developing a
4 new food research program under that heading,
5 it's timely to have a review of that and see
6 how it all fits together in this Center.

7 In addition, the Center for Food
8 Safety and Applied Nutrition has a director who
9 is relatively new to that position, so to
10 provide Joel Levitt with the benefit of a
11 review as a basis for structuring the research
12 component of CFSAN in the future, it's timely
13 to have this review and provide that benefit to
14 him.

15 So what we will do is present some
16 thoughts today about the background of this
17 Center; and the person we have to do it is Alan
18 Rulis, the acting Deputy Director for Planning
19 in CFSAN. Alan?

20 DR. RULIS: Thank you. Well, as many
21 people in the agency, I have multiple jobs, and
22 the one I'm now currently filling in, actually
23 occupying for the purposes of this meeting is

1 the acting Deputy Director for Programs -- a
2 slight change in what you said there, and my
3 name tag is slightly different over there.

4 Our Center is divided into two parts;
5 the so-called program side of the house and the
6 support side of the house. And the program
7 side of the house has about seven offices, and
8 I am charge of day-to-day operations in those
9 seven offices for Joe Levitt during the interim
10 while he's assembling his senior management
11 team.

12 Part of the major responsibilities
13 he's given me during this time period is to
14 look at CFSAN research in a global way; sort of
15 stepping back and looking at the big picture,
16 and that exercise has put me in a position to
17 be able to address to you today the idea of a
18 review of our research program in CFSAN. And
19 as you know, of course with the advent of the
20 Food Safety Initiative, we have already
21 reallocated many of our resources in that
22 direction, and during FY98 we repositioned much
23 of our resources in the laboratory toward Food

1 Safety Initiative research.

2 What this involves is stepping back
3 and looking at the entire picture of CFSAN's
4 research, FSI and non-FSI so to speak research,
5 and asking the relevant questions about how
6 closely it's coupled to our regulatory mission
7 and how effective it is and how effectively is
8 it administered so that we can make sure that
9 what is developed in the laboratory is as
10 effective as possible in helping the Center
11 achieve its goals.

12 Now I've got just a few overheads to
13 put up here for you, and then we can have a
14 little discussion.

15 [Overhead]

16 I'll start off with a mission
17 statement for the Center. This is like
18 statements, but I think it's important to see
19 the focus on microbiological safety; but as
20 well other areas of research and regulatory
21 impact are relevant here: microbiologically,
22 chemically, nutritionally and toxicologically
23 safe food supply. And of course the cosmetic

1 part of our mandate is visible as well. And of
2 course the labeling of those products is part
3 of our mandate at the same time.

4 In looking at my version of your
5 handouts, some of your handouts might be
6 slightly out of order; so I will ask you to
7 flip to the proper page when needed.

8 [Overhead]

9 This particular overhead is the left
10 half of the organizational diagram that was on
11 the table out there, and is split into two
12 pieces in your handouts. I wanted to focus
13 most on the left side, because that's where the
14 so-called program offices are; and you will
15 see, this is updated as of just a few months
16 ago when some new folks were assigned to roles
17 in the Food Safety Initiative, and in this case
18 myself in that role and Joe Levitt as director.

19 You'll see here seven large blocks of
20 program offices. These offices have a number
21 of both regulatory functions as well as
22 laboratory research functions. And I'll just
23 spend a minute, I think for your benefit, to

1 get a flavor of some of the types of research
2 that go on in these various program offices.

3 For example, in Cosmetics and Colors,
4 there are laboratory researchers looking into
5 the composition of cosmetic products, the raw
6 materials that go into those products, product
7 testing, in vitro toxicity analysis,
8 percutaneous absorption is another area where
9 folks are interested in developing information
10 that's relevant to our regulatory mission;
11 phototoxicity of dyes; all are areas of
12 interest in here.

13 Nitrosamines of course are a concern
14 with respect to cosmetics. Fragrances, there
15 are literally thousands of fragrances used in
16 small amounts. Some of them are not benign.
17 They're similar to if not identical to
18 substances that occur naturally, but there's no
19 assurance that even in small amounts they would
20 be totally benign.

21 So there's a lot of interest in many
22 aspects of cosmetics and colors that are
23 investigated in the laboratory there.

1 Strangely enough, the Office of Food
2 Labeling has and supports laboratory research
3 in some areas, methods development on trans-
4 fatty acids is going on this office.
5 Methodology for detecting folates in food, a
6 timely subject. Effects of hydrogenation on
7 vitamins, such as Vitamin K. Analysis of foods
8 for fiber.

9 Over here in the Office of Plant and
10 Dairy Foods and Beverages, this is a very big
11 what I call FSI office, a lot of Food Safety
12 Initiative research is going on in here as well
13 as what I call non-Food Safety Initiative
14 research. The boundary line is not as distinct
15 or clear as one might think. But for Food
16 Safety Initiative research obviously, pathogen,
17 sampling of produce, trying to figure out how
18 to minimize if not eliminate pathogens on
19 produce, investigations on the virulence of
20 microorganisms. Molecular pathology of
21 salmonella, PT104, assessment of technologies
22 for pathogen reduction; and as well in this
23 office we have what I call non-FSI research,

1 but still important to the public health
2 protection. Investigations of botanicals,
3 their identity and their toxicities; pesticide
4 residue is historically a very important
5 research area in this office, and heavy metals
6 as well. Detection of heavy metals and
7 understanding something about the problems of
8 them, in ways in which we might be able to
9 minimize human exposure to them.

10 Also premarket approval is where food
11 additive petitions are reviewed. You may be
12 surprised to find out that in here we have
13 laboratory resources directed at, direct and
14 indirect food additive issues such as sulfites
15 in food, detecting sulfites, whether bound or
16 unbound; packaging materials and food contact
17 substances.

18 And as well we have a strong Division
19 of Molecular Biological Research and
20 Evaluation; I'll point it out here, where we're
21 doing research on molecular mechanisms of
22 pathogenesis. Cutting edge research, the kind
23 of thing you'll find when you open up Science

1 Magazine.

2 Office of Seafood, obviously very
3 strong in the Food Safety Initiative area,
4 characterization of pathogenic aquatic
5 microorganisms, control of viral and bacterial
6 human pathogens in seafood. Pfisteria research
7 is an example of some of the work that's going
8 on in that office.

9 Office of Special Nutritionals, fatty
10 acids in infant formula, not in FSI --
11 obviously an FSI area, but one that's important
12 to public health. Infant formula always
13 extremely important. Teratogenic effects of
14 hyperphenylalaninemia. Analytical methods for
15 Vitamin A and beta carotene in dietary
16 supplementary products.

17 This is a dietary supplements focus in
18 this office, but one which if you're reading
19 the papers these days, you realize is on the
20 cutting edge of a lot that's happening. Carol
21 Sugarman's article in the Post today on
22 functional foods raises the importance of the
23 kind of work that's going on in this office.

1 [Overhead]

2 Over here in Special Research Skills,
3 a lot of Immuno and neurotoxicological,
4 pharmacokinetics and in vitro toxicity
5 research. Much of it being done at Mod 1 in
6 Beltsville.

7 That's a flavor; but I just wanted you
8 to hear some of that because it's a wide range
9 of types of work and both FSI and non-FSI,
10 which I think makes it very important for us to
11 take a broad look at things.

12 [Overhead]

13 Here's an overhead, it's in your
14 packet, that I did for a review that Joe Levitt
15 wanted us to conduct in the Center about
16 crosscutting issues in research, in CFSAN. And
17 as one of the first outputs of my little piece
18 of research I discovered these numbers.
19 Obviously we knew the general magnitudes of
20 these numbers, but we now have some
21 quantification of the amount of research that's
22 focused specifically on Food Safety Initiative
23 projects directly related in that direction,

1 and the amount of research that's focused on
2 what I call non-FSI research, many of the
3 things that I mentioned just momentarily ago.

4 This boundary line between the two
5 compartments obviously will change from time to
6 time; and we expect that over time we will be
7 seeing some of the research that's called non-
8 FSI research, v. actually agreed upon by folks
9 as being Food Safety Initiative-related. What
10 is food safety? It's a broad definition, and I
11 think one that's got some flexibility.

12 Dr. Blout.

13 DR. BLOUT: Just referring to your
14 previous slide, and talking about what's in the
15 press, where do you put, or do you have any
16 research going on on fat substitutes, in the
17 Agency?

18 DR. RULIS: Well, the research that's
19 going on with respect to trans-fatty acids and
20 the composition of structured fats is probably
21 the laboratory research that's happening in
22 that area. There's a lot that's unknown about
23 let's say the clinical aspects of long term

1 intake of fat substitutes, but that's clinical
2 research and we're not doing th at.

3 DR. BLOUT: There's nothing in CFSAN;
4 that's what I meant.

5 DR. RULIS: No.

6 [Overhead]

7 Just to get into a little more detail,
8 and I don't want to dwell on this, but I had
9 split the data in the previous slide out among
10 the various offices that I described in my
11 organizational chart; and you get a sense for
12 how the FSI and non-FSI research partitions out
13 from office to office. And you can see that in
14 some cases, the offices are very heavily
15 involved in FSI; in some cases not. There's a
16 mix of research going on in most offices in our
17 Center.

18 Getting into the question of a review
19 of the science in the Center, we would expect
20 that any subgroup of this award that would take
21 on the task really needs to look at the
22 following major aspects of our research.

23 [Overhead]

1 Quality of science, obviously; the
2 integration of that science internally, and of
3 course with respect to the Agency at large,
4 productivity and impact are obviously
5 candidates for evaluation, and relatedness to
6 our mission and to the Center priorities, and
7 the adequacy and utilization of resources. How
8 well is it being administered, given the fact
9 that we are under tremendously tight budget
10 constraints and constraints that are likely to
11 be getting even tighter in coming years.

12 [Overhead]

13 We intend for this review to be broad-
14 brush, global in nature, not getting into
15 specific instances of individual researchers or
16 their projects. Looking at the bigger picture.

17 DR. NESTLE: Question. Could you
18 explain a little more than that. I don't
19 understand how you can assess research at an
20 office level without looking at individual
21 projects?

22 DR. RULIS: One possibility would be
23 to have the subcommittee take on the project of

1 looking in detail at every project, every
2 research project, and interview every
3 researcher, going into depth in terms of what
4 the researcher is doing.

5 I think that that level of detail,
6 while it would be nice to be able to get
7 feedback from a panel on that, would be
8 tremendously labor-intensive, both for us and
9 for the reviewers, in terms of just the time
10 spent reading all the material. Tremendous
11 number of projects.

12 That would be the ideal. Clearly if
13 we could afford it, and folks on the panel
14 could afford the time and we can afford the
15 preparation time, I think it would be desirable
16 to do that. What's anticipated here is to make
17 use of detailed reviews that have taken place
18 in some areas; for example our chemistry area
19 and our microbiology have been reviewed,
20 recently that is within the last couple of
21 years, at the detail level. Those reviews are
22 documented. The information about the projects
23 is collated and compiled in ways that make it

1 possible for someone to come in and take a look
2 at them without necessarily being buried by the
3 details.

4 Combining those summaries with a broad
5 brush look at the other aspects of research in
6 the Center, the hope is, and I think maybe Dr.
7 Schwetz might want to speak to this, too; that
8 we can get a good picture of the administration
9 and productivity of the research with respect
10 to our mission without getting lost in details.
11 That's just the intention.

12 I think it's a question of optimizing
13 your time, the time of the reviewers and our
14 time and expenditure of resources.

15 DR. SCHWETZ: Throughout our centers
16 we have review mechanisms for looking at
17 individual projects and individuals that are
18 already ongoing. But what does intend to
19 happen is for somebody to come in and look at
20 what's going on in the whole center. Because
21 you look at one division one time, one division
22 the next time, and nobody ever looks at how it
23 all fits together, meeting the Center

1 objectives.

2 So these reviews are intended to look
3 at the whole Center; but knowing that other
4 boards of scientific counselors or science
5 advisory boards will be coming in and looking
6 at what, where you left off.

7 DR. KIPNIS: Les, could you comment on
8 how --

9 DR. BENET: I can tell you, it's not
10 possible to not look at individual projects and
11 individual sciences, but that's not the
12 objective.

13 I think it is important that this
14 review committee have on it members who have
15 served on these specialty committees in the
16 past and have the expertise. The review
17 committee will have the reviews, as we did in
18 CBER, but the idea is to say how do these
19 things fit into the overall goal of this
20 office, and how does this office fit into the
21 overall goal of the Center?

22 And it can be accomplished even; and
23 it's important that the chair make sure that

1 you don't dwell down into the small areas, and
2 the committee always looks at what the overall
3 objective is. But we made specific
4 recommendations in the CBER report that this
5 was not a good area, and these projects weren't
6 good in this particular area, so it wasn't
7 meeting the goals. So you can't do both; but I
8 think Dr. Rulis is correct; the overall
9 objective is to do that in terms of the
10 overall.

11 DR. KIPNIS: But I would not put that
12 up -- what will be reviewed. I don't think
13 that that's the correct mission to give the
14 review committee. And that is that although
15 you can't do individual in depth, you can do it
16 groupings in fairly substantial depth.

17 For example, one of the things that I
18 -- was also the identified areas for
19 collaborative interactions could increase
20 productivity and quality as well as total
21 quantity by organizing into different
22 agreements.

23 I don't think you can do that just by

1 looking at the top down. Somehow or other you
2 do have to get mixed up in the very substance
3 of it. So I would prefer not to see that put
4 in as the mission statement, where you don't
5 assess individual projects. You assess them in
6 accord with what -- the opportunities to
7 present themselves and other reviews that are
8 there.

9 DR. LEVEILLE: This is unrelated --
10 well, related, but tangentially to that. Alan,
11 in describing the organization here, I don't
12 see any mention of JFSAN or the Chicago Center,
13 and I don't know where that falls
14 organizationally and how that research would be
15 looked at.

16 DR. RULIS: Let me speak to that for a
17 minute. Dr. Schwetz did such a nice job of
18 introducing me by talking about the changes
19 we're undergoing, I kind of scrapped my
20 introductory remarks. But if I had said them,
21 they would have focused on the changes that are
22 occurring in the imminence of our move to
23 College Park and the creation of JFSAN as a

1 reality, and our research as it exists in a
2 number of different centers throughout the
3 country; both in the Moffett Center context,
4 ___ Island at Mod 1, and in the downtown EPA
5 building.

6 We are going through a lot of changes.
7 JFSAN is a reality. It's a reality more I
8 think conceptually and on paper at this moment,
9 but it is going to be a reality in terms of
10 actual bodies doing research as time goes on
11 and as we move to College Park in the spring of
12 2001.

13 By the way, Sam Page, who is our
14 Center lead person on JFSAN is in the room, so
15 if there are questions about that I think they
16 can pretty well be deferred to him and he will
17 speak better about that and more
18 authoritatively than I can.

19 The Moffett Center -- for example,
20 Moffett Center researchers are in the
21 organizational chart; they're in a division of
22 the Office of Plant and Dairy Foods and
23 Beverages in that chart. The researchers who

1 will be the FDA components of JFSAN of the
2 future are in the chart that you saw. So while
3 there will be leveraging and collaboration with
4 our counterparts in the University of Maryland
5 and elsewhere, what we're talking about now are
6 CFSAN people, people under the roof of our
7 organization.

8 DR. LEVEILLE: It may be worth having
9 Sam make a few comments on that, because as I
10 see it, it would be critical in this review,
11 since you're looking in the future at the
12 Maryland site as being one of the major focal
13 points for research in the Food and Nutrition
14 area, that that be looked at very critically
15 since it's in the inception stages.

16 DR. PAGE: First, to use this as an
17 opportunity to announce, for those of you who
18 haven't heard, that Dr. Dave Lineback will be
19 joining us as the JFSAN director November 16th.
20 And also, I don't believe it was announced
21 before, but Dr. Charles Sizer took over as the
22 director of the Moffett Center this past
23 spring. So I would certainly hope that they

1 would have an opportunity to visit with the
2 Science Board at one of the future meetings to
3 discuss the operations there.

4 Mr. Levitt is looking at a number of
5 possibilities as far as the organization and
6 structure to include the Moffett Center and
7 JFSAN. I don't think any final decisions have
8 been made to date.

9 One of the things that is not in the
10 chart which is under consideration is a CFSAN
11 science advisor, comparable to the agency, head
12 of the Office of Science. So a number of
13 issues there; who would be reporting to whom
14 are still up in the air at the moment as far as
15 how the organizational structure sites out.

16 Just as a point of how we are
17 beginning to work on our coordination of how
18 science is reviewed, obviously those products
19 that are funded under JFSAN are really not
20 directly under FDA control or directly under
21 University of Maryland control; that they're as
22 part of the science board of JFSAN, and the
23 same is true with the Moffett Center.

1 The way this is doing, for the project
2 proposals that come in, FDA line management has
3 the opportunity to review those and in fact if
4 there are problems with conflict of interest
5 that they see or problems that they view in the
6 nature of science, this will weigh heavily on
7 the review by the joint FDA-University of
8 Maryland review panel. And the same is true
9 with those project proposals coming into the
10 Moffett Center.

11 So I think we are having to consider
12 here another level of review that is really
13 outside of the FDA directly, but obviously FDA
14 has a significant input into these proposals.
15 But I think this is one area that I think we
16 have to be cognizant of; and in fact the line
17 management is not totally sorted out yet, but
18 it will be in the near future.

19 Essentially now I'm reporting directly
20 to Mr. Levitt, which is not quite parallel to
21 the Moffett Center; that's one of the things we
22 have to work out. They are currently reporting
23 through the Office of Plant and Dairy Foods and

1 Beverages, as they have been historically. But
2 I think that will probably change as we sort
3 out, as there are minor modifications to the
4 structural system in CFSAN.

5 DR. KIPNIS: Could you briefly tell us
6 what JFSAN is? Several of us don't know.

7 DR. PAGE: The Joint Institute for
8 Food Safety and Applied Nutrition, which is a
9 real center as opposed to the virtual center
10 under the Food Safety Initiative, which is the
11 Joint Institute for Food Safety Research, which
12 is the coordination of all food safety research
13 in the federal government.

14 JFSAN is under a memorandum of
15 understanding between the University of
16 Maryland and the Food and Drug Administration,
17 integrating our research programs in food
18 safety and animal sciences with those of the
19 University. It includes research at the Center
20 for Food Safety and Applied Nutrition as well
21 as at the Center for Veterinary Medicine. And
22 it gives us the opportunity, through the
23 university system, to have more direct

1 interactions say with the National Science
2 Foundation or National Institutes of Health as
3 well as with private sector partners in
4 supporting these kinds of research and
5 education and outreach activities.

6 DR. FRIEDMAN: Let me say that for
7 those of you who don't know, what's envisioned
8 is a physical plant at the University of
9 Maryland campus which would house laboratory
10 investigators, clinical investigators.

11 If you think about the consolidation
12 efforts that the Agency should be pursuing,
13 veterinary and food issues are being
14 concentrated at the Maryland campus -- we're
15 hoping that the rest of the Agency will be
16 concentrated at a White Oak facility at some
17 more distant date in the future.

18 It's a very big physical investment,
19 of getting our scientists together there, and
20 it promises to be a unique relationship between
21 an academic center and us.

22 DR. NESTLE: Can you tell us what
23 units from the University of Maryland are

1 involved?

'2 DR. PAGE: Basically all units at
3 College Park. We're also branching out to the
4 University of Maryland Baltimore Campus,
5 particularly the Medical Center there; the
6 University of Maryland-Eastern Shore,
7 University of Maryland-Baltimore County.

8 The memorandum of understanding would
9 essentially include any unit in the University
10 of Maryland system.

11 DR. NESTLE: That's dealing with food
12 and nutrition issues?

13 DR. PAGE: That's right; that's
14 correct.

15 DR. NESTLE: Are there specific
16 departments that are involved?

17 DR. PAGE: Oh, initially. There are
18 obviously those where there is more interest.
19 But for example, we had a very quick hit with
20 the computer science department. They were
21 developing an algorithm for searching databases
22 which we utilized in association with our TSE
23 conference and our web site to basically pull

1 together information from other web sites
2 throughout the world and to develop this into a
3 more usable form.

4 We are also going to be branching out
5 to other schools, particularly on the social
6 side. Because if you're talking about
7 communicating with populations, if you're
8 developing risk communication paradigms or
9 trying to develop educational programs, it's
10 not sufficient.

11 For example, to translate your
12 training materials into the language, if you
13 have to translate it into the social structure.

14 So these types of interactions with
15 other departments I think are going to be
16 critical to, where we're developing a science
17 communication aspect of the programs. So it's
18 basically any department that wants to
19 participate is going to be welcome, and we're
20 branching out a lot faster in those areas than
21 we had anticipated. Obviously the initial core
22 was planned to be the Veterinary Sciences
23 School, the Departments of Chemistry and

1 Biochemistry, Microbiology and Food Science and
2 Nutrition. But it's all on an individual
3 scientist basis.

4 DR. KIPNIS: How was this funded?

5 DR. PAGE: There is a memorandum of
6 understanding and then the cooperative with the
7 University of Maryland that, for the long term,
8 the major funding will be from extramural
9 sources, both public and private sector.

10 For example, we this past summer
11 received our first contract from Department of
12 Defense for developing a rapid method to detect
13 terrorist agents in food supplies. And we have
14 a number of CRADAs and contract proposals that
15 are going out. We certainly hope to tap into
16 some of the NIH funding for food safety, since
17 they did very well in the last Congress.

18 There is a lot of money in those types
19 of cooperative programs that we can develop
20 with U.S.D.A. and NIH through the university
21 system, given that that's a land grant college.

22 DR. SCHWETZ: There are many aspects
23 of this JFSAN and the Moffett Center that

1 paralleled the items that we were talking about
2 before, as the structure of science and the
3 culture of science within the Agency; and I'm
4 sure Sam would be happy to come back at another
5 time -- and we can talk more about it today,
6 too; I'm not cutting it off. But to provide
7 additional detail about how this is structured,
8 what our expectations are, how it connects with
9 partners and funding and all of these other
10 aspects. So if you'd like we can bring this
11 back.

12 DR. FRIEDMAN: I think you would
13 actually benefit from a formal presentation,
14 you know, with giving you all ahead of time
15 some of the background material so you can read
16 and digest it. I think it really deserves a
17 formal discussion with preparation.

18 DR. PAGE: We would welcome that
19 opportunity, because we are into it enough now
20 where we see some of the problems and we're
21 really making some what we think are very, very
22 positive and rapid strides. But it would be
23 very useful to us to get some feedback from the

1 Science Board. It would help tremendously.

2 DR. KIPNIS: Thank you very much.

3 Thank you, Sam.

4 DR. RULIS: Just finish off, I wanted
5 to put this last overhead up --

6 [Overhead]

7 -- to remind you of the breadth of the
8 types of scientific disciplines that we would
9 need to focus on in a review of CFSAN's
10 research; and you see it's broad, of course.
11 No surprises there.

12 I think with that I will conclude my
13 comments and take any questions you may have.

14 DR. FRIEDMAN: Alan, could I ask you
15 to put back up the charge to the reviewers?
16 It's one of the earlier slides.

17 DR. RULIS: Yes.

18 DR. FRIEDMAN: If I may, I'd like to
19 just reinforce David's point, which is, I
20 really like this as a bill of particulars to be
21 pursued. The quality, integration, and the
22 relatedness -- these are all critically
23 important areas.

1 What I would say is, give us that --
2 however you do it, at whatever level it takes
3 to do it, and I accept the comments that were
4 made about, you do need to look at some
5 specific project, but you don't want to be lost
6 in that, you want to look at overall
7 integration and so forth.

8 I like this a lot. I think that
9 really is the charge for all of our Center
10 evaluations. And I would say whatever it takes
11 to get us that is what I'd like the review
12 activity to produce.

13 DR. KIPNIS: Are there any questions
14 that Board members have of Dr. Rulis or Dr.
15 Schwetz?

16 If not, thank you very much.

17 DR. RULIS: Thank you.

18 DR. KIPNIS: I would like to suggest
19 that Dr. Leveille and Dr. Nestle agree to serve
20 on this committee that will do the review, and
21 suggest that they also recommend names to Dr.
22 Schwetz as well as to Dr. Blout, as to other
23 members of the committee reflecting expertise

1 needed and even suggest a potential chairman or
2 chairperson. I would like to get started as
3 soon as possible.

4 DR. NESTLE: Does somebody from the
5 Science Board chair?

6 DR. KIPNIS: Not necessarily.

7 DR. BLOUT: Good. Good, Marion.
8 Whoever is the appropriate person.

9 DR. KIPNIS: It's not constrained to
10 that.

11 DR. FRIEDMAN: There are real
12 advantages in that.

13 DR. KIPNIS: Oh, yes.

14 Are there any other questions that
15 anybody has concerning the CFSAN research?

16 If not, we open this meeting to
17 participation by the public, for any questions
18 they may have or any comments on any of the
19 subjects that have been dealt with at this
20 meeting.

21 Public Comments

22 DR. MCGREGOR: I'm Jim McGregor from
23 CDER, and I thought I must just take the

1 opportunity to call attention to the FDA
2 Science Forum, which is the annual meeting of
3 FDA science, which this year will be December
4 8th and 9th at the Washington Convention
5 Center.

6 I'm chairing the event this year. The
7 focus of the meeting is biotechnology. We made
8 a particular effort this year to try to reach
9 out to the stakeholder community, and within
10 the areas that we're covering, to try to really
11 bring in the best scientists to lead the
12 scientific presentations and discussions, so
13 we've reached out to the industry and the
14 university and tried to advertise this fairly
15 widely.

16 Hopefully everyone on the Science
17 Board has received information on the meeting.
18 As I say, anyone that's interested that hasn't
19 received the information, either see me or Dr.
20 Susan Homire, who is over here on the side, who
21 is organizing this meeting through the Office
22 of Science.

23 DR. KIPNIS: Thank you very much.

1 Yes, sir.

2 Dr. Goldman: I'm Neil Goldman, I'm
3 from the Center for Biologics.

4 I thought it would be appropriate,
5 since you're going through reviewing the
6 various centers and you will see certainly
7 their budgets and the resources they have --
8 that in fact is one of the last things you were
9 to ask -- we're charged to look at, how are our
10 resources allocated.

11 But I thought it would be important to
12 at least let the Board know that there is in
13 Congress now two bills, one in the House; it's
14 4514; and one in the Senate, S.2217, both on
15 the Federal Research Investment Act. The
16 intention there is to double the investment in
17 research, and this is of course -- and they go
18 through it in the bill, identifying that there
19 is really no difference or they're not going to
20 try to make a difference between basic and
21 applied research.

22 This is medical, biomedical type
23 research across-the-board, and they target a

1 number of agencies that would benefit by an
2 increase in funding. The increase over the 12
3 years would be about doubling. Right now,
4 according to the figures, about 2 percent of
5 the budget, the federal budget, goes into
6 research. This would obviously double over
7 that 12 year period.

8 They go through to identify the
9 various agencies that would in fact benefit
10 from additional funding for biomedical
11 research. And they of course include the ones
12 that you would have expected; the NIH, the NSF,
13 also NIST -- and of course they are very
14 important in the standards area -- NASA, NOAA,
15 the CDC, the Department of Energy, the
16 Department of Agriculture, the Department of
17 Transportation as well as the Department of
18 Interior, Veterans Affairs, Smithsonian
19 Institution, the Department of Energy and the
20 EPA. And I end there.

21 And it is interesting that you serve
22 upon a board whose focus is to protect and
23 enhance the public health, for which this is

1 all about, and FDA is not listed. So I bring
2 these two bills to your attention. I thought
3 that that was -- I'm hoping to give a copy of
4 each, the House and the Senate bill, and maybe
5 that can be distributed to your members.

6 DR. KIPNIS: Be happy to distribute
7 it. You recall that earlier in the meeting, I
8 asked specifically what we might be able to do
9 to bring to the attention of the Legislative
10 Branch the importance of research and the FDA,
11 and it's defined by the committee as well as
12 within the FDA now.

13 So I think that that kind of input
14 would be very important; and certainly the next
15 commissioner has his or her job well designed
16 for giving that kind of input also. So I don't
17 think you'll find any disagreement with anybody
18 here.

19 DR. BLOUT: I know, Dan, you've been
20 following this subject through previous bills.
21 What do you suggest we do?

22 DR. GOLDMAN: Well, at this point I
23 understand that it has been bouncing about in

1 different committees. I would say that, once
2 you get in contact with those -- for example,
3 the Senate bill is being sponsored by Senator
4 Frisk. I would say one has to actually get in
5 contact with these people and let them know
6 that in fact there is another agency whose
7 charge it is to protect, to be responsible for
8 25 cents out of every dollar that the consumer
9 spends; because that's what we do when we
10 regulate.

11 When we regulate foods, drugs,
12 biologics we are responsible for 25 cents out
13 of every dollar that's spent by that consumer.
14 I think it would be nice to make them aware
15 that it's just as important to ask them to
16 consider putting FDA -- I'm very careful,
17 because I'm not allowed to express myself too
18 strongly without it being misinterpreted
19 because I'm a federal employee. But how
20 important is it to have the FDA as vigilant as
21 others in terms of the research they do to see
22 to it that first -- not only just to protect,
23 but in addition, make available. Because

1 that's another thing that the FDA's
2 responsible. If we regulate something, we're
3 making it available to the public.

4 If you wish to make it available and
5 get it out there as quickly as possible, often
6 you need the research going on to help do that.
7 The research often drives that as well. I just
8 think that that's where I'm hoping this Board -
9 - it was mentioned that Dr. Varmus goes before
10 Congress and makes his plea, and he can bring
11 in the fact that his establishment is
12 externally reviewed -- so is ours -- and I
13 think you as part of those external review
14 committees could have as much influence as Dr.
15 Varmus does on what ends up here.

16 DR. BENET: We have approved the CBER
17 report; there is a paragraph in the CBER report
18 directly on this issue. It doesn't speak to
19 the numbers of the bills because the bills have
20 happened since that time; but I think the
21 Science Board, since we have approved this, we
22 could take that subtext and indicate that this
23 is the report of the Science Board and forward

1 that issue. Because we specifically addressed
2 that issue in the report. Separate that out
3 and forward it on, because that is now the
4 position of the Science Board.

5 DR. KIPNIS: I think one other
6 comment, though; and that is, I think the
7 committee can do whatever is going to be in the
8 best interests, but nevertheless we're
9 identified as a science committee. So
10 inevitably somebody will say, "Well, they're
11 prejudiced in the Science Committee."

12 We had a report today from
13 stakeholders. The first time I heard that I
14 thought it was -- as a food nutrient. But if
15 you had a meeting with stakeholders, those
16 stakeholders should be encouraged to express
17 their opinion. Because if you have 25
18 stakeholders sending letters of encouragement,
19 it's going to be certainly equal if not better
20 than the Science Committee sending its
21 encouragement to be included. I mean, that's
22 what they usually respond to.

23 So I would encourage, if you're going

1 to the extent to where you have stakeholders
2 come in and give us all of this information,
3 that's only half; the other half didn't even
4 deal with science. So I'd find out who they
5 are and encourage them; and I don't mind
6 circulating whatever the Science Committee's
7 statement is or position in, sending it to
8 stakeholders, too. It's a public document;
9 you're saying it in public.

10 DR. BENET: I'd like us to be more
11 active than just to say "someone else should do
12 this." I had a committee that was almost half
13 of the regulated industry, and that committee
14 unanimously took that position. I think the
15 Science Board should forward that
16 recommendation and the membership of that
17 committee as a position that we have agreed
18 with, and at least say that we do that as
19 opposed to someone else.

20 DR. KIPNIS: I'm agreeing to all of
21 that. We should do that. Nevertheless, if you
22 have stakeholders out there that you're
23 calling, that's an additional means of getting

1 it.

2 DR. GOLDMAN: If I just may mention
3 that a week ago, the chairman of BIO, the
4 biotechnology industry organization, spoke
5 before the Commerce Committee and did just
6 that. So they are in fact speaking out on
7 their own.

8 However, like Dr. Benet, I think it's
9 important that they also know that you who see
10 us most directly also feel the same way.

11 DR. KIPNIS: Any other comments?

12 DR. BLOUT: Yes. You mentioned that
13 Hal Varmus goes before the Congress. That's
14 fine, and it has a influence. But I don't know
15 who from FDA does that.

16 DR. GOLDMAN: If I may respond,
17 certainly that would -- it comes out most often
18 when, during the budget process that
19 commissioner or the acting commissioner twice
20 during the year affected, because there are two
21 budget meetings, has the opportunity at that
22 time to go before the committee; and for us
23 it's the Agricultural Committee. They have the

1 opportunity then to indicate the needs, for
2 example.

3 So it's usually the commissioner who
4 has the ability to go before Congress.
5 Potentially at any time, I would think. It's
6 also the commissioner who has the opportunity
7 to go to the Department as well, to the
8 Secretary, and at least indicate what is
9 happening.

10 So hopefully that also tends to move
11 it up; at least that chain of command as well.

12 DR. KIPNIS: Any other comments?

13 MS. UNN: I'm here from the FDA Office
14 of Consumer Affairs, Office of the
15 Commissioner.

16 In addition to that, we will notify
17 the consumers next week by way of a technical
18 review called the Consumer Letter, of the need
19 to respond to this request, make them aware of
20 the need to respond. And we'll send you a
21 letter

22 DR. KIPNIS: Excellent.

23 Any other comment?

1 Let me summarize. I think that those
2 were very useful comments, and I certainly will
3 get to the rest of the Board to see if a
4 general statement can be made to which we add
5 the membership of both the subcommittee, the
6 CBER committee, as well as the Science
7 Committee, which had a broad representative,
8 all coming up with the same request.

9 I've been asked on this agenda to
10 summarize what we've done today. One was the
11 statement of support for the agency budget in
12 science and research, which we will do; the
13 recommendations of the CBER report have been
14 approved and submitted to the Agency, and a
15 recommendation to form a subcommittee to review
16 CFSAN has been made.

17 Are there any other comments?

18 DR. BLOUT: Well, there are two
19 additional things, David, if I may say.

20 One, we've talked about possible
21 changes in the Science Board and asked for
22 recommendations; I think we should put that in.
23 And we've talked peripherally about the search

1 for a chief scientist. And I would like to
2 again indicate that that is really at the
3 beginning, but we need any suggestions from the
4 Science Board of who could fill this role, who
5 would you find ideal for this role?

6 Then the last point, that has just
7 come up now, is the relationship of the science
8 part of the agency to the Congress. How are we
9 going to handle that? We haven't done a very
10 good job up to this point. What can we do now?

11 DR. KIPNIS: Well, certainly we can
12 think of Varmus as chief scientist.

13 DR. BLOUT: He has one job.

14 DR. KIPNIS: Well, the chief scientist
15 of the FDA was going to have one job, too.

16 DR. LEVEILLE: It strikes me, one of
17 the issues is obviously you're dealing with a
18 different funding committee in Congress, from
19 the FDA side than you are at NIH. A committee
20 that has a different perspective in many ways
21 than the committee that NIH deals with; and
22 that's awfully important to keep in mind. And
23 whatever is done for science would have to be

1 consistent with whatever the total agency
2 approach of Congress is going to be.

3 So that may be something we'd want to
4 spend time on at some meeting to understand
5 more fully how FDA as an agency deals with its
6 budgeting process, and its approach to
7 Congress; and perhaps from that we could see
8 some opportunities for more effectively making
9 a plug for science funding in that process.

10 So I'd like to suggest that as a
11 future agenda item.

12 DR. KIPNIS: Any other comments?

13 Is there a motion for adjournment?

14 [Moved and seconded]

15 DR. KIPNIS: So be it.

16 [Whereupon, at 12:48 p.m., the meeting
17 adjourned.]

18

- - -

19