

1 thought that our conducting this study to
2 really look at the pharmacokinetics of
3 estrogen, I think they had a couple of cases of
4 breakthrough bleeding and a couple of cases of
5 alleged pregnancies, but they didn't have
6 confidence that the women were really taking
7 the oral contraceptives as prescribed.

8 And they were the main impetus because
9 they wanted to feel confident in their label
10 statements about St. John's Wort and oral
11 contraception.

12 DR. LANGER: We'll take a few more
13 comments.

14 Bob.

15 DR. BUCHANAN: I do want to take a
16 moment to return to dietary supplements and try
17 to explain a little bit about the law that
18 underlies it, at least within the limited
19 framework of a scientist trying to evaluate a
20 legal issue.

21 And this is a good example of where

1 science and law directly interface, and why you
2 have to consider science in terms of the
3 framework that we regulate these products.

4 DSHEA is a new regulation. Basically,
5 we look at two different areas: Health claims
6 that are made about dietary supplements and
7 then also the safety of those dietary
8 supplements.

9 There is a somewhat different bar that
10 has to be met for both of them, and both of
11 those are different from foods and from drugs.

12 We've gotten into the situation now
13 where we're under active review on what is the
14 degree of scientific consensus that much be
15 reached before you evaluate the safety of those
16 products; what is the extent of scientific
17 consensus that must be reached when you make a
18 health claim.

19 This process is actively being
20 challenged within the court system, and so we
21 see things like the Pearson case and the issue

1 of First Amendment rights.

2 So it's very clear to us that the
3 burden of proof lies with us in order to make
4 these decisions, and we need to be able to
5 acquire the data that's needed and we need to
6 be able to make sure that it stands up to the
7 rigor of science, but it's still unclear at
8 what level the bar is going to be set, and part
9 of this is as in any food regulation, not only
10 is it the law and the act, but it's the
11 subsequent interpretation of those by the
12 court.

13 And because this is still early in the
14 process, that interpretation is not totally
15 clear.

16 DR. LANGER: I'll take three more
17 comments: Mike, Bob, and Rita, and then we'll
18 take a break for lunch.

19 DR. BUCHANAN: Susan, does the Office
20 of Women's Health Science have an Advisory
21 Board or a group to help advise them as to what

1 the priorities might be?

2 DR. WOOD: No. And I think we're
3 limited under, well, policy and statute,
4 probably, of having an unofficial Advisory
5 Board. But we do have ways of I think of
6 generating both our priorities.

7 I think in terms of both the review
8 process and in evaluating the proposals that
9 come in either intramurally or extramurally, we
10 reach out across the agency and in some cases
11 to external reviewers.

12 But in terms of other priorities, for
13 example, I did mention next week we'll meeting
14 not with an Advisory Board but with about quite
15 a few people involved -- leaders of health care
16 organizations, women's organizations who may or
17 may not have ever worked with FDA, as well as
18 women's health groups, to talk about starting
19 out with three priority areas -- clinical
20 trials, product safety, and health education,
21 and outreach.

1 And to start some conversations around
2 those three topics, two of which are -- well,
3 potentially all of them can be researched
4 based, but certainly the clinical trials and
5 product safety aspects of them are pretty
6 relevant to the types of research that we may
7 be funding in future.

8 But not through a formal advisory
9 process, but we're trying to keep consultation
10 ongoing.

11 DR. DOYLE: Well, just as a thought,
12 as a follow-up, I've been very impressed with
13 the Institute of Medicine Food Nutrition Board.
14 And if you're looking at dietary supplements,
15 that might be a resource you could consider for
16 input in terms of prioritizing topics that
17 would be useful to pursue for your funding.

18 DR. WOOD: Yes. We're also looking
19 at -- I mean, for dietary supplements we work
20 with NIH's Office of Dietary Supplements and
21 the Center for Alternative Medicine, I guess

1 is what they are.

2 So we do get scientific input from
3 those places as well.

4 DR. LANGER: Thank you.

5 Do you want to add to that?

6 DR. BUCHANAN: Yes. I've heard a
7 couple of comments about advisory committees
8 and advisory boards, et cetera.

9 DR. LANGER: Microphone.

10 DR. BUCHANAN: Advisory committees and
11 advisory boards, and being responsible for a
12 couple of them. These are very formal
13 processes, and to establish a new one takes
14 clearance up, I guess, through the departmental
15 level at this point.

16 DR. WOOD: Probably to OMB.

17 DR. BUCHANAN: It is under great
18 restrictions about adding new ones. Normally,
19 you have to get rid of one before you're
20 allowed to add a new one.

21 It's a big hurdle to just bringing

1 people in, and there are very strict rules
2 about how they can be used, who can be on them,
3 et cetera.

4 So recommending --

5 DR. NEREM: Can you have ad hoc
6 visiting groups?

7 DR. WOOD: Yes. I think that's a
8 process we can consult widely on an informal
9 basis because you can't limit your input unless
10 you go through this very formal process, and so
11 therefore the alternative is to get very wide
12 input, which in our case I think is appropriate
13 as well.

14 DR. LANGER: Bob and then finally
15 Rita.

16 DR. NEREM: Yes. This is really a
17 comment directed to David, but listening to
18 Susan -- why am I directing it to you, because
19 it sensitized me to the fact that in the CDER
20 to review, presumably there are devices that
21 are used both in men and women where in fact

1 there may be gender differences, and that ought
2 to be part of what we look at, is how the
3 science knowledge about those differences is
4 incorporated into the review process in CDRH.

5 DR. FEIGAL: That's a good point.

6 In fact, there are examples in
7 cardiovascular medicine where devices have much
8 higher complication rate in women than they do
9 in men.

10 There are different effectiveness
11 rates of results from valve replacement in
12 women versus men that aren't totally explained
13 by premorbid conditions at the time of surgery.
14 So there are many issues here as well, and
15 there are also many issues about differences in
16 access between men and women.

17 DR. NEREM: Well, I'm saying is as we
18 do the review we ought to --

19 DR. FIEGEL: Yes.

20 DR. NEREM: -- at least have some
21 examples where we can look at that.

1 DR. FIEGEL: We do look at that, we do
2 ask for that kind of information, particularly
3 in the areas where we've been sensitized by
4 past experiences.

5 DR. LANGER: Last question.

6 DR. COLWELL: I would like to perhaps
7 re-ask Ed's question, and ask if what we've
8 been hearing is sort of bottoms up perspective
9 of the kinds of problems that need to be
10 addressed when, in fact, looking top-down,
11 there may be some crosscutting fundamental
12 issues that need to be established such as
13 metabolic rates and weight versus -- gender
14 differences in weights and so forth.

15 That would really cut across the whole
16 Agency, and maybe that would give the kind of
17 priority setting that you were driving for, Ed.

18 DR. SCOLNICK: I'm really apologetic.
19 I have never thought about it before. It's
20 been brought up, and it's clearly an
21 interesting and complicated problem.

1 So if you're going to refund research
2 in this area, you kind of need to look at the
3 whole thing and decide what's really important
4 that you're going to fund because you can't do
5 everything at once, and I'm not able to do that
6 because I've never thought about it before and
7 I'm not getting it today.

8 DR. COLWELL: I would agree with you,
9 but from the perspective of saying, wait a
10 minute, let's step back and let's look at the
11 fundamental crosscutting principles, and then
12 address each of the issues that are indeed
13 important.

14 DR. SCOLNICK: I agree.

15 DR. LANGER: I think this is
16 excellent. Good.

17 Why don't we take a 40-minute break
18 and be back here at 1:20. Would that be okay
19 with everybody?

20 (A luncheon recess was taken.)

21

A F T E R N O O N S E S S I O N

1
2 DR. LANGER: I wanted to start by
3 seeing if anyone wanted to make any public
4 comments. Is there anyone that would like to
5 make any public comments?

6 (No response.)

7 DR. LANGER: Okay. Then we'll just
8 continue with the agenda as it is.

9 The session that we're going to do now
10 is preparing to meeting Scientific Workforce
11 Challenges. This is a continuation of a series
12 of discussions we've had regarding the work
13 force challenges that FDA faces.

14 We've talked about recruitment and
15 retention issues, but there needs to be an
16 emphasis on training in order to retain the
17 best scientific workforce and keep pace with
18 rapidly changing technology.

19 The FDA university, and this is going
20 to be presented by Jim Heslin, FDA's training
21 officer, is a burgeoning concept for FDA to

1 address some of these training needs.

2 We'll follow this with the
3 presentation by Ed Scolnick, so that the FDA
4 could see what other groups do and benchmark
5 where appropriate.

6 **Preparing to Meet Scientific**
7 **Workforce Challenges**

8 MR. HESLIN: Good afternoon. My name
9 is Jim Heslin from the Office of Human
10 Resources and Management Services within FDA.

11 I'm temporarily on assignment to the
12 office of Dr. Jacobson to work on an FDA
13 University proposal at the request of Dr.
14 Schwetz.

15 We have about an hour, which I think I
16 need to share with Dr. Scolnick.

17 DR. SCOLNICK: You can have 45
18 minutes.

19 DR. LANGER: It's flexible.

20 (Laughter)

21 DR. SCOLNICK: I'll take a quarter of

1 it.

2 MR. HESLIN: Well, cut me off whenever
3 you need to.

4 My normal job at the agency is as the
5 Agency training officer, the FDA training
6 officer. Essentially what that means is I have
7 a small staff and responsible for certain
8 agency-wide training policy and programs.
9 Essentially for us, that means leadership
10 training.

11 There's a common leadership training
12 program that FDA has and there's some
13 information, some handouts, as well as a poster
14 here describing our FAME program, which is the
15 Formula for Achieving Managerial Excellence,
16 and it's been pretty successful, and a lot of
17 supervisors and managers in FDA have gone
18 through these various courses.

19 You may have noticed, if you had
20 looked ahead into the package of materials,
21 that the last two slides, there's a series of

1 questions. We don't have to wait until the end
2 to ask those questions or to comment on that,
3 so I would sooner this be a discussion than a
4 presentation.

5 There's certain information I want to
6 convey, but certainly from my perspective, the
7 most important purpose for me it to gather your
8 ideas and input because the term burgeoning is
9 good in describing where we're at in terms of
10 the FDA University.

11 We're really trying to get a handle on
12 what is this thing going to be, what it's going
13 to look like, how it's going to be structured,
14 what's going to be included, and of course
15 we're going to want to involve as many people
16 in getting answers to those questions as
17 possible.

18 (Slide.)

19 The first thing I'd like to do during
20 the discussion here is talk a little bit about
21 the concepts, characteristics and rationale for

1 an FDA University, to list the 10 steps to
2 develop an FDA University.

3 This is just something I came across.
4 I also came across seven steps in some booklet,
5 but 10 sounded much better, so I thought we'd
6 list all 10.

7 Also, to discuss the possible
8 components of an FDA University, and I think
9 that there will probably be no shortage of
10 ideas for this. Maybe the more challenging
11 task will be trying to organize those things
12 and assign priorities and do the right things
13 first.

14 And, lastly, to solicit your ideas and
15 recommendations.

16 If there are things that you don't
17 have the opportunity to comment on today or
18 don't think about it, certainly you can follow-
19 up with me later. We do have a mailbox that's
20 set up now. It's fdau@oc.FDA.gov. I'll write
21 that out later. But you're free to send in

1 your comments or questions on that as well.

2 I wanted to talk about what the
3 current state of training is at FDA, and this
4 is a question that's not easily answered.

5 But, essentially -- and I'm going to
6 generalize here from my perspective as the
7 Agency training officer. The training function
8 is largely decentralized. There are certain
9 components, such as our FAME leadership
10 training program, that are handled centrally,
11 but most of the training activities really
12 occur at the Center and Office level.

13 (Slide.)

14 Most centers have what they refer to
15 as staff colleges, and if they don't have one
16 they soon will because the Center for
17 Veterinary Medicine and the Center for Food
18 Safety are now beginning to establish staff
19 colleges to go along with the organizations
20 that most of the other centers and ORA already
21 have.

1 Just to give you a sense of what is
2 being done at FDA rather than tell you about
3 it, in the handout package, there are some
4 representative things including the Center for
5 Drugs course catalog, which is interesting,
6 because it really gives you not only a sense of
7 the scope and extent of the training, but in
8 terms of the courses and the disciplines, but
9 also the different ways that training is made
10 available.

11 So if you have an opportunity, you may
12 want to look at that, but that's really just
13 representative. That's the kind of stuff
14 that's going on in the other Centers as well.

15 I've also included two simple email
16 messages which are representative of what some
17 of the Centers are doing, and in this case it's
18 the Center for Biologics, and the Center for
19 Devices, where they send out weekly updates on
20 what's going on in training within their
21 organization.

1 I think you'll be impressed when you
2 see the broad range of training activities that
3 are described there.

4 I also included a little handout on a
5 brochure on our FAME leadership training, and
6 also a Skillsoft Distance Learning initiative,
7 and I'll talk more about that later. But
8 that's just all the piece of the picture.

9 To give you some idea of the
10 investment that FDA has made in training, at
11 least count, and this is based on a report we
12 did, actually it's almost two years ago now,
13 the American Society for Training and
14 Development does a benchmarking survey each
15 year, and aside from the fact that it's very
16 challenging to gather the information they're
17 asking for, certain things came out.

18 The last report said we had 86 people
19 who are dedicated to training. These are folks
20 on the Center and Office staff colleges and
21 training staffs.

1 In addition, there were roughly 450
2 additional people at FDA who had some
3 responsibility for training, whether it was in
4 coordination in periodic instruction, design
5 and development of materials. But in a sense
6 all employees at FDA are responsible for
7 training, and I think that's one of the shifts
8 that's occurring, that training isn't something
9 you do to somebody, but it's an individual
10 responsibility as well that you need to take
11 upon yourself to learn what you need to know to
12 do your job better.

13 In terms of dollars, again, this is a
14 little bit dated, and I understand the number
15 may have declined, but it's certainly fairly
16 flat; and that is, overall, \$12 million spent
17 on training.

18 It's certainly not a meaningless
19 figure, and I think it reflects to a large
20 extent the investment that the Agency has made
21 in training and development, but you have to

1 consider that that 12 million includes employee
2 travel and per diem, which is frequently the
3 largest cost of training in an organization as
4 well as the cost of courses and contractors and
5 so forth.

6 Also, more and more centers are
7 engaging in the use of technology for the
8 delivery of training. Key point here is that
9 it's a tool and it's not the training, it's
10 just a different methodology for getting the
11 training out.

12 One area of interest is using the web
13 as we are doing with our SkillSoft training
14 initiative, which is kind of going on in many
15 different centers, and ORA, the Office of
16 Regulatory Affairs, is establishing a Virtual
17 University and they're building courses that
18 will be accessible by the web.

19 Now, I just wanted to mention that not
20 all training, obviously, is going to be
21 appropriate for delivery on the web, but in

1 certain cases from ORA's perspective and I
2 shouldn't speak for them, but they have a
3 widely disbursed audience.

4 They need to get new information out
5 to people quickly. If they can get it to a
6 person's desktop, you know, for them, that's
7 the best way to go for certain kinds of
8 training. But you have to go through that
9 process of deciding, you know, what's really
10 the best way to provide the training.

11 So that's in a nutshell the state of
12 training at FDA. There are a lot of training
13 activities going on. It's more than just the
14 number of people who are attending classes or
15 the dollars spent.

16 There are other, more innovative ways
17 of learning that are being used in the various
18 centers.

19 (Slide.)

20 What is an FDA University?

21 Well, this is really something, in

1 part, that you need to tell me. I'm not coming
2 here with a standard definition of what the FDA
3 University would be. We want this to be
4 something that is defined by FDA not by some
5 textbook or some other model.

6 But there are certain common
7 characteristics. One is that it is
8 organization-wide. This would be an FDA-wide
9 orientation not specific necessarily to any
10 particular center or office within FDA.

11 What seems to characterize these kinds
12 of efforts also is the emphasis on strategic
13 objectives. That is to say that if the
14 Agency's strategic plan wants to focus its
15 resources and efforts in particular areas, the
16 FDA University would be in support of those
17 activities.

18 That's not to say that there are
19 certain other common crosscutting needs that
20 could be addressed best centrally, anywhere
21 from effective briefing techniques to Microsoft

1 Word, but the key to the University approach,
2 if you will, and this is still a working title,
3 by the way, is to focus on the strategic
4 objectives of the Agency to bring some focus
5 and attention to what's the most important in
6 view of the leadership of the Agency.

7 This is also a lot about fostering
8 collaborations and partnerships, sharing of
9 resources. Very few of these efforts, whether
10 it's in the corporate sector or in the
11 government are really efforts to consolidate;
12 that is to say, we're going to close up the
13 shops out there in the different parts of the
14 organization and bring it into a little red
15 schoolhouse, and all training and development
16 will emanate from there. That's not the case.

17 This is going to be much more of a
18 facilitative process trying to use the
19 resources and the capabilities that are
20 existing out there.

21 Again, common core and critical. Is

1 there a common need across the Agency, is it
2 core to the mission of the Agency? And in
3 terms of critical, those things are the ones
4 that support the strategic objectives of the
5 agency.

6 The University approach can also
7 extend the reach of training both in terms of
8 just making available resources more available
9 to people whether it's through collaborative
10 efforts or through the use of some technology
11 approach or satellite broadcasts or whatever
12 the methodology may be.

13 Maybe a little more importantly is why
14 would we do this. Again, it has a lot to do
15 with bringing an agency-wide focus. Two things
16 that are the most important to the agency, and
17 certainly the area of sciences is one of the
18 top things on the list, to help support new
19 initiatives.

20 There are things that are coming down
21 the pike that don't have, in my words, a

1 natural home, that it really doesn't belong in
2 one particular center or another but rather is
3 something that is important and really needs to
4 be done on an agency-wide level. Yet, as a
5 practical matter, there's no place for that to
6 fit right now that sort of thing.

7 An example is the agency needs to get
8 involved in training of employees for
9 accessibility -- handicap accessible to the
10 web; that is to say, if a person has a
11 disability and they're impeded from accessing
12 the worldwide web, what do you need to be aware
13 of?

14 If you're writing documents that
15 appear on the web, how do you write
16 differently, and there are different
17 requirements for that.

18 So this is something that really is
19 common in crosscutting, and I think would be an
20 ideal candidate for inclusion in the FDA
21 University and is certainly something new.

1 It's just emerging now.

2 Also to foster cultural change. I'll
3 just use an example that I heard of.

4 The Tennessee Valley Authority has one
5 of the oldest government universities. There
6 are a lot in the private sector, increasingly
7 government agencies are getting on board as
8 well.

9 But what TVAU did is they made an
10 intentional decision to foster the use of their
11 own staff as instructors, and they used their
12 university approach to recognize, to train, to
13 bring those people in so that they use their
14 own folks as instructors as opposed to, in the
15 past, having gone out and used various
16 contractors and consultants.

17 That was sort of a cultural issue for
18 them, and in order to make that happen, they
19 used the TVA University as the vehicle to do
20 that. I'm sure there could be lots of other
21 applications here as well.

1 From everything I've seen or heard,
2 FDA, while the budget may be increasing
3 somewhat, there's always an issue of scarce
4 resources, and certain things just seem to make
5 more sense if it's done on a central level,
6 even simply from the point of acquisition.

7 If you're buying a particular product
8 or service, is it better to have each
9 individual center do that or if you were to do
10 it on an agency level, could you maybe strike a
11 better deal? I mean, I think there's lots of
12 opportunities to see, to do that, and also to
13 find out what's going on in the agency, what
14 can be made available to other people and
15 spread that around. And it's not only to the
16 FDA employees.

17 Potentially, an FDA University could
18 be involved in training for states, joint
19 training ventures with industry, and possibly
20 even sort of a public education component as
21 well.

1 We also see this as a way to aid in
2 recruitment and retention. I think all of you
3 are probably aware of the numbers. There's a
4 lot of us, including me, who will probably be
5 moving on in the next five to seven years or
6 so. How do you bring people into the Agency,
7 how do you keep the best people here?

8 You have to look for whatever point of
9 leverage you may have, and one of the points of
10 leverage I think could be an FDA University as
11 an incentive, both as a recruitment and in
12 order to encourage people to stay. Those
13 people -- especially targeted on those people
14 have the skills you want to keep.

15 Lastly, to create a learning
16 organization. If you've done any reading of
17 Peter Sangie and the Fifth Discipline, number
18 one, I feel sorry for you. But, second, I
19 think that the idea in there, though, that you
20 integrate learning as part of your daily work,
21 that you're in a continuous learning mode, I

1 think that's something that you can help foster
2 through an FDA University.

3 DR. FENNEMA: Can I ask a question on
4 that point?

5 MR. HESLIN: Sure.

6 DR. FENNEMA: It's probably buried in
7 those points that you're making, but it seems
8 to be of critical importance to me. And that
9 is, keeping your scientists abreast of
10 scientific advances in their field. That
11 strikes me as so important that it ought to be
12 one of your points in this particular list.

13 That's got to be a difficult thing to
14 do, and I would think it would be a very
15 important function of this University.

16 MR. HESLIN: Thank you. Thank you for
17 that comment.

18 To some extent, that's -- maybe I'm
19 going to respond a little bit to it here. Why
20 are we doing this now. Well, one of the issues
21 has to do with the short shelf-life of

1 knowledge, and the rapidly changing science,
2 just that body of knowledge. You may have a
3 degree, come to work for the government, but
4 how long is that really going to last? I mean,
5 you need to continue to be engaged in learning
6 and development in order to maintain the life
7 of that knowledge and to learn new things.

8 Also, in terms of the FDA University,
9 why would you do it now? Well, one reason
10 would be that there are new technologies out
11 there now that weren't there a few years ago
12 that you could leverage in order to make
13 training more available and in a different way
14 to folks. So there's certain technological
15 aspects that kind of are on that list of why is
16 it a good time to do it now.

17 Dwindling resources, I think I
18 mentioned. Not that the FDA University would
19 necessarily be a big cost-saving organization,
20 but hopefully it would help facilitate
21 maximizing the resources that are here.

1 And credentialling. This is important
2 to a lot of organizations, and this is related
3 to not only the credibility of people doing the
4 work of the Agency and being accepted and
5 having their opinion respected by others, but
6 within the Agency as well there is this growing
7 need to establish competency models curricula,
8 some accreditation or credentialling process.

9 In fact, the center for during
10 evaluation and research has done a lot of work
11 on competencies for scientific reviewers and
12 others, and they're mentioned in that catalog.

13 CDER's training staff just recently
14 won the Deming award from the Association for
15 quality and productivity, which is a fairly
16 significant group, and the award is a great
17 recognition, I think, of some of the efforts
18 that are going in, in particular in CDER and
19 their work on competencies.

20 Maybe most importantly is because the
21 opportunity exists. I mean, this is something

1 that Dr. Schwetz has a particular interest in.
2 There's been a lot of discussion going on
3 within the training community, and people have
4 an interest in that. People are open to trying
5 some new approaches.

6 So I think the time is right to move
7 forward on this, and that's what we're doing.

8 Just briefly: The overall process
9 that we hope to follow is kind of take a look
10 at what the current state is. And we've
11 already started this.

12 That is, to see what are the needs of
13 the agencies, do an inventory of activities
14 that are currently going on;

15
16 Try to identify those resources that
17 are shareable.

18 Basically, pick the low-hanging fruit.

19 There are certain things that are out
20 there right now that could easily fit into an
21 FDA University structure. But we need to take

1 a look at what's the current state, and then
2 the next step is really -- and this is part of
3 it -- is looking at what's the desired future
4 state?

5 How would you conceive of an FDA
6 University? A highly-functioning FDA
7 University? What would it look like? What
8 kinds of courses or programs would it offer?
9 How would it be organized? Who would be
10 leading it? Who would advise it?

11 So there's lots of things that we
12 need -- and this is really where the focus is
13 for us right now.

14 And then lastly is kind of trying to
15 figure, okay, how are we going to get from
16 where we are to where we want to be. And,
17 obviously, there are going to be some
18 roadblocks. How do we overcome that.

19 Funding is going to be an issue, staff
20 resources will be an issue. I'm sure that
21 there will be a number of things that we

1 identify, but as part of this process, we want
2 to be able to put forward some alternatives and
3 some different approaches to overcoming some of
4 the obstacles that we identified.

5 This is the 10-step piece that I
6 talked about. I'll just move through it
7 quickly.

8 But crafting a vision;

9 Determining the scope. That is to
10 say, you know, we can start at one place and
11 certainly end up in a different place, but in
12 terms of the scope, is this going to be limited
13 strictly to FDA employees?

14 Will it focus more on one discipline
15 than another? Should it? Will training for
16 state people be part of this?

17 We want to get a handle on what is the
18 ultimate scope of this or certainly the
19 beginning, and then ultimately what might be
20 included.

21 And to identify stakeholders and their

1 needs, input from this group is something that
2 would be very important to me.

3 Also, devising a measurement system.
4 You know, you go back to the \$12 million that's
5 spent on training, and the question is well, so
6 what.

7 We need to really do a better job, and
8 I'll speak for myself and my staff and the
9 leadership training we're involved in. We do a
10 great job of asking people walking out the door
11 what they thought of the training, and of
12 course they loved it, and it's well received,
13 and we've even been brave enough to go back and
14 say, "Now that you're back on the job, are you
15 using it," and they say, "Yes."

16 The questions that don't get asked too
17 often are, is it making any difference to the
18 organization given the investment you've made.

19 So we need to develop a more
20 comprehensive measurement system to make sure
21 that we're doing the right things and doing it

1 the best way.

2 The governing body -- some of the
3 things that we've been discussing is how is
4 this led. Is there a dean and, if so, what
5 does that person look like? Is it somebody
6 from the training and development community, is
7 it somebody with a science background? Is it
8 somebody with all of that?

9 We need to be able to define what the
10 similar position would be and who potential
11 candidates may be, where should we be looking
12 for this person; and also any ideas on how to
13 run the FDA University.

14 Clearly, we're not talking about a
15 large staff, okay? I mean, I'm looking at this
16 in terms of learning facilitators who are
17 trying to foster collaboration and cooperation,
18 and if there is a need and if it's appropriate,
19 doing certain things on an agency-wide basis.
20 But this is not going to replace the center
21 staff colleges.

1 They need to exist. They fulfill an
2 important role, not only in terms of what
3 they're doing for their organizations now but
4 what they can contribute to an FDA University.

5 Funding strategy. Of course, the
6 question comes up, regardless of what we do,
7 where is the money coming from?

8 If it's important enough, is the
9 Agency going to come up with the funds
10 centrally to support this. Do you go in the
11 direction that other organizations have gone in
12 and you go on a fee for service or chargeback
13 system where different organizations pay to
14 participate in some of the training and
15 development activities?

16 Develop products and services. The
17 tendency is to think, you know, which courses
18 will go in here, but there's other things.
19 There are other kinds of relationships with
20 colleges and universities, trade associations,
21 even regulated industry.

1 Develop a technology strategy. I
2 mentioned a little bit about that in terms of
3 how do we take advantage of the technology, and
4 it's not all about web-based training. In
5 fact, I'm very careful. Some people hear FDA
6 University and think, well, that means it's all
7 on line and it's on the web, and that's not
8 good. It's not that.

9 What we want to try to do is where
10 that approach makes sense to do it, but it
11 doesn't always make sense.

12 SkillSoft, which is a commercially
13 available web-based training program, there's
14 some good products there, but Skillsoft will
15 tell you this is not going to be a substitute
16 for classroom training.

17 They advocate a blended approach where
18 possibly some content that can be delivered
19 over the web comes out in advance but then
20 people are brought together later to explore
21 that further.

1 So I've heard organizations, in fact,
2 one, and they're part of HHS, where they
3 decreed that they will no longer do software
4 classroom training, that it's all going to be
5 on the web.

6 Well, I've got a problem with that
7 because while it may be inexpensive and have
8 certain benefits in terms of reaching out to
9 people wherever they are, the any time, any
10 place kind of approach, if I have a question
11 and I don't have somebody I can turn to, that's
12 going to leave me high and dry.

13 And there may be a component to send
14 email messages and at chat rooms and so forth,
15 and these are better. But there's certain
16 things that I feel strongly are going to have
17 to be done or connected in some way to a
18 classroom. So web based training has its
19 place. We just have to find what that is for
20 FDA.

21 And communicate. We want to be able

1 to promote this, get support for it. And in
2 that whole process, make this as inclusive and
3 collaborative as possible. That's my main
4 directive at this point.

5 We want to include all of those
6 people, organizations, individuals, that we
7 need to include to get this things launched and
8 to sustain it.

9 This is just a conceptual thing on
10 what a model might look like. Originally, I
11 had drawn a circle around the whole thing, and
12 somebody says, well, wait a minute that sort of
13 applies that FDA University is running it all.
14 That's not the case.

15 In theory, each one of those circles
16 should have an arrow or a line to each of the
17 other circles, because these are training
18 functions, development functions, that are
19 going to stay in place, and I'm sure expand and
20 help other parts of the FDA University.

21 DR. NEREM: What's the Science

1 Academy?

2 MR. HESLIN: That's a conceptual
3 thing, that if there are -- because Dr. Schwetz
4 had talked about it a couple of years ago at
5 one of our training officers retreat -- about
6 an FDA science academy where the focus would be
7 solely on science.

8 It may be that in the process of doing
9 this, that there is certain common crosscutting
10 science training that would make sense to put
11 it in a science academy, but maybe not.

12 The Leadership Institute is kind of
13 the agency-wide leadership piece that I was
14 talking about. You look at a model and it's
15 like, well, that's pretty nifty, but then you
16 really have to be careful, because you're
17 communicating a lot of messages about what it
18 is and how it's going to function so we want
19 people's reaction to this and what their own
20 ideas are.

21 This is just sort of a laundry list of

1 potential things that could be included. Going
2 outside of the Agency to your point, I know
3 Dr. Henney, because I saw this in an email
4 message, said that she felt strongly that
5 scientists from FDA need to go outside of the
6 Agency for learning and development, that they
7 need to interact with their peers in industry,
8 in academic settings, and she would encourage
9 people to do that through conferences or other
10 types of activities. So it's not all an
11 inwardly-directed thing.

12 But there's lots of possibilities.
13 Again, the point for the FDA University is to
14 help facilitate those things, not necessarily
15 do it for the particular organization.

16 Down in the lower right-hand corner,
17 Knowledge Management, and I think somebody had
18 referenced something like this morning.

19 There's a lot of concern about the
20 fact that a lot of people are going to be
21 leaving FDA. I had gotten a call from one of

1 the district directors about two years who said
2 he suddenly realized his three key people who
3 collectively had over a hundred years of
4 experience were all retiring.

5 And his concern was, how do I download
6 all of that institutional knowledge and
7 everything that they know so that it can be
8 passed on to others?

9 I don't want to get stuck on the
10 jargon because the knowledge management is sort
11 of an elusive concept, but to me it means
12 trying to get a hold of what do people know, in
13 some fashion storing that, and making it
14 available to other people who need to know it.
15 That could well be a component as well.

16 Again, these are just possibilities,
17 and I'm looking for others.

18 Who needs to be involved in this? Who
19 needs to hear this story from me? Who do I
20 need to talk to to get their input not only
21 from within the Agency but outside as well?

1 Are there other models of this that would be
2 helpful for us to know about?

3 Also, what should be included? You
4 wouldn't want to count on me to come up with
5 all of the good possibilities, but every time I
6 talk to somebody about this I hear a new idea,
7 and that's what we're looking for, what kinds
8 of programs should be included. Just what
9 should be in this FDA University.

10 I'd really appreciate some comments on
11 how it should be structured and led. We're
12 kind of using the University model.

13 It brings up for me, I recall a
14 conversation I had with somebody from the
15 University of Maryland who was in a new
16 position, and his task was to help people
17 outside the University system access the
18 resources of the University, and what he was
19 saying was the University of Maryland system
20 has multiple state universities, it has a
21 presence overseas. It has all kinds of

1 resources.

2 But how do you navigate through the
3 system in order to get to the people you need
4 to get to and to form partnerships to help
5 foster learning.

6 That stuck with me because that, in a
7 way, is what I think one of the roles of an FDA
8 University could be, that is, to have that
9 learning facilitator, have that person who can
10 help facilitate the sharing of resources, the
11 development of new programs, and bringing focus
12 to certain activities.

13 And, lastly, how can it be marketed
14 and promoted? Again, the FDA University is
15 sort of a working title. We're saying to
16 educating those who protect and promote the
17 public health. That's a pretty bold statement.
18 Is it really going to be that? I don't know
19 because that pretty much encompasses the entire
20 population of the United States.

21 But anything that you could suggest

1 that would be helpful for us to present this,
2 to get people engaged and interested in this
3 approach, would certainly be appreciated.

4 DR. LANGER: Did you want to make a
5 comment now or finish?

6 MR. HESLIN: That pretty much brings
7 me through my part of this so I welcome --

8 DR. LANGER: Let me just get a
9 logistical thought. Would you rather go now to
10 help guide this discussion or would you rather
11 have questions? What is your thought based on
12 your own --

13 DR. SCOLNICK: It doesn't matter to
14 me. It's whatever the Committee would prefer.
15 I had one question because he mentioned
16 something that I have never heard of before,
17 and I don't know anything about it, which is
18 Center staff colleges. I wondered what that
19 was. I don't know anything about it.

20 DR. LANGER: Okay.

21 DR. SCOLNICK: Other than that, I'll

1 do whatever you want. I have no preference.

2 DR. LANGER: Your talk will sort of
3 relate to maybe some suggestion?

4 DR. SCOLNICK: My talk will be talking
5 about the general concept. It will not be
6 exactly in this direction, as Jim knows. I
7 told him by email the thrust of my comments,
8 and asked him if he thought it was appropriate
9 or people wanted to hear it.

10 DR. LANGER: I'm sure everybody --

11 DR. SCOLNICK: Well, I wasn't sure and
12 so I asked him ahead of time.

13 DR. LANGER: What would be your
14 preference? Should we have Joe and then have
15 questions or would you like questions now?

16 MR. HESLIN: I guess if it's okay with
17 you, to have the questions or comments now?

18 DR. LANGER: Absolutely.

19 MR. HESLIN: But to respond to your
20 question about the staff college, I've been
21 here 10 years, and I've sort of seen a big

1 change in training at FDA, both in terms of the
2 training staffs and the kinds of activities
3 people are involved in.

4 The first organization with a staff
5 college was the Center for Drug Evaluation and
6 Research. That model is being replicated in
7 other Centers as well or has been.

8 Essentially, this is my perspective,
9 it was transitioning from the more traditional
10 training staff to an approach that, for
11 example, included employees as faculty. That
12 was used as a recruitment tool as well.

13 A lot of the people were coming out of
14 the academic ranks and they wanted to be able
15 to do this, so the staff college was something
16 that was attractive to folks.

17 And also the staff colleges really
18 take a broader perspective on learning and
19 development, and we're getting away,
20 thankfully, from the training of just how many
21 of these courses do you need, how many of these

1 courses do you need and scheduling them and
2 hope people show up.

3 More focused on performance
4 improvement and building competency models.

5 And, again, I can't speak for the CDER
6 staff college, but from discussions I've had,
7 there's been a transition there and a
8 refocusing.

9 DR. LANGER: Why don't we open this up
10 to questions now. I can see lots. So we'll do
11 questions and comments.

12 DR. ANDERS: I think this is a really
13 interesting idea. So as a lifelong academic,
14 the necessitate -- as a lifelong academic, I've
15 witnessed and been part of curriculum revision
16 after curriculum revision that all lacked any
17 reasonable measure of outcome, and I noticed
18 that's sort of on one of your slides, but it's
19 really important for you to know where you want
20 to go and how you're going to know if you got
21 to where you want to go.

1 So that is something that has to
2 happen every year, every semester, however your
3 time unit is, on and on and on. So you correct
4 what isn't working and replace it with
5 something that might work. So I think that's
6 really crucial for you.

7 Following on that, I didn't know the
8 Center Staff College system, and you said the
9 FDA University won't replace it, but by
10 definition a University is comprised of
11 colleges.

12 And isn't that an inefficient use of
13 resources if you don't exploit the talent that
14 exists in these so-called colleges and maybe
15 reduce the redundancy, because I would guess
16 there's redundancy among these colleges.
17 You're probably missing a chance to be a more
18 efficient organization.

19 What's the employee award for becoming
20 a student of the FDAU?

21 MR. HESLIN: What's the reward? Well,

1 one of the things I know people have talked
2 about is to offer through an FDA University
3 programs that provide CEUs or programs that
4 would provide credit with colleges and
5 universities that could go towards attaining a
6 degree.

7 For the individual, I think it's
8 mostly the availability, hopefully, of learning
9 resources.

10 For the Agency, it's bringing focus
11 and some direction to what that is.

12 DR. ANDERS: Are there things that you
13 can think of that would be an attraction to an
14 individual? That's hard for me to answer,
15 because I just like to learn things.

16 What would motivate an employee too --
17 this would I presume be done during their
18 normal work hours or is this a Saturday morning
19 activity or a 7 to 9 p.m. activity? If its out
20 of work hours, what would motivate them to take
21 their time to do this? Now I understand

1 there's some obvious motivations, promotions,
2 and advancement within the agency, et cetera.
3 That's reasonably straightforward.

4 But I mean the training will go
5 forward from vocational, presumably, to fairly
6 high level. And so what's the reward for
7 people to become engaged in this?

8 MR. HESLIN: Well, hopefully there
9 won't be disincentives in terms of like when
10 would a person do this. I mean, it's certainly
11 possible that people would do it on their own
12 time, but part of the commitment of the Agency
13 might have to be reflected in granting official
14 time to take courses and programs, and that
15 happens now. You know, maybe it will happen
16 now.

17 Are there other ideas about that?
18 Because clearly this is going to be something
19 that continues to come up. You know, what's in
20 it for employees, but also managers may ask the
21 same question, what's in it for me, and losing

1 a person's time while they're away at training
2 or costing me money.

3 DR. LANGER: I'm also going to
4 mention, we're not going to take a formal
5 break, but there is food up there, like
6 brownies, if anybody wants anything. That being
7 said, we'll just go around like this.

8 DR. ROSENBERG: The comment you just
9 made I think is crucial to this. If your
10 management doesn't buy into this, it just isn't
11 going to work at all. It's got to be almost
12 management driven. People have to see that the
13 environment demands their continued education
14 to even, as far as I'm concerned, to keep their
15 jobs, never mind to get promotions.

16 This is to maintain -- I mean, some
17 people are self-motivated, and as you say you
18 don't have to convince them to do this. But if
19 they think their managerial staff isn't driving
20 this, so you don't have the environment right
21 right from the start as to how acceptable this

1 is, you'll never get this to work.

2 MR. HESLIN: Yes?

3 DR. WOOD: This is just a response to
4 that. CDER's program that we won the award
5 for, the core competency program, defines
6 levels of what we call master reviewer progress
7 where you progress up in promotion and you must
8 have mastered even to become like not an
9 apprentice. You must either have those skills
10 or take the courses to complete those skills
11 within a certain time frame. So that is how
12 that's set up.

13 DR. DAVIS: I applaud the broadness of
14 this for sure. This is not something that we
15 don't already deal with, getting people
16 training. If you're going to become a
17 supervisor, you have to have certain course
18 skills. So to me this isn't surprising.

19 What does concern me a little bit,
20 though, is I think when we first started
21 talking about training, I didn't envision this

1 broad base training but rather keeping
2 scientifically competent. And one of the
3 things that was off to the side was the Science
4 Academy, and when asked about that it sounded
5 like, well, we weren't sure where we were going
6 to go with that, et cetera, et cetera.

7 My concern for the Agency and Agency
8 staff isn't what it takes to be a manager, et
9 cetera, et cetera.

10 My real core or gut concern is how do
11 we keep the people at the Agency scientifically
12 competent given the booming technology that's
13 out there and giving limited resources, et
14 cetera?

15 So what I'd like to hear more is if we
16 don't do the Science Academy, then how do we
17 make sure in all of the Centers, all of the
18 offices, all of the people who are reviewing
19 the packages are scientifically advanced as
20 those of us who are following the documents?

21 DR. L. JACOBSON: I agree with you.

1 That is the big challenge that we face and it's
2 what we talked about at our November meeting,
3 too. If you look, you only have one catalog in
4 there, because I think only CDER puts out a
5 nice catalog like that.

6 You'll see that a lot of the courses
7 are very scientifically based, technical type
8 training to give people additional skills in
9 their particular discipline, whatever that is.

10 One of the visions of this University
11 was that there are some courses, though, that
12 an individual Center might have -- several
13 Centers might have a need for. And we already
14 have a little pilot going in the Office of
15 Science. Susie Fitzpatrick has been heading a
16 series of courses that are FDA industry courses
17 on broad-based topics that lots of centers have
18 interest in.

19 We've done some on nucleic acid
20 testing. We've done some on sterilization
21 technologies. Things that sort of cross center

1 boundaries. And the idea is that's sort of a
2 template for what the FDA University can do, we
3 hope, in terms of providing that kind of
4 specialized training.

5 So we really have scientific training
6 being presented in a number of venues. One
7 will be the staff college offerings.

8 Another would be the FDA University
9 cross center trainings, and then there are lots
10 of other things that Jim had on the slide that
11 would be not really classroom based or training
12 course based but either on-the-job type
13 trainings or sabbatical programs, things like
14 that. I mean, the whole purpose of that is to
15 try to do something to address the needs that
16 we described at the meeting in November.

17 DR. DAVIS: Let me just go on record,
18 then. When I first saw the Science Academy, I
19 actually liked that, because I thought it was
20 an attempt to highlight or centralize this
21 whole focus on staying scientifically abreast,

1 so I really don't care how you do it, but I
2 liked it when I saw it on the slide and was a
3 little taken aback that it was, well, we may do
4 this, we may not.

5 I see that as a way of centrally
6 structuring scientific courses, lecturers,
7 spending money, whatever, across the agency,
8 focused on staying scientifically abreast,
9 which you can do in a less centralized fashion,
10 but the tendency might not be to spend the
11 money appropriately or the word doesn't get out
12 or whatever. So I actually like the concept
13 the way you had it.

14 DR. LANGER: Bob.

15 DR. NEREM: Maybe my comment would be
16 better after Ed Scolnick. I'm not sure what
17 Ed's going to say, so I'll go ahead and make my
18 comment, and then we can worry about whether we
19 discuss it or not.

20 The thing that jumps out to me is are
21 we talking about a super college, or are we

1 talking about a real university, or are we
2 talking possibly about a research university?

3 Because I look at this one slide or
4 whatever you call it, Why establish an FDA
5 University, and the six points there all could
6 relate to having a more centralized research
7 focus to support new initiatives, foster
8 cultural change, in the context of emerging
9 hybrid technologies, to marshall and deploy
10 scarce resources, we all know that the research
11 resources of FDA are very scarce.

12 To aid recruitment and retention, to
13 create a learning organization, we're talking
14 about the major challenge being how to stay on
15 top of the science.

16 I think a learning organization
17 somehow has to be integrated with a research
18 organization. So that's my input.

19 DR. LANGER: Good comment.

20 Go ahead.

21 DR. PICKETT: This isn't a response,

1 it's a comment.

2 Again, my comment is in part what
3 Marty had brought up, is basically assuming
4 that this is a good idea, is one of
5 implementation. And what I haven't really
6 heard during the discussion and presumably you
7 have a lot of very valuable employees within
8 your organization, is whether or not there have
9 been real focus groups with the employees to
10 ask them what they feel their needs are from a
11 training perspective.

12 MR. HESLIN: Under this particular
13 effort, not yet. This is really the first time
14 I've come out with this discussion. But
15 clearly trying to engage as many employees as
16 possible and the offer is going to be made to
17 go to the various centers to talk to their
18 staffs, I just need to know who it is that I
19 need to get to.

20 DR. FENNEMA: I'm a strong supporter
21 of what you're doing, as I've indicated, and I

1 am also concerned. This has been expressed
2 with the keeping abreast of the scientific
3 efforts and making this a major focus of the
4 activities.

5 But even beyond that, it goes through
6 my mind as to why are you limiting this to the
7 Food and Drug Administration. NIH has these
8 needs, FDA has these needs, EPA has these
9 needs, CDC has these needs, and many of those,
10 particularly from -- there are a lot of generic
11 things that apply to all of these organizations
12 as well as highly specific details in the
13 science area that would deal with many of these
14 organizations.

15 I don't know whether that's a feasible
16 thing to do or not, but it seems to me you
17 ought to look at it because the economics of
18 that might be even better.

19 DR. LANGER: Thank you.

20 David.

21 DR. FIEGEL: I just wanted to make a

1 couple of observations. One program to look
2 back at, it's a different model, and it was
3 perhaps a different time, but we haven't told
4 you very much about the radiological health
5 program. But that was a program that was
6 merged into FDA. It was largely staffed by
7 Commission Corps.

8 If you go back to the early days,
9 maybe not that early, but if you go back 20, 25
10 years ago, what you'll find is that there was
11 an expectation that this was a type of work
12 that you probably wouldn't have learned in the
13 outside world and that it was reasonable to
14 actually have dedicated time for new career
15 employees. Of course, the Corps was a
16 militarily like commitment.

17 So people were sent away for degree
18 programs for one to two years of training, and
19 it wasn't just the national program that ended
20 up training, but many of the state programs.

21 And what's impressive when I meet

1 people in State radiation control programs is
2 one of the things they almost always mention to
3 me is oh, yeah, I was trained during your
4 program, or I got my degree during your
5 program.

6 And there was a very active leveraging
7 between that program and the universities that
8 offered this typically at graduate level,
9 master's level, types of programs.

10 As the FDA scaled back and stopped
11 doing that, I'm not quite sure it's because it
12 saturated the market or if the public health
13 agenda changed, the graduate programs went away
14 as well.

15 One of our challenges in that
16 particular area is sort of how do we build the
17 next generation of radiation health physicists
18 and other health professionals at a time when
19 we really lost the infrastructure and there's
20 all the nuances of how to work with the Corps
21 as well.

1 But I think that's an interesting
2 investment to look back at, because now in the
3 sort of year-by-year congressional planning,
4 user fees, account for every dollar, show what
5 you're doing, it almost seems unthinkable to
6 many of our managers and employees, gee, I get
7 sent away for two years on a federal salary to
8 get specialized training that's mostly of use
9 to the government.

10 I think the comments about culture are
11 right on the money. There are groups who have
12 the expectation that after you've been to FDA
13 for two years one of the perks is that you have
14 a half day that you're entitled to take
15 professional development to work in the lab, if
16 you're a clinician work in the clinic.
17 Something to keep your skill sets up.

18 But there's other places, and I'm
19 afraid our center is one of them, where that's
20 viewed as a luxury, and the problem is that
21 many of us have in boxes we never get to the

1 bottom of, and that's the way the reviewers are
2 as well.

3 And if you don't stick to training
4 somewhere in the middle of that in box, they'll
5 always be saying I've got reviews to do, I've
6 got meetings to schedule, I've got company
7 meetings to go to, and they never set the time
8 aside and don't do it. So there does have to
9 be commitment for the top to say this is a
10 priority, you need to do this, this is part of
11 what makes us strong and gives us the
12 competence we need.

13 For the people that feel like there's
14 these big time constraints and they're being
15 beat up for faster, faster, faster, they're
16 sort of feeling like yeah, right, when am I
17 going to get the rest of my work done. But
18 we've got to think through that and need to
19 find a way to create that.

20 We also need to look at the
21 opportunities where it is a worthwhile

1 investment to send someone back to school.

2 Someone that Janet knows very well is
3 a pharmacist who is in the division that I was
4 in when I was in the Center for Drugs who went
5 back and got epidemiology training at USTES
6 while he worked half-time in the Center, and he
7 is now the chief information officer for the
8 Center for Drugs, something he never would have
9 had the background to do as well as he does now
10 if we hadn't made that investment five or six
11 years ago.

12 But it's very hard to kind of frame
13 those programs. I think they are very
14 valuable, and the final sort of rambling
15 comment I'll make is \$12 million sounds like a
16 lot. It's less than one percent of payroll.
17 And if you look at even some other federal
18 agencies in terms of their training budgets,
19 they're 2, 3 percent.

20 We would have to make a serious
21 commitment to alter the balance of our payroll

1 to our operating dollars to free up enough
2 money to train the people that we have since it
3 seems unlikely that Congress would give us 1 to
4 2 to 3 percent increase just for training, per
5 se.

6 I think that's something we have to
7 show our commitment by willing to restructure
8 and reorganize our priorities if we're really
9 serious about this.

10 DR. LANGER: We're going to have to go
11 now --

12 DR. SCOLNICK: Actually, I think he
13 set up my talk.

14 (Laughter)

15 DR. LANGER: I'll go up here even
16 though I don't have slides just because I think
17 it's probably the best place to talk from, but
18 I don't have slides. I do have some notes.

19 I think you've really set up the
20 conundrum here in this discussion.

21 **How Scientists in a Non-Academic Institution**

Keep Up With Cutting Edge Science

1
2 DR. SCOLNICK: As I thought about
3 this, my first reaction when I was asked by
4 Susan to do this was this is Motherhood and
5 Apple Pie. I do not understand the context for
6 this question, what should we do to keep up our
7 scientists so that we are increasingly
8 competent to do --.

9 And then the question was rephrased to
10 me, what do we do internally in a place like
11 industry, West Side Park, to keep our
12 scientists up.

13 So, again, I thought what is the
14 purpose for this question because it's fairly
15 obvious what general mechanisms are for keeping
16 up in science, and they're all listed on this
17 set of slides that we just saw.

18 I think that the real key to this is
19 actually two or three things when you stop to
20 think about it.

21 First of all, you've all made the

1 point that the scope of science is accelerated
2 in a dramatic way, and the information content
3 changes rapidly and the technology that
4 supports that information content changes
5 rapidly.

6 Now, you've all pointed out about the
7 scarce resources that the FDA has and the head
8 count restrictions you have, and that in the
9 real world that is not about to change.

10 That's the reality that you live in
11 and it's unfortunate, but it's a fact, and it's
12 not likely to change.

13 So I think the idea of talking about a
14 university, which to me means in a more
15 conceptual way opening up the process that you
16 use to do review and you were getting into that
17 this morning, is really a critical way to look
18 at it, and that is that I actually think that
19 the key to your having your scientists keep up
20 is to really institutionalize peer review and
21 in a way that you're beginning to do, I think,

1 from the discussions we had this morning and to
2 also think creatively about how you utilize
3 your internal staff and the global science
4 community outside to help you review
5 applications.

6 You know, in a company like Merck,
7 where we do, we are in many ways I think
8 analogous. I think in some ways we do what's
9 analogous to what you do, in that we're in a
10 sense an applied research organization. Basic
11 science is done to some degree, but much more
12 basic science is done outside of Merck than is
13 ever done inside of Merck in a global way.

14 And you're a different kind of applied
15 science organization. Okay?

16 Well, we would never think of trying
17 to do all the basic science internally. We're
18 always reaching out to the global world of
19 science to get help in what we do.

20 I think that one of the things you
21 need to do is institutionalize peer review, and

1 the other thing, on a continuing basis, all
2 through the FDA structure for the reviewers,
3 for the researchers, for the division
4 directors, for the head of the organization,
5 for the commissioner.

6 And I'm going to make some specific,
7 provocative suggestions in that regard which
8 you are free to clearly reject.

9 (Laughter)

10 But I think also you need to think of
11 yourself more in the context of the way
12 companies and journals work, and that is
13 journals have an editor. They have an
14 editorial board and they have editors.

15 The editorial board does not do all
16 the primary reviews for all of the
17 applications. They are the conduits for that
18 and they are the quality control for that. But
19 there would be no humanly possible way that the
20 editorial board for a journal, even in one
21 field, could keep up sufficiently to do all of

1 the primary reviews in-depth of the plethora of
2 papers sent into that journal.

3 And I think you're faced with an even
4 more difficult situation because you are
5 inundated by companies all over the world and
6 all over this country that are interested in
7 registering their products in the United
8 States, and you cannot possibly have a staff
9 and you cannot possibly expect your staff in an
10 applied setting to be, no matter what you do in
11 educating them in courses, to keep up with the
12 science and the technology that it takes to do
13 quality scientific reviews, which you can then
14 review and take actions on, reserving that
15 prerogative to yourselves because you're
16 legally empowered to do that and there should be
17 an organization, the FDA, that in the end makes
18 the final decisions.

19 But I think the structure by which you
20 do reviews is too narrowly structured for
21 today's world of science and that you need to

1 open up your reviews more than you do today and
2 in a different way than you do to your public
3 advisory committee meetings, which are a focal
4 point for a subset of what comes through your
5 organization, and that you need, in a sense,
6 each division needs -- you know what I was
7 thinking about when I really got into this is
8 each division that deals with a therapeutic
9 area needs a Scientific Advisory Board, which
10 in a sense could function the way an editorial
11 board of the Journal functions, and they'll do
12 the primary reviews for you, and the people you
13 have internally will take those, digest them
14 and take actions on them, and you can quality
15 control the process by virtue of whom you
16 assign to those advisory boards.

17 You can do that in each division, you
18 can do it at an FDA level too. You can think
19 of yourselves in the way a company thinks of
20 itself. We have a Board of Directors at Merck,
21 we have a Board of Scientific Counselors for

1 our research lab.

2 The Board of Directors and the company
3 meets with company senior staff on a monthly
4 basis, and they hear what's going on in the
5 company, and a good company will present the
6 most important problems that they're dealing
7 with to their board at those meetings to get
8 feedback and input from highly talented people
9 who they've brought into their process.

10 I've always wondered why doesn't the
11 FDA structure a scientific body that functions
12 that way for its division directors and its
13 Center directors where they can discuss with
14 the very best scientists on the outside whether
15 by things like net meeting or in-person
16 meetings or some combination thereof to get the
17 very best input you can in terms of the science
18 that's driving drug discovery or device
19 discovery rather than relying fairly
20 exclusively until the end on internal people
21 who every year they're away from University are

1 more and more removed from the intellectual
2 content they need to do the reviews.

3 So that's one aspect of it.

4 I think the other aspect of it really
5 is the peer review system that you're beginning
6 to open up.

7 I think that no matter how well
8 intended any scientist is and no matter how
9 well motivated any individual scientist is,
10 there is no substitute for any system have
11 excellent external peer review group --
12 external peer review group and internal peer
13 review system that constantly quality controls
14 the content of what is being put down on paper
15 and the processes that you're using to arrive
16 at those conclusions.

17 I think those are the two keys to what
18 a university atmosphere rather than simply
19 university would look like.

20 In some ways, it's radical, and I
21 understand that, and I am sure there's enormous

1 consternation at some of my remarks. But I
2 would tell you that they are made from the
3 perspective that I fervently, from my 20 years
4 at Merck, believe in a concept of a strong
5 scientifically excellent Food and Drug
6 Administration. It's critical for regulating
7 the products that American consumers use.

8 I think there is a better way to do
9 that than you do it today, and you don't need
10 to be wedded to the processes for doing that
11 because times have changed, the world has
12 changed, your budget situation has changed,
13 there are many thing that have changed.

14 That's what I wanted to say.

15 DR. LANGER: Thank you. That's
16 excellent.

17 Any questions?

18 DR. FENNEMA: I don't have a question
19 but comment.

20 That in a sense FDA, CFSAN, has
21 exploited that technique not quite the way

1 you're describing but almost with utilization
2 of a life sciences research office of FASB to
3 do reviews of food additives. When the process
4 happened, that was done under kind of the
5 system that you're suggesting. And there's no
6 reason that that general system could not be
7 extended to considering petitions of various
8 kinds for the Food and Drug Administration
9 under the details that you've talked about.

10 I think that is an absolutely splendid
11 concept which would allow the Food and Drug
12 Administration to much better use their
13 resources than they're doing now.

14 DR. LANGER: David.

15 DR. FIEGEL: A couple of comments.

16 I like the emphasis on peer review.
17 Sometimes I feel like we're doing our work so
18 close to the deadline that it's hard even for
19 the supervisor who may have more experience
20 than the primary reviewer, to really engage on
21 very many issues, and I think we need to look

1 at the way that we organize, the way we do our
2 work, so that there is the appropriate internal
3 peer review.

4 Some of your suggestions about
5 external would require some work-arounds with
6 the Federal Advisory Committee Act and some
7 things like that. But skipping that problem, I
8 think there are ways to work around that.

9 One of the experiments in external
10 expertise in the area for Center for Devices is
11 third party review. And we've actually argued
12 with industry that they should not -- they've
13 been sort of slow to use it because it's an
14 extra cost to them and currently we're almost
15 as fast. They're a little bit faster than we
16 are, but it's dealing with a new party and so
17 forth.

18 But we've actually made the scientific
19 argument to them that they should keep this as
20 an option for us to have scientific expertise
21 to call on because the third parties can go to

1 experts.

2 If, for example, we developed through
3 the pipeline a large number of very similar
4 examples, genetic testing is one example of
5 something that's on the horizon where there's
6 thousands of tests, and we have to do
7 geneticists.

8 So it would be great if there was a
9 third party that would ramp up, specialize in
10 this, be able to provide expertise to us, and
11 even better than just relying on industry to
12 voluntarily pay for the third parties, we ought
13 to have enough funds that we can contract with
14 them directly.

15 DR. SCOLNICK: Yes, that's my point.

16 And I think there's another aspect to
17 it, David, also. I've been out of lab science
18 for a long time, and I realized it
19 increasingly, and that is what are the
20 qualifications you need to review research,
21 which is what you're really being asked to do?

1 Well, to teach students in University,
2 to do research on a Journal, you really have to
3 be au currant with not just the intellectual
4 content of what's going on but the technology
5 that generates that data, or it's extremely
6 difficult to interpret the data.

7 I find that in my own case
8 increasingly difficult every year and you have
9 to work at keeping up, and you all have a much
10 more limited set of resources and time to do
11 that than perhaps I do.

12 I think for you to not be relying on
13 the expertise that exists in the American
14 university system or in the global university
15 system, to help you do those reviews where
16 people are really close to the technology, the
17 artifacts that are generated by this and that,
18 et cetera, just is not taking advantage of
19 what's open to you to do quality reviews.

20 DR. FIEGEL: No. The other comments I
21 would make, and I think your emphasis on this

1 is very interesting, is something that should
2 really be explored. But when you look at what
3 industry also values, they value working with
4 the same team repeatedly over time and getting
5 consistent approaches, and I think that's
6 another reason that often they haven't gone to
7 third parties is that they've cultivated an
8 understanding of how the FDA team works, right
9 or wrong, and I think that ends up with some
10 idiosyncrasies.

11 But we'd really have to sort of think
12 through and prioritize what we want reviewed
13 and at what level.

14 Our Center has probably about 500 FTEs
15 in pre-market review, in round numbers, and we
16 get about 65 submissions per day. So about
17 every 10th day, our reviewer gets a new
18 submission to review, and a submission ranges
19 from a simple protocol amendment to a 500-pound
20 application.

21 But it's prioritizing sort of what do

1 we send out for review, and how do we make sure
2 that there's consistency.

3 I think those things can be worked
4 out.

5 DR. SCOLNICK: Well, again, let me
6 give you the analogy that I started with.

7 When you're an academic scientist and
8 you're deciding where you're going to send your
9 manuscript, you get used to sending it to a
10 small set of journals, and you know the kind of
11 idiosyncrasies, as you put it, of a given
12 editorial board. And you take that into
13 consideration.

14 Over time, if you had a consistent
15 group of external reviewers in a sense for your
16 various therapeutic areas, companies would get
17 used to that. They'd understand what's
18 expected and they would begin to work with it.

19 DR. FIEGEL: Yes.

20 DR. LANGER: Liz and then Bob.

21 DR. L. JACOBSON: I was just thinking,

1 far from causing consternation, you've got a
2 lot of agreement on the kinds of things you're
3 suggesting, not that they're very doable at the
4 present time given our resources, et cetera,
5 and all the other constraints.

6 I just wanted to add one more thing to
7 the mix, which is, it isn't just the scientific
8 expertise that's necessary to do good reviews
9 or good regulatory actions or good postmarket
10 surveillance, or whatever else it is.

11 That is an absolute necessity, but
12 it's not sufficient because there's the whole
13 understanding the regulatory structure, and
14 that's another contribution that we see the FDA
15 University as needing to figure out how to do.

16 In your construct, whether we would
17 have that --

18 DR. SCOLNICK: You would have to be
19 doing --

20 DR. L. JACOBSON: -- partly us and
21 partly the Editorial Board, or us --

1 DR. SCOLNICK: Well, you would have to
2 play a very important role --

3 DR. L. JACOBSON: Right.

4 DR. SCOLNICK: -- in that regard, and
5 anyone you bring into the review process,
6 giving them the background for thinking about
7 it in a regulatory environment --

8 DR. L. JACOBSON: Yes, but that's not
9 trivial.

10 DR. SCOLNICK: It's not trivial, but
11 that would be part of your responsibility.
12 You're expert at that, you'll always be expert
13 at that because the laws don't change that
14 fast. And it's easier to teach that to outside
15 people than to keep the technology up, I think
16 in some sense.

17 But I agree it's --

18 DR. L. JACOBSON: It's just
19 additional --

20 DR. SCOLNICK: -- the science and
21 technology is not sufficient. It's critical

1 necessary. It is not sufficient.

2 DR. LANGER: Bob.

3 DR. BUCHANAN: Any thoughts as you go
4 through this process? One of the things that
5 we've been facing has actually been a decrease
6 in willingness of scientists to serve on panels
7 because of the increasing demands on financial
8 disclosures.

9 Have you any thoughts on how we handle
10 that because certainly some of our stake
11 holders are increasingly vehement about
12 absolute disclosure of all involvement of any
13 scientists on any board?

14 DR. SCOLNICK: No, I think you have to
15 have disclosure. I don't think you should be
16 excluding people from your review boards who
17 have financial involvement with "X" or "Y," but
18 it should be of public record that that exists
19 so that their comments and reviews and whatever
20 they say and write can be viewed as to whether
21 they have a conflict of interest or not.

1 They should be willing to do that to
2 serve on your boards, and if they're not, then
3 I agree, you should not have them participate.
4 Schwetz.

5 DR. SCHWETZ: Let me point out why I
6 think this discussion is particularly timely.

7 Now, the rapid change in technology
8 and science is certainly one of the reasons,
9 but I don't think it's the most telling one for
10 the agency.

11 As you've heard before, 25 percent of
12 our employees are going to retire within five,
13 six, seven years. And while there are a lot
14 of people who sit around and wring their hands
15 about that, it's also a wonderful opportunity.
16 And we will never have an opportunity like this
17 again for another whole generation of FDA
18 employees.

19 If we replace every one of those
20 people and a few more as we grow, in kind, as
21 they live one by one, we're going to be as

1 inflexible six years from now as we are today.

2 So if we want to change the culture
3 and if we want to use some more innovative ways
4 of getting our work done, we have to resist the
5 temptation to replace every person when they
6 leave.

7 And we have to have a strategy that
8 determines now what we want to look like in
9 five years so that if we want to put money in
10 training programs in ways of building teams of
11 people who can work for us, not as permanent
12 government employees but like you are, as
13 temporary government employees, we have to have
14 that all laid out now or it will never happen.

15 So your discussion I think is
16 especially timely.

17 DR. LANGER: Bob.

18 DR. NEREM: You can yell.

19 DR. LANGER: There you go.

20 DR. NEREM: Interesting discussion. I
21 guess my first comment may in some way to be

1 addressed to Ed. And then I have an additional
2 comment.

3 I suspect, Ed, that your organization
4 is able to take advantage of the global science
5 community as well as you do because you have
6 in-house expertise which is, those people are
7 themselves at the forefront of science and
8 technology.

9 DR. SCOLNICK: In part true.

10 DR. NEREM: So when we think about
11 FDA, yes they can do a better job of using the
12 broader community, but they also have to figure
13 out a way to actually have in-house capability
14 that truly is at the forefront.

15 DR. SCOLNICK: Well, I think that's
16 important. I think you're almost defining a
17 chicken and an egg kind of situation, and I
18 think that you can have a little of both and
19 build it up over time. But I think that having
20 a good external group to work with for a few
21 years that can help any given division give

1 them advice, give them current knowledge,
2 interpretations of new technology, while
3 recruitment is being done and training is being
4 done -- you know, it's kind of an evolutionary
5 process. I completely agree, you can't get
6 from A to Z in one fell swoop, and it's
7 complicated.

8 DR. NEREM: The other comment I wanted
9 to make, and I guess maybe I don't totally
10 understand the FDA review process; but if they
11 think about -- well, I thought about the
12 editorial model and that actually led me to
13 think about models of reviewing proposals; NIH,
14 NSF. And yes, there is a panel in most cases,
15 but there also are external mail reviews. In
16 other words, every input to a review doesn't
17 have to be someone who comes to Washington and
18 sits on a panel. And I don't know how much FDA
19 takes advantage of that broader input where you
20 don't necessarily need someone who understands
21 all of the ins and outside of the FDA review

1 process, but is the best person in the world to
2 address a particular scientific or technology
3 issue and raise the right questions.

4 DR. LANGER: Yes, Harold.

5 DR. DAVIS: This is a complicated
6 issue. I want to go back to something I said
7 earlier. I think there is a place for the FDA
8 University concept in terms of just growing up
9 people, whether they be reviewers or whatever;
10 that they function at the FDA. People need to
11 have a career path to know how to get from A to
12 B. So I think that's very important; I don't
13 want to lose sight of that.

14 My comments about the science academy
15 I like; the proposal that -- and maybe that's
16 too strong a word. The comments that Ed made,
17 I just want to highlight again, are very
18 provocative and sometimes you have to be
19 careful what you ask for.

20 It seems to me at the table there
21 seems to be this unanimity that these are good

1 ideas, but I won't be naive enough to think
2 that (1) everybody at the FDA and all of the
3 Centers will be "Oh, yeah, Ed, we're with you
4 here, there, this isn't so" --

5 DR. SCOLNICK: I expect to be tarred
6 and feathered.

7 DR. DAVIS: These are very different
8 ideas that are in fact thrown out. My
9 experience with the agency over the years stems
10 to, we have a responsibility to the public, you
11 know, and you can't disseminate that further
12 down. There is the political truism that once
13 you have these reviews done by other people and
14 they come back -- Ed, you say that the agency
15 will have the final say. I know that if it
16 comes back and the FDA does something different
17 than what this review group does, there will be
18 hell to pay for that. So it is a very
19 complicated thing, but I think it's worth
20 considering.

21 I don't see how, if we continue, we

1 being the agency and industry, continue on the
2 path that we're on, and given that you're going
3 to lose all of these people, a lot of
4 seniority, a lot of expertise, a lot of
5 experience, that in some ways it's going to
6 make the job even worse if you continue to try
7 to do it the way you're doing it, just because
8 you are losing these people. And that's even
9 if science stayed the same, and science is not
10 going to stay the same.

11 So you've got both of these things
12 coming together at the same time. So I think
13 together you are going to have to put your
14 heads, we and you are going to have to put our
15 heads together and come up with something that
16 may not be exactly what we thought we'd like to
17 see and may not be exactly what the agency
18 senior staff thought they would like to see,
19 but I think it's going to have to look a little
20 different.

21 DR. LANGER: Yes.

1 DR. DAVIS: And you will be tarred and
2 feathered.

3 (Laughter)

4 DR. JACOBSON: It's always fun to talk
5 about controversial stuff, though; it gets you
6 thinking.

7 The one comment I'd like to insert
8 here is that we've been talking very much --
9 the talk seems to keep slipping back to talking
10 about reviewers.

11 Certainly the review component of the
12 agency is a really important component, but
13 it's just as important for us to have people
14 who know what they're talking about, for
15 example, who are walking into a plant to
16 inspect a software manufacturer, and that's a
17 very different kind of thing. So I just want
18 to remind us of that.

19 DR. PICKETT: My only comment is that
20 it's -- I don't think it's necessary to sort of
21 rediscover the will here. In terms of

1 scientific excellence and fostering scientific
2 excellence in an organization, be it in a
3 academics, industry, or in government.

4 And the fundamental things that I
5 think all of these organizations have depended
6 on to build excellence, scientific excellence,
7 has been peer review systems, both internal and
8 external peer review systems, and secondly,
9 relying on state-of-the-art scientific input
10 with regard to issues as they come up.

11 So I think those two components have
12 to be integral in maintaining any type of
13 scientific excellence in any organization.

14 DR. LANGER: All right. Yes?

15 DR. FEIGAL: As long as we're being
16 provocative, one thought I have sometimes is
17 whether or not by mimicking other scientific
18 products, our reviews look very much like
19 science papers; and when the reviewers are
20 given extra time, they write them longer, they
21 document them better, they reference them --

1 maybe that isn't the best way for us to use our
2 science and add value, because the real
3 critical issue are a series of decisions and
4 the underlying process of that decision-making.

5 I think one of the questions we sort
6 of have to ask ourselves at some point is, do
7 we even really have the process right? Of
8 knowing where we apply the science and what
9 it's for. We don't need to get into a
10 competition between our toxicologist and your
11 toxicologist about who can do a better summary
12 of that study; or our statisticians and your
13 statisticians about who can think about how to
14 look for the robustness of the data.

15 It really comes down to saying,
16 "What's the underlying assumption that you
17 really want to take apart in terms of why
18 things may not be what they seem, or if there's
19 enough evidence" or those types of issues. And
20 what really has added to the length and the
21 duration of our review process has been the

1 model that we currently use.

2 I think at some point it probably is
3 healthy for us to go back to first principles
4 and say "Really what is our mission, how are we
5 accomplishing it?" "What are the tools that we
6 have to accomplish it?" How is it that we
7 really do add value with the resources we have
8 and the external resources we can tap?" Maybe
9 we'll come back to the system that we have now,
10 but there may be other areas where we'll
11 conclude we have backed into a way of doing
12 things that isn't as efficient as it can be.

13 DR. SCOLNICK: I agree with some of
14 the implications of your comments. It's too
15 complicated to go into here.

16 DR. LANGER: Any other comments?

17 Any particular, as we think about next
18 meeting, are there any other emerging science
19 issues that people would like to go over? For
20 example today we went over tissue engineering
21 to a certain extent. We don't have to decide

1 that today, we can do that by e-mails. But if
2 there are any suggestions --.

3 DR. NEREM: Well, in some ways I'd
4 like to see a continuation of the discussion.
5 I very much see --

6 DR. LANGER: The discussion of?

7 DR. NEREM: Well, the discussion of
8 everything. Because I see an intersection of
9 the research capability of FDA -- its training
10 capability and its ability to review products.

11 DR. LANGER: I totally agree with you.

12

13 I was actually going to make comment
14 anyway. I apologize. I think that one of the
15 things I was just talking to Liz and others
16 about, is making sure we follow up with this
17 particular set of discussions next time. I was
18 almost taking that for granted. I should have
19 said that. But I didn't know if there were any
20 other ones.

21

DR. DAVIS: Well, on that, Ed sprung

1 this provocative -- for which he shall be
2 tarred and feathered -- sprung this provocative
3 thing. But I think to be fair to the agency, I
4 would like to give them a chance to think about
5 this idea in any fashion in terms of, is this
6 way too out in left field? You know, maybe
7 there is some happy medium or something -- I
8 think we're only going to -- and I wouldn't
9 even begin to believe that Ed's ideas are the
10 right ones; you know, that's where we're going,
11 but I think it serves as a point of departure.

12 DR. LANGER: Right, a platform.

13 DR. SCOLNICK: Actually, I was going
14 to say the same thing, Bob. That I think what
15 would be interesting is, meetings don't take
16 place that often; there's a few month gap.

17 DR. LANGER: Right.

18 DR. SCOLNICK: There's a lot of time
19 for the senior group at FDA that's here or
20 others that they interact with, to think out of
21 the box, which is the point of stimulating the

1 discussion, about what -- if they had had their
2 druthers, they lived through various systems
3 over the years; they've thought about it, they
4 care about the quality of what they do. What
5 would they put in place if they really had a
6 tabularasa. This is a good group to interact
7 with, it's pretty open, you know, and what
8 would they say in response to all the comments
9 that have been made?

10 DR. LANGER: Good. That's definitely
11 an agenda item.

12 Yes, Bob?

13 DR. BUCHANAN: I'd just like to throw
14 out, because part of this is where are we going
15 with our science, and I really want to
16 challenge you a little bit, and particularly
17 about our infrastructure, where we put our
18 research dollars.

19 Part of where we put our research
20 dollars is where we do our work, and I read an
21 interesting quote the other day about the

1 difference between industry and regulatory
2 activities, and it's by Richard Hall, a book
3 that appeared in the Seventies. And the focus
4 of industry is to work towards and establish
5 the benefits of the products. As opposed to,
6 our orientation is largely, at least on the
7 food side, examining the risk associated with
8 those products.

9 And we approach things differently, we
10 have different end products that we're looking
11 at very often, or endpoints, and it sets up a
12 certain dynamic tension that it's really the
13 system's there to take advantage of, and I'm
14 not sure that where we should be putting some
15 of our research dollars is the same place that
16 you think that we should.

17 For example, our ability to evaluate
18 risk, to estimate risk; our ability to develop
19 technologies for looking at adverse events are
20 critically important to us. I'm not sure that
21 they're as critically important to the