

FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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FDA SCIENCE REVIEW SUBCOMMITTEE

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EXTERNAL SCIENCE REVIEW

+ + + + +

OPEN SESSION

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WEDNESDAY,

JULY 25, 2001

+ + + + +

The Subcommittee met in Room O, Center for Devices and Radiological Health, 9200 Corporate Boulevard, Rockville, Maryland, at 10:19 a.m., Dr. Robert M. Nerem, Chairman, presiding.

PRESENT:

ROBERT M. NEREM, Ph.D., Chairman

ALEXA I. CANADY, M.D., Co-Chairperson

ROGER C. BARR, Ph.D.

BARRY H. BEITH, Ph.D.

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PRESENT (Continued):

LOUIS J. BLAZY, Ph.D.

ANNE B. CURTIS, M.D.

DOMINIQUE M. DURAND, Ph.D.

JOHN D. FISHER, M.D.

PATRICIA L. GARVEY, Ph.D.

KINLEY LARNTZ, Ph.D.

ELIZABETH N. PIETERSON

RHALL E. POPE, Ph.D.

HANY W. DEMIAN, Executive Secretary

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C-O-N-T-E-N-T-S

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P-R-O-C-E-E-D-I-N-G-S

(1:01 p.m.)

CHAIRPERSON NEREM: Okay. We are now in public session, and I want to welcome any who might have joined us for this public session.

I believe Hany will read some things into the record.

MR. DEMIAN: Good afternoon, everybody. We're ready to begin this public portion of the meeting of the Subcommittee to the FDA Science Board for the Center Devices and Radiological Health science review.

My name is Hany Demian, and I'm the Executive Secretary for this panel.

I will read two statements that must be read into the record. The first is the deputization for temporary voting member statement.

Appointment to temporary voting status. Pursuant to the authority granted under the Medical Devices Advisory Committee charter, dated October 27th, 1990, as amended August 18th, 1999, and November 16th, 1999, I appoint the following individuals as voting members of the CDRH Science Review Subcommittee of the Science Board to FDA for this meeting on July 24th, 25th, and 26th, 2001:

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1 Roger Barr, Barry Beith, Louis Blazy, Alexa Canady,
2 and Curtis Dominique Durand, John Fisher, Patrician
3 Garvey, Kinley Larntz, Elizabeth Pieteron, and
4 Rhall Pope.

5 For the record, these individuals are
6 special government employees and are consultants to
7 CDRH or to panels under the Medical Devices
8 Advisory Committee. They have undergone the
9 customary conflict of interest review and have
10 reviewed the material to be considered at this
11 meeting.

12 And this is signed by the Director for
13 CDRH, David Feigal.

14 The second statement is the conflict of
15 interest statement.

16 The following announcement addresses
17 conflicts of interest issues associated with this
18 meeting as made part of the record to preclude even
19 the appearance of any impropriety.

20 To determine if a conflict existed, the
21 agency reviewed the submitted agenda and all
22 financial interests reported by the subcommittee
23 participants. The conflict of interest statutes
24 prohibit special government employees from
25 participating in matters that could affect their or

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1 their employer's financial interest.

2 However, the agenda may determine that
3 participation of certain members and consultants,
4 the need for whose services outweigh the potential
5 conflict of interest involved, is in the best
6 interest of the government.

7 For the participation in this three-day
8 meeting, all of the subcommittee participants have
9 been granted general matters limited waivers for
10 their employment, professional relationships, or
11 financial interests in firms that could be
12 potentially affected by the subcommittee's
13 deliberations.

14 These individuals are: Dr. Robert
15 Nerem, Martin Rosenberg, Roger Barr, Barry Beith,
16 Louis Blazy, Alexa Canady, and Curtis Dominique
17 Durand, John Fisher, Patricia Garvey, Kinley
18 Larntz, Rhall Pope, and Ms. Elizabeth Pieteron.

19 The waivers permit these individuals to
20 participate in all general matters before the
21 subcommittee. Copies of these waivers may be
22 obtained from the agency's Freedom of Information
23 Office, Room 12A-15 of the Parklawn Building.

24 In the event that the discussions
25 involve any issues not related on the agenda for

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1 which an FDA participant has a financial interest,
2 the participant should excuse him or herself from
3 such involvement, and the exclusion will be noted
4 for the record.

5 With respect to all other participants,
6 we ask in the interest of fairness that all persons
7 making statements or presentations disclose any
8 current or previous financial involvement with any
9 firm whose products they may wish to comment upon.

10 Before turning this meeting over to Dr.
11 Nerem, I would like to introduce our distinguished
12 panel members who have generously given their time
13 to help FDA in matters being discussed today and
14 other FDA staff seated at the table.

15 So we'll just go around the room and
16 have everybody introduce themselves and give their
17 area of interest.

18 Dr. Nerem.

19 CHAIRPERSON NEREM: I'm Nerem from
20 Georgia Tech, professor in biomedical engineering
21 at Georgia Institute of Technology.

22 DR. CURTIS: Anne Curtis. I'm a
23 cardiologist at the University of Florida.

24 DR. FISHER: John Fisher, cardiologist,
25 Albert Einstein College of Medicine.

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1 DR. BLAZY: Louis Blazy, software
2 engineer from NASA.

3 DR. BEITH: Barry Beith, human factors
4 psychologist, Human Centric Technologies.

5 DR. GARVEY: Patricia Garvey, Vice
6 President of Regulatory Quality and Clinical for
7 Edwards Life Sciences.

8 DR. POPE: Rhall Pope, Vice President
9 of Research and Development, Deltec.

10 DR. LARNTZ: Kinley Larntz. I'm a
11 statistician, professor emeritus, University of
12 Minnesota.

13 MS. PIETERSON: Beth Pieterson. I'm
14 Director of Medical Devices, Bureau of Health,
15 Canada.

16 DR. DURAND: Dominique Durand,
17 professor of biomedical engineering, Case Western
18 Reserve University.

19 VICE CHAIRPERSON CANADY: Alexa Canady,
20 professor of neurosurgery at Wayne State
21 University.

22 CHAIRPERSON NEREM: Okay. Well, I want
23 to again welcome everyone who's joined us for this
24 public session.

25 I am chair of this subcommittee, and

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1 Alexa Canady is my co-chair, and I would like to
2 note that for the record, and that we constitute a
3 quorum as required by 21 CFR, Part 14.

4 We are now in the open public hearing
5 session of this meeting, and I would ask at this
6 time all persons addressing the panel come forward
7 and speak clearly into the microphone as the
8 transcriptionist is dependent on this means of
9 providing an accurate record of this meeting.

10 We are requesting that all persons
11 making statements during the open public hearing of
12 the meeting disclose whether they have financial
13 interest in any medical device company before
14 making your presentation to the panel. In addition
15 to stating your name and affiliation, please state
16 the nature of your financial interest, if any.

17 At this time is there anyone wishing to
18 address the panel? I'm looking for a show of hands
19 of individuals who might wish to address the panel.

20 Was there a hand?

21 Oh, I'm sorry.

22 MR. DEMIAN: You're FDA?

23 MR. YOUNG: I'm from NTEU.

24 MR. DEMIAN: Okay.

25 MR. YOUNG: Well, good afternoon. The

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1 first thing I'd like to do is thank all of the
2 members of the panel because you really do a great
3 service, and we really appreciate it.

4 We basically need all of the help we
5 can get, and anyone who can help us do our job more
6 efficiently, make this a better place to work, and
7 increase the degree of consumer protection we offer
8 to the American people certainly are welcome.

9 I sat for 20 years as a trustee of the
10 Jackson Labs up in the, as they say, Bar Harbor,
11 Maine, and, you know, they're outside panels, and I
12 hear with the work they do, and it really does
13 contribute.

14 What I'd like to do today is I know we
15 have a meeting schedule tomorrow at two o'clock,
16 but you're leaving at 2:45, and if you've seen the
17 traffic out here, you're probably scared already.
18 So what I want to do is just give you some
19 background material on the information on the
20 union, and I want to try to find out what you
21 really want to hear about because it's easier to
22 speak to you or address, you know, whatever concern
23 you have if we know ahead of time.

24 It's like you guys are all medical
25 devices. So it's like putting off an X-ray, a

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1 chest X-ray. You tell the radiologist, you know,
2 "What is this?" They'll just describe it.

3 But if you have a particular problem,
4 when you give it to them, they have a much easier
5 time trying to help you out deciding what a
6 particular patient has.

7 NTEU is a federal union. It has been
8 around for about 60 years. It's mainly Treasury
9 employees because that's where it got started. So
10 the bulk of the members are in the IRS and U.S.
11 Customs.

12 About ten years ago, this Union began
13 organizing outside of Treasury, and that's how FDA
14 happens to be in a union that's mostly Treasury
15 employees.

16 The chapter here at FDA headquarters is
17 called Chapter 282, and we represent the employees
18 in headquarters in the Washington, D.C. area.
19 There are approximately 4,000 employees in this
20 unit.

21 The national union, the union overall
22 represents about 150,000 federal employees. Some
23 people are interested that we actually have unions
24 in the federal government, but actually federal
25 unions represent more than half of the federal

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1 employees. So over one and a half million
2 employees.

3 So the purpose of having the unions in
4 the federal sector is the same as it would be in
5 the private. Hopefully what will happen is by
6 having the employees contribute to what's going on,
7 meaning not the management of the enterprise, but
8 at least the operation of it, basically everybody
9 comes out with a better product.

10 This union has been certified for four
11 years now, and our contract was signed about a year
12 and a half ago. So we're really just getting
13 started. There was never a union before at FDA in
14 headquarters. We've had unions outside in the
15 field offices, such as the districts or the
16 regions, but not here. So everybody, meaning FDA
17 and the employees who are just getting started
18 working together.

19 So if you can indicate to me kind of
20 what you're interested in for tomorrow it would be
21 just easier for us to try to address it.

22 CHAIRPERSON NEREM: You've talked
23 already to -- one of your colleagues, Cathy --

24 MR. YOUNG: Cathy Hobbs, one of our
25 Vice Presidents.

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1 CHAIRPERSON NEREM: Yeah, right. I
2 think we view the employees of FDA, the staff of
3 FDA as an extremely important part of the whole
4 activity as we think about the future and think
5 about how FDA can not only continue to do the job
6 it's doing, but enhance its activities, issues
7 related to staff support, career paths, processes
8 that are in place are important, and so that's why
9 we reached out to have a conversation with you and
10 others that you might choose to have joining you.

11 MR. YOUNG: Right. Well, tomorrow we
12 have something like 20 Vice Presidents. They're
13 mostly organized along unit lines. So there are
14 four in Drugs, for example, and three, I think, in
15 CDRH.

16 Actually I work in Drugs, and so Cathy
17 is one of the Vice Presidents, and Joy Lazaroff is
18 the Executive Vice President for the entire
19 chapter, but actually the both of them are CDRH
20 employees.

21 CHAIRPERSON NEREM: It would be good if
22 they were there. What I'm looking for is meeting
23 the 20 people, but a small group of three or four
24 people.

25 MR. YOUNG: Right. Okay. They're

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1 going to be here tomorrow.

2 Let me tell you just a little bit about
3 the federal employees under --

4 DR. BLAZY: If I could amplify --

5 MR. YOUNG: Sure.

6 DR. BLAZY: -- you asked a question
7 about what we would be interested in. What are the
8 issues from the union's perspective in terms of
9 your priorities and representing the employees?
10 What are the issues that are most dominant in terms
11 of labor relations, management relations?

12 That's what we would be interested in.
13 This could be with regards to training. This
14 could be with regards to promotion potential,
15 better work environment, office sites, a whole host
16 of issues that could be brought to one steward and
17 union representative as conditions of employment.

18 Which ones have surfaced that are
19 priorities to you representing your employees that
20 you can discuss with us very concisely?

21 CHAIRPERSON NEREM: Bob, once this
22 public session is over, I'd be glad to meet with
23 you and talk to you one on one.

24 MR. YOUNG: Sure. Let me just spend a
25 couple more minutes. Let me tell you under the

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1 statute, which is, you know, everything operates
2 under statute, including devices; under the
3 statute, you know, there's a federal employee. You
4 can have federal employee unions. That's so long
5 as the employees want it, meaning they have to
6 vote, and the majority have to vote in favor of it.

7 The union is going to address what are
8 called the conditions of work. They cannot get
9 into the work itself. How the work itself is done
10 and what the work is and how the work is assigned
11 belongs to the agency, and I think that's properly
12 so because they're responsible for it.

13 CHAIRPERSON NEREM: Can we actually
14 talk about this tomorrow?

15 MR. YOUNG: Yeah. I just thought I'd
16 just spend a second on this just to frame it a
17 little bit for the questions.

18 We could only get involved in the
19 conditions of work. That's the work environment
20 itself, and that's, I think, what you're interested
21 -- it sounds like the kind of thing that you're
22 interested in. So we'll look at that tomorrow.

23 I just wanted to draw the distinction
24 between the work itself and the conditions of work.

25 CHAIRPERSON NEREM: Well, I'm sure

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1 we'll have many more questions. So thank you very
2 much, and even though you're at the end of our
3 session, tomorrow, you know, this activity, the
4 committee will be going on beyond that to write the
5 report.

6 MR. YOUNG: Great.

7 CHAIRPERSON NEREM: So your input will
8 be timely. Thank you very much.

9 MR. YOUNG: Okay. Thank you.

10 CHAIRPERSON NEREM: Is there anyone
11 else who raised their hand to make a comment in
12 this public session?

13 There is a letter to be read into the
14 record.

15 MR. DEMIAN: Yes. I'm going to
16 summarize this letter. This letter was sent by
17 King & Spalding, Ed Basile and Ashley Whitesides,
18 and it was addressed to Dr. David Feigal.

19 It says, "Urgent immediate attention
20 requested." To summarize this letter, basically Ed
21 Basile was concerned that this is a three-day panel
22 meeting and that 22.5 hours of the meeting are
23 going to be closed to the public to discuss trade
24 secret and/or confidential information, and Ed was
25 unclear why we needed to have that much of the

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1 meeting closed because there's only one hour for
2 open public session.

3 We are justified in closing the
4 meeting, and we only had to indicate that we would
5 be discussing trade secret and/or confidential
6 information.

7 The report will be presented to the FDA
8 Science Board on November 16, 2001. So that will
9 be the culmination of this subcommittee and the
10 report will be aired out in the public.

11 Okay. I think now we're going to clear
12 the room because this meeting, the rest of this
13 meeting will be closed to the public again. Only
14 previously designated individuals who have proper
15 identification will be permitted to stay for this
16 closed session of the meeting to discuss trade
17 secret and/or confidential information.

18 (Whereupon, at 1:17 p.m., the Open
19 Session was concluded and proceedings resumed in
20 Closed Session at 1:18 p.m.)

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