

1 and, you know--I agree with Richard. It's not menopause,
2 and maybe it's menopause. The whole point is, it's
3 hypogonadotropic hypogonadism; that category of high FSH
4 levels with ovarian failure is due to lots of
5 things--anything from removing the ovaries to chromosomal.

6 3. And so I don't think that that's a confusion; that
7 the confusion is, again--there is a true medical indication
8 when the individual comes in who doesn't have enough
9 estrogen, but whose ovaries are still there; who simply--her
10 brain hasn't kicked in; she had a brain tumor, a
11 craniopharyngioma, or some other--you know, they need
12 estrogen. And there is a real indication.

13 Now, the question is, under "symptoms"--vasomotor
14 symptoms, which is what Dr. Hammond is bringing up--I mean,
15 if you're symptomatic due to low estrogen, then the
16 vasomotor studies should be sufficient. If you're trying to
17 treat other things of hypogonadism--breast development,
18 these kind of things--then I think you're going to need to
19 have a separate indication and a separate thing in it.

20 And that--I'm just trying to distill the thoughts
21 of the committee. Please disagree with me.

22 DR. HAMMOND: But, again, you need a short-term
23 end-point--breast development takes months to years. So
24 that I think you're--I still say the vaginal-vulvar thing
25 may be a good end-point--for estrogen, for feminization, for

1 whatever.

2 CHAIRMAN AZZIZ: I'm not sure--why do you say we
3 need to have a short-term? There's no--I mean,
4 osteoporosis, which is an indication, is certainly not a
5 short-term end-point. I mean, if you're talking about
6 feminizing a hypogonadal individual, I mean a 24 month, or
7 12 month, or 18 month study is necessary. I mean--I just
8 wanted to clarify --there's no mandate here that says it has
9 to be a short-term study. Osteoporosis is not, for example.

10 DR. DATTEL: I guess I'm getting confused, because
11 I--these are--we're talking about clinical trials for drug
12 companies that come forward--not patient labeling right
13 now--right? We're talking about clinical trials.

14 And, I guess, how likely is it--I mean, most
15 people are coming forward to treat the most common problem.
16 They're not coming forward to develop a drug to treat
17 Turner's syndrome. So you're not--I mean--so even though
18 we're really all talking about hypoestrogenism, from--what
19 I'm looking at is really you're talking about menopause, or
20 symptoms of hypoestrogenism. And they're not going to
21 list--you know, come forward and develop a multi-million
22 dollar drug trial to treat Turner's syndrome.

23 I'm sorry--

24 DR. RARICK: Sorry--absolutely. The trials that
25 we see are for vasomotor symptoms, sometimes vulvar and

1 vaginal atrophy. What we're trying to point out is that the
2 previous class labeling then allowed, often, for a whole
3 list of indications to exist--except osteoporosis, they had
4 to do trials for that.

5 The question is: is that list appropriate to apply
6 to products who have done studies only in the menopause;
7 and, if not, is there a way that they could still have that
8 indication if they wanted it? What kind of trial would be
9 necessary.

10 It's a kind of a combination discussion of both
11 class labeling and clinical trials, because if this
12 committee says they shouldn't be given automatically, then
13 the class labeling will change subsequently to say:
14 vasomotor symptoms, you know, do studies to support; vulvar
15 and vaginal atrophy, do studies to support; hypoestrogenism,
16 you should just simply be listed. It doesn't say do studies
17 to support. You may be recommending that if somebody wanted
18 to do breast development in the Turner's patient or
19 somebody, you would want to see trials. Or maybe you're
20 saying, 'No, they should just be able to go ahead and use
21 the doses approved for the menopause.

22 CHAIRMAN AZZIZ: Just to remind us, that there are
23 trials--plenty of drugs that have been forward for Turner's;
24 I mean, growth hormone, stanazol--these have come to the
25 FDA. So there is a potential. It isn't--not the majority,

1 but if somebody wants to have--again, why do people want to
2 have specific indications? Well, they can market it
3 specifically. So I think that that's an issue--but--

4 Is the feeling of the Committee that we
5 should--that this is a separate indication? It should be
6 listed as an indication if they want to pursue, but it
7 shouldn't be an automatic indication.

8 Is that the sense of the committee?

9 [Pause.]

10 CHAIRMAN AZZIZ: Disagreement?

11 Okay.

12 Let's move on to number a: abnormal uterine
13 bleeding due to hormonal influence--hormone thing--I'm sorry
14 "imbalance"--whole hormone thing. Yes.

15 Comments, please.

16 DR. HARRIS: What is "hormone imbalance," and what
17 does that mean? Is that based on a dysynchronous
18 endometrium, or symptoms of dysfunctional uterine bleeding
19 in a peri-menopausal woman, where we would not describe it
20 as pathological, potentially malignant, or malignant
21 etiology post-menopausal bleeding--or is it something else?

22 CHAIRMAN AZZIZ: Well, I don't know. I mean, my
23 patients in Alabama all have hormonal imbalance that is
24 ruining their lives, so they can tell you very quickly about
25 that. But I think your point is very well taken.

1 The real problem we have with this is not really,
2 I think, the indication. I mean, this is chronic, normal
3 usage of pills and estrogens and so on and so forth. The
4 problem is, this is a 1952 definition. So I think we
5 perhaps need to decide whether we want an indication like
6 this and, if it is, how should it be worded.

7 DR. HAMMOND: Since you have, at least in your
8 draft document, deleted this as an indication, do you still
9 need to have it at all in the studies section? Am I not
10 correct? It's already deleted in your draft document for
11 indications.

12 DR. RARICK: We're proposing to delete it, and we
13 want your comment before that becomes sort of a final
14 deletion. If you don't want it deleted, I want your
15 comments about how you would study it. We are proposing
16 deleting it.

17 CHAIRMAN AZZIZ: I mean, I don't agree that it
18 should be deleted. I think that it should be a category.
19 I'll just simply give a suggestion, and hear what the
20 Committee has to say.

21 Estrogens are certainly an adjuvant to control
22 uterine bleeding due to--and I like "hormonal
23 imbalance"--but, I mean--but it is an adjuvant to control
24 uterine bleeding. And I think that's all that needs to be
25 stated. I don't think we need to go on to all the causes,

1 because that's really where we get caught is in that.

2 And so that's what I would propose as just a brief
3 indication--again, not being automatic.

4 What was the rest of the Committee's feeling,
5 please?

6 DR. DATTEL: I think the other caveats that you
7 had in the wording in the document; it's not due to
8 pathology--I think--isn't that--that's the other important
9 caveat to it, that--no underlying pathology as a cause of
10 the uterine bleeding. And I think as long as that's in
11 there, you can get rid of the hormonal stuff. But as long
12 as you--because it's implied, without saying it; but to make
13 sure it's not treating cancer.

14 CHAIRMAN AZZIZ: We have to be very careful,
15 though, because if we start getting very specific, should we
16 then somebody who has uterine fibroids and bleeding, can we
17 use it where you can treat it with birth control pills,
18 or--you know, these kind of things. It becomes a little bit
19 tricky. But I think "endometrial pathology" would work
20 better, rather than uterine pathology.

21 Further comments on this indication, please.

22 [Pause.]

23 CHAIRMAN AZZIZ: Very well.

24 Let's move on. This is number 3; we are now back
25 to 5: Are there any other comments or suggestions for the

1 FDA on the draft guidance document entitled, "Guidance for
2 Industry: Labeling Guidance for Non-Contraceptive Estrogen
3 Drug Products--Prescribing Information for Health Care
4 Providers, and Patient Labeling."

5 The floor's open.

6 DR. RARICK: Could I just hear that the
7 Committee--do they all agree that we need to add at least
8 something back about sort of the lifestyle and counseling
9 information on the osteoporosis section? Again, I want to
10 clarify for the audience and the Committee: the intention is
11 not to remove the indication. The prevention of
12 osteoporosis continues to exist in the physician labeling
13 and in the patient labeling for those drugs that have that
14 indication. But I want to make sure--I know, Ricardo, you
15 said that you'd like, not necessarily to see a
16 page-and-a-half about, you know, get enough, and eat right,
17 and reduce your stress, but at least some of the important
18 risk factors and counseling information you do want to see
19 back.

20 And that is a little bit of a departure from
21 normal labeling, I would point out to the Committee. We
22 don't normally remind people not to smoke, and wear their
23 seat belts, and all that kind of stuff in a label. I just
24 want to point that out.

25 CHAIRMAN AZZIZ: I don't think we're asking for

1 lifestyle changes. I think that there is other information
2 to state in there: you know, this will be more effective if
3 you use calcium; this is more or less effective--these are
4 medical indications--not so much that we want to have a
5 prescription for osteoporosis on the label. I think that
6 may be exaggerated, but there's lots of places where the
7 labeling indicates, you know, "X drug is really going to be
8 less effective--"--in such-and-such a situation; or, you
9 know, in addition to this, "You should see your
10 physician--"--or whatever it is.

11 So there is room in the traditional sense, simply
12 to say what osteoporosis is, and what other drugs are going
13 to affect the outcome of this disorder. And the other
14 reality is that that's what patients really are focusing on.

15 But, again, that was my comments. I didn't--we
16 didn't hear any dissention at that time, but any--Lisa wants
17 to make sure that the Committee is in agreement.

18 If you--I would like to hear any nays or yeas at
19 this moment, please.

20 DR. HAMMOND: The only think that I would say is
21 that I think that it's important to put in some very
22 objective information, but I don't think that it should be a
23 hard sell. I mean, it shouldn't be a marketing tool.

24 CHAIRMAN AZZIZ: Looks like everybody's in
25 agreement, as far as we can tell.

1 Any other comments on 5? I don't have much
2 myself--so does the Committee have anything on the Guidance
3 for Industry. I think that it is a marked improvement over
4 the last nine-arm studies that you had people do. I mean,
5 that was really a significant improvement over that.

6 I do have a comment on the wash-out for prior HRT.
7 You have one week for vaginal. I am really not sure that
8 that is--you have eight weeks for oral, four weeks for
9 transdermal, one week for vaginal. There is abundant
10 evidence that vaginal replacement is just as good or better
11 than transdermal, so I don't think you should do any
12 different time for vaginal than transdermal. I think it's
13 four weeks and four weeks. It would be my opinion.

14 Does the Committee agree, please?

15 [Pause.]

16 CHAIRMAN AZZIZ: Nobody has their phone on, but
17 everybody's nodding "yes." That's right. Okay.

18 DR. RARICK: Dr. Azziz, can I ask a quick
19 question? Back to the labeling--we heard from the National
20 Women's Health Network, two areas that I'd like your
21 comments on. One is the information that estrogen use may
22 increase the density of the breast, and thus women should
23 know that when their getting their mammograms done.

24 The second area is we did delete a whole section
25 that used to be called "When estrogens are not effective,"

1 and it included information about mood and skin.

2 CHAIRMAN AZZIZ: Comments from the Committee,
3 please?

4 This is, again, the proposal by Amy Allina on the
5 four points that she had brought up a moment ago in the
6 public speaker.

7 Comments from the Committee, please.

8 [Pause.]

9 CHAIRMAN AZZIZ: I have a few comments, of course.
10 [Laughter.]

11 CHAIRMAN AZZIZ: There are four points here, and
12 that is that, one, labeling should include a potential for
13 breast increase--breast cancer increase. I think the
14 potential is there. It is not well confirmed, but a think a
15 sentence to that effect is probably appropriate in today's
16 world; a sentence in regards to mammography--in that same
17 sentence, a sentence followed by the same sentence is not
18 inappropriate, either. I think it's an appropriate--I would
19 like to see that data better, so I would have the staff
20 review that objective data. If it isn't very objective and
21 a very well established fact, I wouldn't do that. I would
22 not mention it. But certainly the first point is okay.

23 I don't think that we need to list everything that
24 estrogen is not effective for, because even though I
25 understand the point, there is a bazillion other things. As

1 I said, in Alabama, we use it to treat pretty much
2 everything, from corns to bad sex life to, you know--these
3 kind of things.

4 [Laughter.]

5 CHAIRMAN AZZIZ: And so I don't think I'd do it,
6 though. But I don't want to have an increasing list that we
7 don't use it for.

8 And I can't read my last point here--oh,
9 fibroids--I'm sorry. I don't think--I think the data
10 regarding estrogen replacement in fibroid is, in fact, very
11 weak to almost non-existent from its strength. And I have
12 reviewed that data myself.

13 I don't think that we should put a statement in in
14 regards to fibroid; in fact, if anything, the new literature
15 is indicating that even low-dose birth control pills don't
16 really stimulate fibroid growth very much, and certainly not
17 hormonal replacement in the menopause. So I think that
18 that's--that would be my--again, my opinion.

19 Does the Committee have any other comments in this
20 regard, please?

21 DR. GREENE: My comment with respect to the breast
22 cancer warning is that there's a tendency to lose sight of
23 the forest for the trees. And although you may pay a price,
24 with a modest increase in breast increase, you're far more
25 likely to die of heart disease if you don't take your

1 estrogen.

2 So that I don't want the labeling to overemphasize
3 a potential modest increase in the risk--lifetime risk of
4 breast cancer. I think we have to maintain sight of the
5 fact that far more women die of heart--good old-fashioned
6 coronary artery disease and heart attacks than die of breast
7 cancer.

8 DR. FALK: I would also like to comment against
9 the inclusion of the mammography item--whereas it's
10 obviously true that when one takes estrogen, the--you get
11 proliferation of granular tissue in the breast and therefore
12 the mammogram shows a denser pattern, the only way
13 around--first of all, it's not been shown that that results
14 in a higher level of missing breast cancers, number one.
15 Number two, the only way around it would be to stop the
16 estrogen for a fairly protracted period of time. You can't
17 just stop it for a day and then get a mammogram. In fact, I
18 think it's a matter of 12 or 14 weeks before the breast
19 tissue decreases again, so that it would not be practical.

20 So the only purpose of including such a statement
21 would be grist for the lawyers' mill, which has already
22 occurred. There have been several lawsuits for people who
23 had mammograms while they were on hormone replacement
24 therapy, and I think that this would be a tragic situation,
25 and I'd be opposed to inclusion.

1 DR. HAMMOND: I have another question, but I'll
2 wait until the light gets back my way.

3 MS. SCOTT: Julia Scott.

4 I also think that the information about breast
5 cancer should be included; I think especially since there's
6 so much we don't know about that, and women are concerned
7 about that. That's not to say that anything should not be
8 put in about heart disease. But I don't think you should
9 omit information on breast cancer because there's another
10 disease that kills women.

11 And I think the issue about mammography really is
12 that many women have become over-reliant on mammography,
13 feeling that it is the answer--almost, you know, or a
14 prevention answer when actually it isn't. And so I think
15 that women need to be cautioned to be ever vigilant about
16 other ways in which to practice good breast health while
17 they're using estrogen.

18 CHAIRMAN AZZIZ: I--as I said before, I would like
19 to have the staff review the mammography data, because I am
20 not as familiar with it. And I think if there is objective
21 data, I think it might be useful for patients as well.

22 I mean, certainly we should always--this
23 statement--and it seems to me like it will be three
24 sentences long, or something of that nature--really should
25 say, "Please discuss with your physician your risk-benefit

1 ratio," or, you know, the relationship to risk, and so on
2 and so forth. Because I agree with Dr. Green, I don't want
3 this to be "You're going to get breast cancer from
4 estrogens. Thank you very much." I think it's a statement
5 that should be put in--you know, "You may have difficulty
6 with mammograms." "You need to obviously self-examine."
7 "Discuss this with your physician"--or something of that
8 nature. A small statement in that regard, I think, would be
9 useful, but certainly we don't want to have a whole boxed
10 warning, obviously, in this regard.

11 Any other comments regarding this point?

12 DR. HOUN: Yes, we can review the literature. I
13 mean, there are just a handful of case-controlled studies
14 that deal with this issue on mammography, density and missed
15 breast cancers.

16 I also would remind the Committee that the
17 technology for mammography is changing, and that newer
18 technology may be able to give better exposure levels, in
19 terms of being able to pick up lesions in dense breasts. So
20 that too will be a changing factor as we go along.

21 DR. DATTEL: Bonnie Dattel.

22 I think the key in that, in order so you don't
23 date your label, is to have a more broad--I'm into
24 generalizations today--but a more broad statement about--and
25 there is a--most reputable mammography centers have a place

1 on your intake form that asks if you are taking hormone
2 replacement therapy, or any other type of hormonal therapy.

3 And, again, it goes into the "talk to your
4 physician," "inform--"--that type of a statement will maybe
5 be more global and more useful, because the quality of
6 mammography still is different throughout the country, as
7 well.

8 CHAIRMAN AZZIZ: Any further comments on question
9 number 5?

10 Any further comments on the points brought up?

11 Okay.

12 DR. HAMMOND: The one that I just wanted to ask
13 again would be on the pregnancy--on the patient--page 16.

14 Dr. Falk had brought up the question--this is very
15 strongly worded, that you shouldn't take estrogens in
16 pregnancy. Are we going to see a revision of that at some
17 point after that's revised? Because this is extremely
18 strong.

19 DR. RARICK: Yes, I see that--and, of course, Dr.
20 Falk raised it in the prescribing information, also, and
21 asked us to think about--or consider other kinds of wording.

22 Again, this is labeling that was intended as
23 post-menopausal estrogen use, and we need to broaden our
24 thoughts in both the prescription information, and then that
25 would be reflected in the patient information.

1 Was the second part of your question whether
2 you'll see this guidance again?

3 DR. HAMMOND: Yes. Today we've made some general
4 recommendations. Will we see this again before it's
5 published?

6 DR. RARICK: I will be--we'll be asking the
7 Committee, at some sort of summary and closure point, how
8 much involvement you want to have with guidance documents.
9 We can send every guidance document to the Committee; we can
10 do it for comment, or we can do it for information--and
11 there's a different administrative process for each of those
12 steps, and we'll need to get your feedback about how much
13 you want to see.

14 CHAIRMAN AZZIZ: Yes, I just want to remind the
15 Committee that this is our opportunity, and the public's
16 opportunity to give feedback to the FDA. While we can
17 potentially see future drafts, the process gets very
18 complicated. So this is our time to do that.

19 Let's move on to number 6. Are there any other
20 comments or suggestions for the FDA on the general topic of
21 the clinical evaluation of estrogen and
22 estrogen/progestin-containing drugs used for HRT in
23 menopausal women?

24 Committee comments, please.

25 [Pause.]

1 I'll start out, in that regard.

2 There is--and I found it very confusing to read
3 this, because I think that there is three--there is actually
4 three different things thrown together here. And you need
5 to separate them out. You have SERMs, you have ethinyl
6 estradiol, and you have other estrogens used for HRT.

7 And, in fact, if you look at what you're reading,
8 all of your data with metabolism is with ethinyl estradiol,
9 which is actually not used for hormone replacement in the
10 menopause. Then you have breast cancer palliative, and you
11 have prostatic, and so on and so forth, and that's really
12 not estrogens, that's SERMS.

13 You--I think that that is an error and, in fact,
14 you need to break it down and say: contraceptive type of
15 estrogens, like ethinyl estradiol; SERMS--because this is
16 going to be a major section of our book very soon; and then
17 your hormonal replacement estrogens. And that is why we
18 keep going around and around and around with these
19 guidelines because, you know, it's an indication--palliative
20 treatment of breast cancer? We just went through this thing
21 in saying it increased your risk of breast cancer. It
22 doesn't make any sense at all. And that's because I presume
23 you're talking about Temoxifin, or something--what are you
24 talking about there?

25 DR. RARICK: That's really old labeling. If you

1 look at palliative treatment of breast and prostate, we're
2 talking mega, mega high doses from a 1972 review where that
3 got thrown in. And those studies were done in the
4 '50s--exactly; major league high dose. I'm talking mega
5 doses of estrogen for those treatments. And we didn't even
6 ask you to comment on those. If a sponsor specifically
7 wants to keep those in their labeling, they'll have to talk
8 with us.

9 CHAIRMAN AZZIZ: But you know what, they're still
10 there under "indications and usage" in the new revised
11 version, on page 6.

12 So--clearly, those, I'm not sure you should have
13 at all. I mean, it's under page 6 of the new revised
14 version; numbers 4 and 5.

15 [Pause.]

16 DR. RARICK: We can certainly amend that--fix
17 that.

18 Again, if somebody has the indication already,
19 because they're a drug from 1949, I doubt that they're going
20 to want to necessarily remove it. But we will talk with
21 each sponsor as we move along.

22 CHAIRMAN AZZIZ: But, again, my point is--and I'd
23 like to hear the Committee's opinion, here.

24 Right now we sort of have this thing lumped all
25 together. Should we break it down? Certainly ethinyl

1 estradiol and HRT separately, or is it okay the way it is
2 right now?

3 DR. RARICK: I just remembered that the document
4 you're talking about in number 6 is not the label. The
5 label is where you're talking about the metabolism, and
6 ethinyl estradiol--and I think that's number 5. So just as
7 long as you know you're jumping around.

8 And there--should I say it? There is one product
9 now, approved Friday, that is an ethinyl
10 estradiol-containing product for the post-menopausal woman.

11 DR. LERNER: I don't quite understand the whole
12 sort of mechanism, or sort of--what the sort of global,
13 global purpose then is. I mean, why can't we separate it?
14 Okay.

15 DR. RARICK: They can absolutely be separated, but
16 I just wanted to clarify that it's not as though there
17 aren't--that ethinyl estradiol never is used in the
18 post-menopausal woman. But we hear your concern.

19 DR. GREENE: In addition to the three areas that
20 you mentioned, I'll just toss in one other, which is that in
21 Europe right now very low-potency estrogens are very popular
22 for vaginal treatment, including estrone, for treatment of
23 vaginal symptoms. And it's been demonstrated that that has
24 significant implications for the endometrium when used even
25 at these low doses for very prolonged periods of time.

1 Now, in this country they're probably going to not
2 come under the FDA's purview as sort of herbal-type
3 remedies. Does the FDA have any concern about those things?

4 DR. HOUN: I think it depends on what the
5 manufacturers have for a claim. If they're going to claim
6 an indication that deals with treatment of disease,
7 diagnosis of disease, monitoring of disease, that would come
8 under a drug claim. Otherwise, if they're dealing with
9 structure or function, to promote general well-being, it's
10 looked upon as a dietary supplement claim, with less
11 regulation. So it depends on what the manufacturers are
12 going to position their product.

13 CHAIRMAN AZZIZ: But I think Dr. Greene's point is
14 that if you have an indication--and this comes back to
15 design, earlier. If you have a manufacturer that's going
16 for vulvar and vaginal atrophy--I think estrene perhaps is
17 one of those, and so on--they need to document and know
18 effect on the endometrium during therapy. So I think that
19 that's a trial issue that we should have mentioned earlier,
20 and I think that is important.

21 I mean, clearly, our perspective is that vaginal
22 products have significant systemic absorption. That needs
23 to be demonstrated--a lack of, or not--and certainly
24 endometrial protection, as well.

25 Any further comments to the FDA on this point?

1 Someday we might get to really discuss things like adrostine
2 dione and DHEA supplementation.

3 [Laughter.]

4 CHAIRMAN AZZIZ: But not today.

5 All right. Without further ado, just so we can
6 stay on schedule--I'm sorry, Lisa, is there anything
7 further? No? --so we can stay on schedule, we are going to
8 proceed now to Daniel Shames, who's Team Leader for the
9 Urology Subcommittee. And I don't know if Mr. Shames is
10 here or not.

11 DR. RARICK: Yes, Dr. Shames is going to talk with
12 us about another subcommittee of this group.

13 This morning you heard mentioned that there is a
14 subcommittee that Dr. Greene heads on pregnancy labeling and
15 reproductive and developmental tox issues.

16 I asked Dan Shames to speak with us today because
17 many of you are not familiar with our entire division, but
18 we review both reproductive and urologic drug products. You
19 haven't met the urologists before. I just wanted to have
20 him come--

21 [Laughter.]

22 DR. RARICK: --speak with you very briefly about
23 the types of work they're doing; the types of things they
24 might take to a committee like yourselves; and also to
25 remind you--all of you--that there are times when you may

1 asked of your interest for sitting on either one of these
2 subcommittees. So keep that in mind as Dr. Shames presents.

3 DR. SHAMES: Okay, we're going to have a real
4 switching of gears here for a moment.

5 I want to thank Lisa giving me the opportunity to
6 explain the role of the Urologic Team in Reproductive and
7 Urologic, and to explain a bit about the process of how your
8 group is going to interact with the Urology Subcommittee.

9 Urology has had some metamorphosis in the last
10 number of years, going from more surgical therapies to more
11 medical therapies, because of drug therapy and also certain
12 other devices, such as lithotripsy. Because of this, we've
13 had a large increase in the number of applications and
14 submissions of urologic drugs.

15 This probably all started, perhaps, when Dr.
16 Huggins discovered that an orchiectomy would result in
17 palliation of prostate cancer, and then later drugs were
18 developed to reduce and treat the hormonal milieu of
19 prostate cancer to improve palliation.

20 As you know, we now have drugs that treat BPH--or
21 prostatic hypertrophy, or the symptoms of prostatic
22 hypertrophy--which can delay or even reduce the amount of
23 surgery that's necessary. In the future I see drugs,
24 perhaps, for treating incontinence or even preventing
25 prostate cancer.

1 As you know, in CDER, drugs are assigned based on
2 clinical areas, and I'm going to discuss, just for a few
3 minutes, what the clinical areas that the urologic team
4 works with. The first area is BPH and LUTS--LUTS may be a
5 term you're not used to; it's "lower urinary tract
6 symptoms." We're now developing the ideas that the symptoms
7 in older men are not always from the enlargement of the
8 prostate; perhaps there are some other etiologies. We
9 currently have drugs for these areas: alpha blockers and
10 5-alpha reductase inhibitors, and there are many drugs
11 coming along. And we--as I will explain later, need
12 guidances on how to develop these drugs.

13 The next area is we deal with hormonal
14 manipulation of prostate cancer--not just with metastatic
15 cancer, but in using hormonal manipulation for adjuvant and
16 neo-adjuvant therapy, and perhaps even eventually for
17 prevention of prostate cancer.

18 Next area is intravesicle treatment of bladder
19 cancer. We also deal with the intravesicle treatment of
20 other types of urologic diseases, such as incontinence and
21 interstitial cystitis.

22 Another area, which some of you may have heard
23 about somewhere along the line, is the area of male sexual
24 dysfunction. We deal with drugs that work on erectile
25 dysfunction--which used to be called "impotence"--and also

1 we have drugs for premature ejaculation.

2 This is an area--male contraception--which has not
3 had a lot of attention, but we do have--there are ongoing
4 studies in this area.

5 Renal stones--we are responsible for drugs to
6 treat renal stones.

7 This area you may particularly find of
8 interest--testosterone replacement. We currently have an
9 internal working group in our division, working on
10 testosterone replacement. There is a lot of confusion in
11 this area--what is male menopause? Is there such a thing?
12 What is normal testosterone--etcetera. So these are some
13 issues you may hear about.

14 Next are voiding dysfunctions and incontinence.
15 We have a lot of activity in the area of incontinence,
16 especially what we call "overactive bladder." I'm sure
17 you've seen ads on television about this.

18 We also deal with a disease called interstitial
19 cystitis, and uresis.

20 Okay--next is a slide of our team. We have four
21 board certified urologists on the team, with a diversity of
22 background from private practice, academia, public health,
23 HMO, laboratory and clinical research experience. Also, we,
24 of course, rely extremely heavily on the other professionals
25 in the Division to hep us with our applications, which

1 include statisticians, project managers, toxicologists,
2 clinical pharmacologists, chemists and the support
3 staff--which are very important.

4 We have begun the process--and I'll explain why
5 we're doing it this way--but we've begun the process of
6 starting to get some people on the Urology
7 Subcommittee--which will be a subcommittee of your
8 committee. The first one that's gone totally through is
9 Peter Albertson, who is expert in prostate cancer, health
10 outcomes and epidemiology. There's Reginald Bruskevitz, who
11 deals with voiding dysfunction and BPH; Stephen Jacobs,
12 who's an expert in oncology and BPH. We've also chosen a
13 statistician, and we have others in the pipeline, getting
14 approval.

15 We also solicit your help, and anyone's help, who
16 wants to suggest any people who might be interested in the
17 areas that I outlined previously.

18 Okay, we can go on to the next.

19 The reason we are forming a subcommittee is that
20 the charter, or the advisory committee guidance says a
21 subcommittee is formed "when the charter of the main
22 committee does not incorporate the activities of the
23 subcommittee, or members of the subcommittee are not all
24 drawn from the main committee." What that means is we
25 need--for the Urology Subcommittee, we need to have some

1 more expertise in some of these urologic areas. However,
2 the Chairman is the chairman of this subcommittee--and I can
3 lend you my copy of Campbell's Urology for that if you want.

4 But there also will be another member of your
5 committee on that committee. So there are two of you. So
6 if any of you are particularly interested in some of the
7 areas that I outlined, you should express that interest.

8 We are way behind our Reproductive colleagues in
9 developing guidances, for various reasons. Actually, there
10 was no part of a real division until three or four years
11 ago; until this division, that had "urology" in the name.
12 So we are currently developing a guidance in a different
13 format, with industry and academics, for incontinence. We
14 hope to develop guidances for industry for BPH and LUTS and
15 for sexual dysfunction. We also are working on
16 guidances--or work with guidances for quality of life
17 indications, which are very important in the urologic area.

18 So we do believe that we are looking forward to
19 having interesting exchanges and advice in the urologic
20 areas, and look forward to working with your committee.

21 Thank you.

22 CHAIRMAN AZZIZ: Thank you very much.

23 Do we have questions for Dr. Shames?

24 I have one--just an administrative one. Most of
25 your members are not members of this committee, is that

1 correct? You said that there's only two--an overlap of two
2 members, the rest are separate--obviously for their
3 expertise.

4 DR. SHAMES: The regulations require that two
5 members of your committee be on the subcommittee. So we
6 have chosen, you know, people on the subcommittee who have
7 expertise in the areas that we deal with. But two members
8 of your committee are on that committee, and you are the
9 chairman of the subcommittee.

10 CHAIRMAN AZZIZ: Thank you.

11 [Laughter.]

12 CHAIRMAN AZZIZ: Any other questions, please?

13 [Pause.]

14 CHAIRMAN AZZIZ: Well, I find that very
15 informative [laughs.]

16 At this point, really, we have completed our fixed
17 agenda. I think Lisa has some final comments, and maybe any
18 additional requests for the Committee.

19 DR. RARICK: Thank you. Sorry I got distracted.
20 The school sent my son on the bus, but there's nobody at my
21 home. Sorry.

22 For closure--I had thought of summarizing the
23 questions and answers, but I think that's a little
24 onerous--for you all to try to sit through at this point in
25 the day. And I know that Jayne will be putting out summary

1 minutes very soon for all of us, to make sure that we've
2 caught it. And we'll do some drafts and make sure that you
3 agree with the conclusions of the meeting.

4 I did want to address in summary, though, how you
5 all would like to see either these guidances or future
6 guidances. There's many, many mechanisms--that we can alert
7 you to new guidances' or revised guidances' existence; and
8 there are mechanisms, depending on how much you want to be
9 involved.

10 Obviously, in the Good Guidance Practice System,
11 we publish guidances for public comment. You can be
12 considered among the public, and we can simply alert you to
13 the fact that a new guidance is available. If, on the other
14 hand, you feel that, for example, one of the guidances you
15 heard about today is something that you really want the
16 opportunity to review specifically as a Committee, we need
17 to know that. If you specifically want to review as a
18 Committee member, you do have to go through the conflict of
19 interest sorts of things that you go through for each
20 meeting--and this is a slightly different administrative
21 process for how you might want to comment.

22 I think it's very useful to have this discussion
23 today. I know, for my own part that I'll want to make sure
24 that our Exec Sec, who is Jayne, is always alerting you of
25 any guidances that we're putting out that are new or revised

1 from old, so that we can make sure that you are always aware
2 and that you have the opportunity to comment.

3 I did want to know, though, if you have any
4 particular mechanism that you'd like to see in a more
5 formalized fashion.

6 CHAIRMAN AZZIZ: I certainly would like to see the
7 drafts--I mean, personally. But I think the Committee may
8 be better off just being alerted to the fact that they're
9 available? We do have e-mail communication with most
10 everybody? Is that right?

11 DR. RARICK: Jayne, do you have an e-mail
12 distribution list for this gang?

13 MS. PETERSON: I believe I do.

14 DR. RARICK: And am I correct that we can alert
15 them to anything that the Division or the Agency, that has
16 impact on this Committee, might be putting out as guidance
17 without official clearance?

18 MS. PETERSON: I believe we can do that. I'd have
19 to check and get and back to you on receiving comments back
20 from the committee. But I believe we can do that.

21 CHAIRMAN AZZIZ: Could I hear from the Committee?
22 Is e-mail a viable way for all of us to be reached?

23 [Pause.]

24 CHAIRMAN AZZIZ: I have one comment--just a
25 question, again, that's sort of left unanswered--the issue

1 of SERMS versus estrogens. Could you comment on that,
2 because that's sort of--is a little bit puzzling, to say the
3 least.

4 DR. RARICK: To tell you the truth, all of the
5 selective estrogen receptor modulators that have been
6 reviewed, and approved to this point have not been in this
7 division. They are all for osteoporosis management, and
8 they are reviewed in another division. We haven't had a
9 great part in those reviews, although we are now being asked
10 about some endometrial effects, and we are getting more
11 involved.

12 CHAIRMAN AZZIZ: That explains a lot. Perhaps the
13 other divisions need to be encouraged to consult with the
14 Reproductive Drugs area, since these are reproductive drugs.

15 Thank you very much. That clarifies things.

16 Any further comments from the Division
17 please--from the Committee.

18 Without further ado, we're adjourned. Thank you
19 very much for your participation.

20 [Whereupon, at 3:53 p.m., the meeting was
21 adjourned.]

22

C E R T I F I C A T E

I, THOMAS C. BITSKO, the Official Court Reporter for Miller Reporting Company, Inc., hereby certify that I recorded the foregoing proceedings; that the proceedings have been reduced to typewriting by me, or under my direction and that the foregoing transcript is a correct and accurate record of the proceedings to the best of my knowledge, ability and belief.

A handwritten signature in black ink, appearing to read 'T.C. Bitsko', written over a horizontal line.

THOMAS C. BITSKO



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