

1 able to interact to have full disclosure of all the
2 information to look at all of the cases and evaluate the
3 full set of information and to come up with a sense of what
4 does this mean. It's very helpful to have that kind of
5 multi-disciplinary perspective and not a single
6 perspective.

7 So, I take your point. I think there are many
8 models and whatever model we come up with would need to
9 factor in the different groups.

10 Back to the issue of efficacy, I think there
11 can be a different kind of link between efficacy studies
12 and registries and that is in trying to recruit information
13 into a registry a couple of models. In the acyclovir
14 registry, there were a number of clinicians who were
15 interested in the question of whether acyclovir prevented
16 neonatal herpes. So, some efficacy studies were
17 established and those efficacy studies were also used to
18 feed information into the registry.

19 In the case of the antiretroviral registry,
20 some of the ACTG studies actually mentioned in their
21 protocols that should a woman become pregnant, then they
22 should be reported to the antiretroviral registry. So, I
23 think we need to not lose sight of the fact that other
24 studies might be used to recruit patients into registries.

25 DR. GREENE: Dr. Kweder, do you have any

1 additional specific questions for the committee?

2 DR. KWEDER: Oh, I could think of lots, but I
3 won't.

4 (Laughter.)

5 DR. KWEDER: One thing. I'd just like to get a
6 general flavor. I think we're not supposed to have a
7 formal vote where we count numbers, but I think as we've
8 been having some of these discussions about registries with
9 the CDC in particular, one of our hopes was to get a
10 general flavor for the group's support or lack thereof for
11 pursuing discussion of this and developing the idea
12 further. It might be helpful if we could get a general
13 sense of that. We've tossed around pros and cons, which is
14 exactly what we wanted people to do, but that doesn't
15 necessarily reflect what people's bottom line view is.

16 DR. GREENE: My parliamentarian here says that
17 not everyone here is approved to vote.

18 DR. KWEDER: Right. I know that.

19 DR. GREENE: So, we'll just ask the committee
20 that question specifically. Okay?

21 DR. KWEDER: Yes.

22 DR. GREENE: We'll sort of go around the table.
23 Thoughts about that?

24 DR. HAMMOND: As a reproductive
25 endocrinologist, we have our ART registry, the Assisted

1 Reproductive Technology registry, which is actually a
2 legislative mandate which is being performed by CDC. We
3 started using the private contractors. People initially
4 kept their own data which turned out to be not very
5 reliable. We went with contracts and then finally went
6 with the CDC, and that has really worked out very well for
7 us because it has eliminated a great deal of the politics
8 and other concerns within the organization. So, I very
9 much support the concept of a central registry.

10 DR. GREENE: Other specific comments or
11 thoughts?

12 DR. MONTELLA: I can just say I wholeheartedly
13 support, certainly support, pursuing it further and all
14 kinds of the ideas that may come out of it. And I hope I'm
15 speaking for the Society of Obstetric Medicine too, not
16 just for myself.

17 DR. GREENE: Well, let's make it a little more
18 formal then. Let's go around the table. Let's start at
19 the end of the table, please.

20 DR. KING: I would support working further on a
21 central registry. I don't think for all drugs, but I think
22 it could be a coordinated function with some participation
23 in a central registry and some being as a more clearing
24 house approach.

25 DR. GREENE: Dr. Sharrar, please.

1 DR. SHARRAR: I think I'm a nonvoter here.

2 DR. GREENE: No. Please express an opinion.

3 DR. SHARRAR: I definitely think it's worth
4 exploring further and discussing further. I don't have all
5 the answers this afternoon. I've heard a lot of
6 interesting points that I'd like to consider in more
7 detail, but surely we can discuss this in more detail later
8 on.

9 DR. HOLMES: As a teratologist, I would put on
10 the table the fact that to prospectively ascertain women in
11 a pregnancy registry is an incredibly important approach to
12 the safety of exposures, and we really need to explore it
13 and figure out how it would work.

14 DR. JONES: I certainly agree.

15 DR. GREENE: You've already expressed your
16 opinion, Dr. Cragan.

17 DR. CRAGAN: I think the question for us down
18 the line becomes at what point is this a commitment that
19 we're going to make this work, and that's the next question
20 for us. But I absolutely would want to pursue the ideas.

21 DR. RHODES: I think we've heard some very
22 different models of how a centralized registry might work,
23 and somebody might think that version A is great and
24 version B is bad and vice versa. Of all the versions I've
25 heard, I think they all would be improvements on what

1 currently exists.

2 MS. SCOTT: I also support pursuing the idea of
3 a centralized pregnancy registry, but I also would like to
4 strongly recommend that the people putting together the
5 conference and further meetings really include the
6 involvement of women and not just getting information from
7 physicians and that there is a mechanism developed that
8 would communicate information to women in a way in which
9 they can understand it because women deal with difficult
10 and complicated issues every day. They can understand this
11 information if it's presented in the right way. So, that
12 would be my strong recommendation.

13 DR. WISNER: I also strongly support the idea
14 of further discussions about a centralized registry, and
15 even if it doesn't come to fruition, I think one of the
16 major benefits of these kinds of discussions are to
17 identify critical points and technical issues. So, again,
18 even if the registry doesn't come to fruition, the
19 knowledge base that comes of a meeting like this and the
20 registries that will function will be enriched, as will the
21 field.

22 DR. WIER: Well, it seemed yesterday there was
23 a great deal of consensus that one size will not fit all.
24 So, if a centralized registry represents another size, how
25 can we not explore it? I guess my plea would be that it

1 not be explored in isolation and that it would be
2 important, in evaluating the advantages and disadvantages
3 of a centralized registry, to do so simultaneously with the
4 advantages and disadvantages of an individual registry
5 using similar objective criteria. I think that would take
6 us eventually further in understanding what are the cases
7 where it's better to use a centralized approach, what are
8 the cases and circumstances where it may be more
9 advantageous to use an isolated approach.

10 DR. MITCHELL: I think I've given my views. I
11 absolutely support it.

12 DR. MONTELLA: I agree.

13 DR. MATTISON: I think it's important to look
14 at this issue in greater detail of being able to enhance
15 the information that is available. But I also think that
16 we need to think very, very critically about the way that
17 that information is then communicated back to the diverse
18 populations that exist in the United States. I think that
19 the issue of communication and inclusion in some
20 participatory way in the diverse group of communities that
21 would be served by such a registry needs to be attended to.

22 MS. CONOVER: Yes, I would second that. I
23 think that information going back is just as important as
24 the information that we're gathering.

25 But that said, my patients and I would be

1 | thrilled to have one more source of information. It's not
2 | adequate or complete, but it's a lot better than what we
3 | have.

4 | DR. MILLS: It's pretty clear that there are
5 | many questions relating to drug safety in pregnancy that
6 | aren't currently being answered, and therefore I think it's
7 | important to continue to explore the feasibility of a
8 | central registry. I would suggest that a key next step
9 | would be for the FDA and industry people to talk and see
10 | just how it can address some of the issues that we've
11 | identified today.

12 | DR. GREENE: Jan?

13 | DR. FRIEDMAN: I agree it should be pursued and
14 | considered in detail and by a broad range of concerned
15 | individuals.

16 | DR. WEISS: Well, I'm going to be on the fence
17 | with this one. My concern is the money and resources that
18 | would go in to searching for the needle in the haystack on
19 | a surveillance type system as opposed to answering the
20 | questions about treatment and safety that the women and
21 | their physicians are bringing up every day and not getting
22 | to be able to answer those.

23 | DR. GREENE: Dr. Andrews?

24 | DR. ANDREWS: I certainly support continuing
25 | discussion because I think, as was earlier said, merely

1 | having the discussion will advance the science and will
2 | enhance the future studies, whether they're done in a
3 | centralized way or not. But I would say that when we have
4 | the further discussions about registry approaches, we
5 | really must consider them in the context of alternative
6 | methods as well and not lose sight of case-control studies,
7 | case-control surveillance and the possibilities of large
8 | automated databases enhancing enrollment and finding out
9 | information. So, I'd encourage us not to look for
10 | registries to do particular jobs where they may not be the
11 | best alternative.

12 | DR. GREENE: Jim?

13 | DR. LEMONS: Yes, I would agree. I thought
14 | Jan's comments this morning in soliciting a consensus that
15 | things aren't good enough and we want to make them better,
16 | as long as we look at this very creatively and openly, like
17 | Allen said. I see it as maybe a central repository, but to
18 | bring to bear all of the existing and evolving databases
19 | and infrastructures to enable industry to properly test the
20 | products is good.

21 | I also thought Julia's comments were good,
22 | although I noted that happily 15 out of I think 27 of the
23 | panel are women today, which is good.

24 | MS. SCOTT: It's a start.

25 | DR. LEMONS: Yes, it's a start.

1 (Laughter.)

2 MS. CHAMBERS: So, how many are men then?

3 (Laughter.)

4 DR. LEMONS: That's not important.

5 MS. CHAMBERS: I think the concept is a
6 valuable one and that it really deserves a group pursuing
7 it and especially addressing the issues of the quality of
8 the data that would be produced and how valuable it could
9 be to pregnant women and health care providers who are
10 desperate for information that's usable for them.

11 DR. GREENE: Sandra, do you have anything
12 further for the committee?

13 DR. KWEDER: I would just like to thank the
14 committee. I think this discussion for us at the FDA has
15 been very useful. All the discussion on both days has
16 actually been quite fruitful for us in thinking about how
17 to revise our guidance document on registries in general.
18 I think I probably speak for the folks at CDC in saying
19 that hearing the discussions and the concerns about ideas
20 for additional models for surveillance studies or
21 registries is very useful as well.

22 Some of the things that we in the agency need
23 to take home and do more work with is the issue of, for
24 those programs that do exist, how to deal with facilitating
25 and making it easier reporting of adverse events under the

1 regulations that currently exist. That does remain a
2 challenge. What others need to recognize is that we do
3 that in an environment of increasing attention to adverse
4 events -- think of gene therapy, troglitazone, cisapride --
5 in the general public currently. So, we have a long road
6 ahead of us.

7 I think one of the things that really didn't
8 come up in the discussion of registries that we will need
9 to tend to -- I think none of us really want to go there,
10 but we will have to -- is this issue of is it a study or is
11 it a surveillance? Is it surveillance? And because we've
12 heard some discussion of, well, it's surveillance and
13 because it's surveillance, we don't get informed consent.
14 Well, it's a study and because it's a study, that's how we
15 want to report our adverse events, like it's a study, but
16 we don't want to get informed consent. So, we have to
17 decide on which side of the fence is it and when. What are
18 the dividing points? And that's going to need a lot more
19 discussion.

20 But nonetheless, I don't think those are
21 insurmountable obstacles. I think I speak for the group
22 who has been thinking about this a lot at FDA. We are
23 undeterred and we will continue to seek your counsel and
24 collaboration in trying to move forward.

25 So, thank you very, very much.

1 DR. GREENE: I would like to thank all the
2 committee members for making my job easy. Thank you.

3 (Whereupon, at 2:55 p.m., the subcommittee was
4 adjourned.)

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