

1 on people when you feel as if you have gone as far as you
2 can go with that system to try to identify a problem.

3 DR. MITCHELL: The answer to the first question
4 is how long should they go, and I don't mean this
5 facetiously. A little longer is the answer. No matter
6 where you are, there's going to be a voice that says let's
7 go a little longer. So, I think your question cuts to the
8 quick. You've got to set some criteria.

9 I would not suggest folding the tents on a
10 registry at 100, and I hope no one interpreted these
11 comments to suggest that.

12 I can't give an answer. So much depends on
13 what your priors are, what the hypotheses are, what the
14 outcomes of interest are. If someone is going into a
15 pregnancy registry concerned about fetal varicella, that's
16 a very specific outcome. If one is looking to assure the
17 prescribing and public community about a drug's safety,
18 however we want to avoid that word, then it's a very
19 different message and a very different process. So, I'm
20 being deliberately unresponsive because I don't know the
21 answer.

22 DR. GREENE: But when you say how long you're
23 going to go, you mean long in numbers or long temporally?
24 Because obviously, that's going to depend upon the
25 frequency of the exposure.

1 DR. MITCHELL: Right. One of the comments that
2 I was going to make earlier was that in some of these
3 scenarios we're painting ourselves a picture where we'll
4 follow the drug until it's no longer used. At that point,
5 the information becomes of historical interest but not of
6 clinical interest. Drugs tend to have life cycles.
7 Although as Karen points out, you get alpha methyl dopa
8 that may arise from the grave, but by and large, that's
9 what I think has to be put into the equation. If I were
10 responsible for deciding about a registry where a drug at
11 the outset of the registry was being used by 3 percent of
12 women and now it was being used by virtually none and we're
13 dealing with finite resources, I'd say, well, as a public
14 health and clinical matter, I think we need to shift those
15 resources into an up and coming drug.

16 DR. GREENE: Thank you.

17 The final speaker for the afternoon will be Dr.
18 Rogers, who will talk about informed consent, please.

19 DR. ROGERS: Good afternoon. Is there anyone
20 in the room who doesn't envy me being the last speaker
21 talking about the Code of Federal Regulations?

22 (Laughter.)

23 DR. ROGERS: I've entitled this Individual
24 Privacy and the Public Health. What is the good balance?
25 I chose this title and posed the question about balance

1 specifically because I think the interaction between
2 individual privacy rights and the public health needs to be
3 carefully evaluated to strike that balance that best serves
4 society while at the same time protecting the interests of
5 the individual.

6 We've viewed the area of drug safety as a
7 surveillance issue in this country as the public expects an
8 alliance among prescribers, sponsors, and government
9 officials to protect them from unsafe pharmaceuticals. But
10 the definition of research in the Code of Federal
11 Regulations would encompass the activities that are
12 involved in our efforts to identify unsafe drugs, and this
13 pushes the assessment in a totally different direction.

14 Today I will review the basis of the code and
15 its provisions and explore the course of the deliberations
16 of the advisory committee to the Antiretrovirals in
17 Pregnancy Registry.

18 First of all, though, because HIV is my case
19 study here, I'd like to make a few points about HIV.

20 HIV infection in women occurs predominantly in
21 racial and ethnic minority populations who reside in urban
22 areas in the rural south, who are not usually aware of
23 their HIV status, who have many unmet socioeconomic needs,
24 and are cared for in resource-poor, understaffed hospitals
25 or public clinics. So, to place this discussion in

1 | clinical context, I will eventually come to the very
2 | specific experiences of having served as government staff
3 | to the Antiretrovirals in Pregnancy Registry, or the APR,
4 | from 1993 through 1999.

5 | Not only are these particular characteristics
6 | important, but the other thing that one has to note about
7 | this, choosing HIV infection in pregnant women as a case
8 | study, is that their pregnancy represents a situation in
9 | which the Public Health Service is actively encouraging and
10 | promoting drug exposure during pregnancy. So, the
11 | importance of obtaining safety information is really quite
12 | important.

13 | The features of the APR were that it was
14 | initiated in 1989 to examine the effects of inadvertent
15 | exposure, and while it was originally intended to capture
16 | inadvertent exposures, the exposure status became
17 | intentional after the results of PACTG 076, which was the
18 | successful trial to interrupt perinatal HIV transmission,
19 | and finally to the latest PHS guidelines in which pregnant
20 | women are to be treated first for their own conditions.

21 | It was modeled on the acyclovir registry that
22 | Dr. Andrews spoke about this morning. It was prospective
23 | in nature; that is, it collected both numerator and
24 | denominator data. The collection of the denominator data
25 | is the key component since it means the data were collected

1 on births to women who had not experienced a reportable
2 adverse drug event.

3 In the registry, the staff interacted only with
4 obstetrician reporters, and this design feature prevented
5 the need or omitted the need for disclosure of identifying
6 information as the child's care moved to the pediatrician.

7 No informed consent from women was obtained
8 because there was no need for identifying information, and
9 indeed no IRB review occurred. This was reviewed
10 frequently by the advisory committee who continued to
11 believe, up until relatively recently, that this was a
12 surveillance activity which was conceived of as an
13 extension of the spontaneous reporting system of the FDA.

14 The limitations of the APR. Interacting only
15 with the obstetrician meant that we only received reports
16 of structural defects that were apparent during the
17 immediate postpartum care of the mother. It relied on
18 voluntary reporting of very busy and stressed clinicians.
19 And it could not be promoted by the sponsors, and
20 consequently, very small numbers were enrolled.

21 At the same time, we had really compelling
22 needs for data. The results of PACTG 076 and its
23 implications for care required a balancing of information
24 that clinicians would give to pregnant women when they were
25 counseling them about making the decision to take

1 antiretroviral therapy. Our recent PHS guidelines for the
2 treatment of pregnant women really encourage, and, in fact,
3 we in the federal government have supported initiatives to
4 promote the implementation of 076.

5 There also is the inadequacy of the safety data
6 on fetal exposure to antiretroviral therapy during
7 pregnancy, and we also have had recent scares. Some
8 information a few years back emerged on very low birth
9 weight infants who had been exposed in utero to
10 antiretrovirals and then the mitochondrial disease that was
11 reported by the French last year.

12 So, really where we find ourselves is we're
13 looking at whether we're doing public health surveillance
14 or whether we're doing research.

15 The counsel of the APR's advisory committee,
16 prior to 1998 when it really became crystallized to the
17 advisory committee, was that the APR activity constituted
18 surveillance not research, and it was uniformly viewed by
19 the committee that the APR was an extension of the
20 spontaneous reporting system for adverse drug events.

21 The advisory committee strongly discouraged
22 staff from accepting any patient names unless no other way
23 to receive the report was apparent. This was consistent
24 with sponsor practice around receiving other adverse drug
25 event reports.

1 The feedback from clinicians was very
2 important. Many staff members were interacting with
3 reporting physicians in those understaffed hospital, inner
4 city and rural clinic/hospital structures where the
5 infrastructure was clearly inadequate, and the response
6 back to the committee through staff people was that if
7 there were a requirement for any other additional burden,
8 other than providing the information, the information would
9 not be forthcoming. They had difficulty in accessing
10 charts. They had difficulty in making sure that patients
11 were seen in a timely fashion, and they usually were quite
12 understaffed.

13 This issue and these deliberations were
14 revisited every time the APR advisory committee met.

15 But in the end the assessment came down to what
16 kind of activity was the APR. In behalf of adverse drug
17 reaction reporting, it did collect ADE data. It interacted
18 with the clinician/prescriber as the spontaneous reporting
19 system does, and it was fulfilling regulatory requirements
20 in collecting information on adverse drug events.

21 What made it different from regular adverse
22 drug event reporting, however, was that by including a
23 denominator, it collected information on women who did not
24 have adverse drug events but simply had exposure, and it
25 provided regular summary reports to clinicians.

1 So, at this time, given that background and
2 that context, of that case study and where we found
3 ourselves, I'd like to now really bore you to death with
4 the Code of Federal Regulations.

5 The definition of research. "Research means a
6 systematic investigation, including research development,
7 testing and evaluation, designed to develop or contribute
8 to generalizable knowledge. Activities which meet this
9 definition constitute research for the purposes of this
10 policy, whether or not they are conducted or supported
11 under a program which is considered research for other
12 purposes."

13 This is extraordinarily broad, and this
14 definition must be applied to all federally funded efforts.

15 Furthermore, if an institution is receiving
16 federal funds for any research efforts and has a multiple
17 project assurance, these regulations are uniformly applied
18 to all of its research activity.

19 I'd like to just tell you what the basis of the
20 code is. It is linked to the Nuremburg Code and to the
21 Declaration of Helsinki. Both the Nuremburg Code and the
22 Declaration of Helsinki are alike in their instance that
23 subject autonomy be respected and in their elevation of
24 concern for the rights of the individual above scientific
25 and societal goals.

1 Specifically, principle 5 from Helsinki says
2 that every biomedical research project involving human
3 subjects should be preceded by careful assessment of the
4 predictable risks in comparison with foreseeable benefits
5 to the subject or others. Concern for the interest of the
6 subject must always prevail over the interest of science
7 and society.

8 Principle 6 says, the right of the research
9 subject to safeguard his or her integrity must always be
10 respected. Every precaution should be taken to respect the
11 privacy of the subject and to minimize the impact of the
12 study on the subject's physical and mental integrity and on
13 the personality of the subject.

14 What you see is a very strong theme in the
15 declarations that I've just pulled out, the principles I've
16 just pulled out. That theme is that individual rights
17 prevail over societal goals.

18 This is very different from regulations that
19 come out of state law that really address communicable
20 disease surveillance and investigations. They would
21 emphasize society's benefits over individual rights in
22 order to prevent transmission. In fact, to some extent in
23 terms of adverse drug event reporting, we have expected
24 that the information from individuals would be gathered to
25 serve broader societal goals.

1 In the Code of Federal Regulations, there are
2 categories of research. One is exempted research. In
3 exempted research, what we have is, in order to qualify as
4 exempted research, there is only involvement of human
5 subjects in research that involves a collection or study of
6 existing data, documents, records, pathologic specimens, or
7 diagnostic specimens, if these sources are publicly
8 available or if the information is recorded by the
9 investigator in such a manner that subjects cannot be
10 identified directly or through identifiers linked to the
11 subjects.

12 This does not happen in any of the registries
13 that we have because there are specific coded subject
14 identifiers that -- with some effort in most situations,
15 but there can be a link back to the subject from which the
16 information is being collected. So, I don't think that in
17 terms of any of the registry formats that we've discussed
18 this morning and for the APR that it can be considered
19 exempted research.

20 Another category of research is expedited
21 research, and this category refers to research activities
22 which involve no more than minimal risk and in which the
23 only involvement of human subjects will be in one or more
24 of the following categories. There are a number of them,
25 but number 8 is relevant to our discussion. Number 8 says

1 the study of existing data, documents, records, pathologic
2 specimens, or diagnostic specimens.

3 What is very important here is that the term
4 "minimal risk" is suddenly in the mix, and let me tell you
5 what the definition of minimal risk is in the code. That
6 is those activities which an average person encounters
7 during an average health care visit or in the course of
8 average daily activities of life.

9 It is not a sliding scale so that you can say,
10 oh, these are inner city women with HIV infection who live
11 in communities where there is a great deal of violence and
12 drive-by shootings, and therefore the risk that's allowed
13 for these women is considerably more than the risk allowed
14 for a housewife in Utah. That's not what minimal risk is.
15 It is not a sliding scale. It is the average.

16 So, for it to be expedited research, it does
17 have to meet that bar of minimal risk, and it does have to
18 be preexisting information, information that's collected
19 not specific for the purpose of the study but being
20 evaluated like a secondary analysis.

21 Much of the registry activity could be
22 conceived of as expedited research for many of the drugs
23 that we've discussed today. However, it's very unlikely
24 that any institutional review board would view our APR as
25 expedited research because it's dealing with HIV infection

1 and HIV infection, because of the increased sensitivity
2 around inadvertent disclosure, represents a special case.

3 I want to talk about the issue of informed
4 consent and to tell you in the code what items have to be
5 addressed in an informed consent and what items an
6 institutional review board would be looking at in order to
7 make sure that an informed consent is adequate.

8 These are the required elements. The purposes,
9 the duration, and the procedures of the study have to be
10 disclosed. Any foreseeable risks or discomforts,
11 reasonably expected benefits to the subject or to others,
12 the disclosure of any alternative procedures that would be
13 available to the subject that he or she could access
14 without being in the study, the confidentiality measures
15 that the investigators have put into place to protect the
16 subjects, compensation, if any, for injury that might occur
17 as being part of the study, contact people for the study in
18 case there are questions or concerns, and the fact that
19 participation is voluntary.

20 The IRB may also require some additional
21 elements. These would be risks to the fetus, circumstances
22 under which participation may be terminated, additional
23 cost to the subject that that subject would incur by
24 participating in the study, the consequences of the
25 decision to withdraw from the study, which should be none,

1 new findings that may emerge from the study would be
2 provided to the subjects, and the approximate number of
3 study subjects.

4 Therefore, we're looking at a rather large
5 number of items that are either required or could possibly
6 be added at the discretion of an institutional review
7 board. The consent process, when it is informed, may be a
8 prolonged process.

9 What we have for a registry like the APR -- and
10 other registries may have the same concerns -- is the fact
11 of the feedback we've gotten from the clinicians who are in
12 the inner cities and in the rural clinics that are
13 understaffed, that this additional process, superimposed on
14 the consent that they are required to give by state law for
15 HIV testing and for the regular care, the issues that are
16 involved in the regular care of pregnant women --
17 superimposed on that and in addition to that, many of the
18 clinicians also do get involved in some of the perinatal
19 transmission trials, that this is such an additional
20 burden, that reporting wouldn't happen.

21 In that instance and because of that
22 consideration, one of the things that can be done is a
23 request for a waiver of informed consent. This is allowed
24 under Code of Federal Regulations, 46.116(d). These
25 particular requirements have to be met. The research can

1 be no more than minimal risk, which I defined before. The
2 waiver will not adversely affect the rights and welfare of
3 subjects. The research could not be practically carried
4 out without the waiver, and whenever appropriate, the
5 subjects will be provided with additional pertinent
6 information after participation.

7 So, given all of this information that I've
8 shared with you, the advisory committee to the APR, seeing
9 that there was a growing focus on institutional review of
10 projects, the fact that this project fell under the Code of
11 Federal Regulations definition of research, and the
12 involvement of federal officials on the advisory committee,
13 the advisory committee in 1998 recommended that the
14 registry protocol be submitted for IRB review.

15 We also recommended that all data be collected
16 anonymously and coded, that the reporting forms be revised
17 because of the way that they had collected information, and
18 we recommended that they seek a waiver of informed consent.

19 Seeking a waiver of informed consent really
20 depends on the study design, which of course follows the
21 study question. For the APR, who is simply looking at
22 structural defects with the potential for detection only
23 during the perinatal period, the waiver seems to be an
24 appropriate mechanism.

25 Finally, the last slide. The experience of the

1 | APR I wanted to share with you in their efforts to seek
2 | this IRB review. They've approached several major
3 | universities, all of whom refused, citing that they had
4 | their own institutional overload with their own protocols,
5 | and they questioned their authority and their jurisdiction
6 | to be doing a review for a registry supported by sponsors.

7 | Private IRBs -- and there are a few across the
8 | country -- required an unreasonable fee to review.

9 | I had an off-the-record discussion with OPRR
10 | about exploring whether the APR could establish an IRB of
11 | their own. What we were trying to see was if OPRR would
12 | issue a single project assurance and allow them to
13 | establish their own IRB that would review. OPRR said that
14 | because there was no federal funding involved, they really
15 | had no jurisdiction to do that, and besides, they were very
16 | busy too.

17 | So, finally, what the APR is doing is the
18 | second option up here. They're collecting that
19 | unreasonable fee from all of the cooperating sponsors and
20 | moving forward.

21 | I think in summary I wanted to make five
22 | points, and I'll make them quickly.

23 | Efforts that collect denominator or exposure
24 | information essentially move outside the standard and
25 | traditional adverse drug event reporting. I think that's a

1 very clear conclusion to make.

2 The second point is that to maintain public
3 trust and confidence, information on women and pregnancy
4 outcomes must be carefully protected.

5 The third point is that this protection is best
6 ensured by external and objective review of procedures that
7 are in place.

8 The fourth one is using the Code of Federal
9 Regulations and the IRB structure that's in place seems to
10 be the best vehicle for accomplishing the protection. It
11 is established, accepted, and known.

12 And five, requesting the waiver of informed
13 consent is an option. It is very study-specific and really
14 requires a compelling justification to occur.

15 Thank you.

16 (Applause.)

17 DR. GREENE: Thank you.

18 This presentation is open for discussion or
19 questions, please.

20 I have one question with respect to
21 guaranteeing the confidentiality of data. It seems as
22 though as time goes on, we realize that less and less is
23 really confidential and really protected. The specific
24 example I guess that I would cite is one recent experience
25 of Dr. Sharin Gabriel in Minnesota. She collected data

1 | which suggested very strongly that there was not, in fact,
2 | a relationship between silicone breast implants and
3 | rheumatologic disorders. In the course of the lawsuit that
4 | the plaintiffs brought against the companies, her data
5 | which suggested there was no relationship was subpoenaed.
6 | She found herself in a position of either refusing to
7 | comply with the subpoena and possibly facing criminal pains
8 | or trying to fight the subpoena for which she had no money
9 | or agreeing to hand over the data and violating the pledge
10 | that she had made of confidentiality to her subjects or
11 | abandoning her research and agreeing never to publish the
12 | data. It was a conundrum that she faced and she elected
13 | just to agree to never publish the data and to basically
14 | bury the results.

15 | What reassurances are there that should there
16 | be determined and clever attorneys, that this data will
17 | remain confidential?

18 | DR. ROGERS: And you want me to answer that.
19 | They subpoenaed names?

20 | DR. GREENE: They subpoenaed her entire
21 | database.

22 | DR. ROGERS: I think one critical piece there
23 | that seems to be missing for me is, did she put specific
24 | identifying information in her database or did she keep
25 | that separate? I think IRBs are very careful to have

1 separate records for clinical shadow records, and there
2 should only be a subject IDs in a database. I think one
3 should be making a distinction in practice and one could
4 make a distinction legally in what one surrenders.

5 DR. GREENE: Well, I think most researchers
6 will tell you that if you're collecting enough demographic
7 information about patients, you only need a half a dozen
8 fields that are sufficiently unique that you can pretty
9 figure out who the individuals are whether they're
10 specifically identified or not.

11 DR. ROGERS: Again, if I were in that position
12 and I were concerned, I would have not only my identifying
13 codes locked over here, but I also would have two subset
14 databases that I could merge on an ID, one with those
15 identifying information -- I mean, there are levels of
16 individual protection I think that one could undertake to
17 prevent one's self from being in that situation.

18 It's wonderful to do that on Monday morning,
19 but I think if we could all learn a lesson from the
20 terribly unfortunate experience that she's had, it would be
21 to put those kinds of layers of personal and subject
22 protections in order to do that, to be able to give that
23 kind of guarantee of confidentiality.

24 DR. GREENE: Allen.

25 DR. MITCHELL: I'm not sure that I agree that

1 | the layers -- they offer some protection, but there's no
2 | reason the attorneys can't go after every aspect of it.

3 | I would offer two responses to that situation,
4 | Mike. First of all, I gather she was not part of an
5 | institution. But we've had that situation where we've had
6 | data subpoenaed and we fought the subpoena. I think it's
7 | very common for academics to roll over when they receive a
8 | subpoena. Whether she did or not, I would urge people who
9 | are confronted with subpoenas not to roll over and to seek
10 | institutional support.

11 | The other is a federal certificate of
12 | confidentiality, which seems to me very relevant. It's
13 | something we've gotten in our studies where we have
14 | sensitive information. CDC has done that as well in its
15 | study and it provides substantial protection.

16 | DR. ROGERS: Well, actually I'd have to correct
17 | that.

18 | DR. MITCHELL: Am I wrong?

19 | DR. ROGERS: We all think it does. It has
20 | never been tested.

21 | DR. MITCHELL: I'm sorry. Yes, I'll qualify
22 | that.

23 | DR. ROGERS: It makes us sleep easier.

24 | DR. MITCHELL: But at least conceptually it
25 | offers a layer of protection that would at least make some

1 attorneys think twice about going after the data and does
2 put the federal government on the line. I think that some
3 courts might view that as a higher authority than simply
4 what we would consider a contract between us and the
5 patient, which we would consider inviolate and a higher
6 authority than any subpoena, but the courts may not agree.

7 DR. ROGERS: Right. I think too the
8 institution would have to have some relationship with the
9 federal government in order to obtain one for data.

10 DR. MITCHELL: No.

11 DR. ROGERS: Well, in our experience it has
12 been study-specific.

13 DR. MITCHELL: Yes. Oh, it's study-specific,
14 for sure. But it only requires a demonstration that
15 there's some sensitivity to these data.

16 DR. ROGERS: And federal funds not involved?

17 DR. MITCHELL: That's correct. I'd have to
18 look but I think that's correct. I'm not sure, Audrey.

19 DR. ROGERS: I'm not sure either.

20 DR. GREENE: Yes. In this particular case, she
21 was part of an institution. She went to the institution
22 and they said we don't have the money to fight this. It
23 could be many hundreds of thousands of dollars and there's
24 no guarantee of success.

25 DR. MITCHELL: That's why they get overhead

1 rates.

2 (Laughter.)

3 DR. GREENE: Dr. Kweder, you had a question,
4 comment?

5 DR. KWEDER: Yes. Audrey has made the comment
6 that when you begin to collect denominator data, you move
7 quickly out of the realm of traditional post-marketing
8 surveillance. I think we have to think carefully about
9 making that sort of a general statement. I think in many
10 respects the kinds of registries we're talking about really
11 are hybrids.

12 One reason to think carefully about that is
13 that historically we have considered data that comes to us
14 from standard post-marketing surveillance, protected
15 information, and where courts have sought to seek
16 identifying information about those individual cases, the
17 FDA has been very rigorous in defending and protecting that
18 information so that the courts couldn't take on and use or
19 lawyers couldn't take on and use that information in
20 malpractice cases or in other types of injury cases.

21 When MedWatch was developed, one of the things
22 that FDA did to try and encourage more reporting was
23 develop a regulation that specifically extended the same
24 kinds of protections to cases that we received from the
25 industry. That was a very important step because

1 | previously those protections only covered practitioners who
2 | reported to the agency directly, but we developed a
3 | regulation to extend that. And it is something that we may
4 | need to think about how that applies to registries as well.

5 | DR. ROGERS: Yes. The distinction I was making
6 | was not the classic case report. I think with the Office
7 | for Protection from Research Risks moving from the Office
8 | of the Director of NIH to Under Secretary level in the
9 | Department of Health and Human Services, that the FDA and
10 | the CDC, as well as NIH -- all of the activities will be
11 | more closely scrutinized. I think it will serve us all
12 | well to understand what their definition of research is.

13 | DR. ANDREWS: I'd like to make a comment
14 | basically echoing Dr. Kweder's comment that it may not be
15 | crystal clear what falls under the definition of research
16 | versus surveillance. One could certainly make a case that
17 | certain types of registries more appropriately fall under a
18 | definition of broad public health surveillance and a number
19 | of organizations, including ISPE and PhRMA have suggested
20 | to HHS in response to their regulations on data privacy
21 | that these kinds of surveillance programs be considered
22 | under the surveillance definition for purposes of being
23 | able to collect data without these potential barriers.

24 | But I think it's an open question and there's
25 | really no clear answer. Part of the reason there's no

1 clear answer is the point that you illustrated well,
2 Audrey, and that is, IRBs have not yet developed a
3 mechanism for evaluating privacy risks uniformly across the
4 country.

5 I think that it would be very useful for
6 additional training to be available to IRBs so that when
7 they're looking at studies where the primary risk to
8 patients is a breach of confidentiality, that the use some
9 standard and consistent measures, which just aren't there
10 now. Researchers should never be in a position of shopping
11 for the appropriate IRB to review a study.

12 DR. ROGERS: I would strongly encourage the
13 committee, as it deliberates, to consider interacting with
14 an organization called Public Responsibility in Medicine
15 and Research, which is the professional educational
16 organization for IRB members. We took on an aggressive
17 educational campaign around adolescent participation in
18 research, which if you think you're in trouble, you might
19 try that. It's worth the investment in trying to educate
20 them through that organization.

21 DR. GREENE: Yes, please.

22 DR. SHARRAR: I'd just like to make one
23 additional comment. Part of the problem is that when
24 you're dealing with HIV infection, you're dealing with a
25 disease that has all other sorts of confidentiality

1 | ramifications.

2 | DR. ROGERS: Absolutely.

3 | DR. SHARRAR: This is not a normal disease
4 | process nor a normal registry.

5 | DR. ROGERS: Absolutely. I'm glad you
6 | emphasized that. I tried to make that point.

7 | DR. GREENE: Other questions? Dr. Kweder?

8 | DR. KWEDER: I actually thought that maybe Lew
9 | Holmes could comment on his experience using informed
10 | consent as part of your study or registry and sort of the
11 | pros and cons of that.

12 | DR. HOLMES: You mean in terms of the
13 | institution's ability to understand what we're doing or the
14 | problems with the women themselves?

15 | DR. KWEDER: Both.

16 | DR. HOLMES: I bring up the institutional issue
17 | because I work at a big university hospital. When we said
18 | we were going to set up this pregnancy registry, they were
19 | not immediately accepting of why this made any sense as an
20 | activity to do at the hospital. One of the problems is
21 | IRBs contain an incredible spectrum of people who do
22 | different kinds of work, and I think just by chance, we
23 | might have gotten somebody else who had no trouble with it,
24 | but IRBs are made up of an interesting spectrum.

25 | We're at a time when our IRB process -- and I

1 | suspect everybody else at universities would echo this --
2 | are very slow and lumbering because of the hot button
3 | issues of confidentiality. If you ever take a blood
4 | sample, heaven help you, because the DNA issues slow your
5 | process down to a snail's pace. The fact that your
6 | approval for last year ran out six months ago is your
7 | problem, not theirs.

8 | Coming to the women themselves, the IRB has
9 | standard paragraphs that they insist are present in consent
10 | forms. When you look at a registry that doesn't have a lot
11 | of the components that would require those paragraphs --
12 | like for example, if you're injured in the process of
13 | participating in the study, we will pay for your care --
14 | well, that kind of thing makes the form longer, and the
15 | longer the form, the more it puts off the woman who is
16 | reading it, even though the content might not be worrisome.
17 | So, it has not been an easy step.

18 | We have not found very many women actually read
19 | the thing and close the door and say, forget it, I'm not
20 | going to do this. But there is a small group, probably
21 | less than 1 percent, who when they see the consent form,
22 | that's it. So, it's not a trivial issue.

23 | I think Don has talked about biomarkers, as
24 | should be discussed, because I think this whole work has
25 | got to go in the direction of biomarkers. Clearly, there

1 | are going to be DNA-based markers that will pick out the
2 | high risk and low risk people. That's clearly where we're
3 | going, but that is the same path that the public is scared
4 | about and the IRBs are scared about.

5 | So, it's complicated now. I think it's just
6 | going to get more complicated.

7 | DR. GREENE: Any other comments?

8 | (No response.)

9 | DR. GREENE: Well, a few announcements before
10 | we finish up.

11 | DR. TITUS: I just want to address a couple of
12 | things. Tomorrow's meeting starts an hour earlier, so
13 | please be here at 8 o'clock.

14 | Regarding dinner tonight, most of you are going
15 | to dinner. We have a van arranged to take you there. It
16 | can only hold about half of you at one time. The first van
17 | is going to try to leave at 6:30, and the second van will
18 | leave 15 minutes later. But you all can't be in that
19 | second van. So, somebody has to come down and mill around
20 | and socialize. So, I would encourage you all to come down
21 | at 6:30. You're really welcome to dress casually. There's
22 | no reason for you to go dressed up. You can be normal.
23 | You can dress down.

24 | See you tomorrow morning.

25 | DR. GREENE: Thank you, everyone.

1 (Whereupon, at 4:48 p.m., the subcommittee was
2 recessed, to reconvene at 8:00 a.m., Wednesday, March 29,
3 2000.)
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