

Capital Reporting Company
Pregnancy Registry Public Meeting 05-28-2014

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Pregnancy Registry Public Meeting

Wednesday, May 28, 2014

1:00 p.m.

Food and Drug Administration

White Oak Campus

10903 New Hampshire Avenue

Silver Spring, MD 20993

(301) 796-9018

Reported by: Erick McNair
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1 A P P E A R A N C E S

- 2 Ms. Vicki Moyer
3 Dr. Leyla Sahin
4 Dr. Janet Hardy
5 Dr. Amanda Golembesky
6 Dr. Lauren Doamekpor
7 Dr. Jeff Ecker
8 Dr. Siobhan Duffy
9 Dr. Albert J. Allen
10 Dr. Cynthia Jones
11 Ms. Kate Ryan
12 Dr. Megan Clowse
13 Dr. Pamela Scott
14 Ms. Kimberly Thomas
15 Ms. Julia Beck
16 Dr. Christina Chambers
17 Dr. Trinka Coster
18 Dr. Elise Berliner
19 Ms. Diana Johnson
20 Dr. Solomon Iyasu
21 Dr. Michael Greene

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1 A P P E A R A N C E S (Cont.)

2 Dr. Susan Andrade

3 Dr. Melissa Tassinari

4 Dr. Lewis Holmes

5 Dr. Alan Mitchell

6 Dr. Sonia Hernandez-Diaz

7 Dr. Lynne Yao

8 Dr. Jessica Albano

9 Dr. Arian Dana

10 Ms. Diana Johnson

11 Dr. Ava Marie Conlin

12 Dr. Janet Cragan

13 Dr. Margaret Honein

14 Dr. Craig Hansen

15 Dr. Michael Nguyen

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

2 MS. MOYER: And we are going to be
3 starting the public comment session shortly. If
4 everyone can please -- the panelists can please
5 find your seats and the attendees if you can find
6 a seat as well. We will be getting started
7 shortly.

8 DR. SAHIN: Good afternoon everybody.
9 We will now begin the open public comment
10 session. Both the Food and Drug Administration
11 and the public believe in a transparent process
12 for information gathering and decision making.
13 The comments provided during the public comment
14 session may be considered for discussion by the
15 panel during the panel discussion session.

16 Speakers are asked to step up to the
17 podium at their assigned time and speak only when
18 recognized. Speakers have been allotted five
19 minutes and we will use a timer to keep track of
20 the time. We will turn the timer on when you
21 begin speaking. A yellow light will come on when
22 you have one minute left signaling you to wrap up.

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1 The red light means you need to stop speaking and
2 return to your seat.

3 Will Speaker Number One please step up
4 to the podium and introduce yourself.

5 MS. HARDY: Good afternoon. I am Janet
6 Hardy. I'm here representing ECCPH and I Chair a
7 Pregnancy Registry Advisory Committee that is
8 sponsored by Teva Pharmaceuticals.

9 It is my pleasure to speak to you this
10 afternoon. And I would like to speak about
11 classifying registry cases as prospective and the
12 importance of test technology.

13 My travel expenses were paid for by
14 ECCPH and I'd like to acknowledge again that I
15 chair this advisory committee.

16 My collaborators are listed on this
17 slide. And I'd like to thank them for their
18 insight and contributions.

19 We've already seen some of this
20 information passed before us so I am going to go
21 quickly.

22 The FDA Guidance published in 2002 notes

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1 that registries should expect to receive both
2 retrospective and prospective case reports.
3 Enrollments of prospective cases minimize the
4 opportunity for selection bias and improve the
5 likelihood of registry success. Essentially
6 prospective means that women are enrolled before
7 they have knowledge of their pregnancy outcome.
8 Prenatal testing, although not perfect, may
9 contribute to knowledge of a pregnancy outcome
10 prior to delivery; an example being a congenital
11 malformation. This knowledge may influence a
12 woman's decision to participate in our registry.
13 This knowledge and even the potential for this
14 knowledge may also pose a challenge for case
15 classification.

16 In the 12 years since the FDA guidelines
17 were issued prenatal testing has undergone a
18 transformation. New and updated tests are
19 administered and provide results yet earlier in
20 pregnancy. Increasingly sensitive tests are
21 available including ultrasounds, scans, genome-
22 wide binocular testing and non-invasive prenatal

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1 pre-diagnosis; these facilitate earlier clinical
2 testing.

3 Additionally direct to consumer home
4 test kits are increasingly available further
5 facilitating some degree of knowledge to women
6 earlier in pregnancy. All of these can make
7 classification of prospective case classification
8 increasingly challenging.

9 The 2002 FDA guidance specifically for
10 case classification as we've already heard is
11 after exposure to a product but before any
12 prenatal tests that could provide knowledge to the
13 outcome is considered a prospective. If prenatal
14 testing has occurred the case is usually
15 considered retrospective. Parenthetically we can
16 appreciate that these may leave room for ambiguity
17 to operationalize these definitions in present
18 times.

19 My colleagues and I look to publications
20 from other pregnancy exposure registries for
21 guidance. I am not going to go through this again.
22 It has already been discussed, the anti-epileptic

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1 pregnancy.

2 We recognize that others may also be
3 challenged with operationalizing case definitions
4 and with being consistent between cases. Through
5 our experience we outlined the following
6 guidelines:

7 1. The earliest record of complete
8 informed consent establishes the date for case
9 classification depending on the protocol oral
10 consent or written consent may be used.

11 2. Ultrasounds conducted less than 12
12 weeks gestational age are not reliable indicators
13 of a congenital malformation.

14 3. Ultrasounds conducted between 12 and
15 18 weeks may reveal a congenital malformation.
16 Each individual case should be reviewed.

17 4. First trimester serum review screens
18 are non-conclusive indicators of a congenital
19 malformation.

20 5. Ultrasounds performed between 18 and
21 20 weeks may reveal a malformation and therefore
22 would be considered retrospective.

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1 6. Absent test or procedure information
2 greater than 18 weeks and prior to birth may
3 permit case classification as prospective; and 7.
4 These guidelines should be reviewed periodically.

5 It is important to understand the
6 timing, purpose, and conduct of each test. For
7 some registries a prenatal test may not be
8 exclusionary. The overarching point we want to
9 make is if a registry's purpose is concerned with
10 malformations and a specific prenatal test does
11 not assess malformations, consider the possibility
12 of serendipitous malformation discovery through
13 testing. I am happy to discuss this later if
14 needed.

15 Our suggested guidelines may be
16 applicable to other pregnancy exposure registries
17 conceptually they may also be useful to consider
18 for the analysis of large data sources when
19 multiple years of data are combined to increase
20 study power.

21 The take-home points from this
22 presentation are a priori defined guidelines

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1 facilitate consistency in case classification.
2 And advances in test technology can impact
3 registries and database studies. Technological
4 advancement may eventually help. Three time points
5 converge; the prenatal booking visit, the prenatal
6 tests and a woman's consent to participate. The
7 purpose of this presentation was to stimulate
8 discussion and draw attention to the importance of
9 case classification as the FDA updates their
10 guidelines.

11 Thank you.

12 DR. SAHIN: Will Speaker Number Two
13 please step up to the podium and introduce
14 yourself?

15 MS. GOLEMBESKY: Good afternoon. My
16 name is Amanda Golembesky. I am the director of
17 Epidemiology at USB Biosciences. Today I will be
18 speaking on a methodological comparison of anti-
19 epileptic drug pregnancy registries and their
20 implications on estimated birth defect rates.

21 For full disclosure this project was
22 funded by UCB Biosciences. And I am myself a full

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1 time employee of the UCB Biosciences and as such
2 receive stock options from UCB. My disclaimers
3 are that these data have been previously
4 published. But full references are available upon
5 request.

6 To begin as we have heard earlier today
7 there are multiple epilepsy pregnancy registries
8 that are in existence: there is the European
9 Register of Anti-epileptic Drugs in Pregnancy, the
10 United Kingdom and Ireland Epilepsy and Pregnancy
11 Register, North American Anti-Epileptic Drug
12 Pregnancy Registry, and the UCB AED Pregnancy
13 Registry. This list is not comprehensive but
14 these are the four that we'll be focusing on
15 today.

16 These registries all share similar
17 objectives mainly to monitor for an increased risk
18 of major congenital malformations or birth
19 defects. But they all have varying methodologies
20 and differ with respect to some key features
21 mainly infant follow up time, their malformation
22 definitions, and availability of internal

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1 comparators. And in fact the impact of these
2 differing methodologies is evident when the birth
3 defect rate for levetiracetam, which is an anti-
4 epileptic drug, is shown across the registries.
5 The monotherapy malformation rates for
6 levetiracetam show tremendous variability with the
7 UCB AED pregnancy registry representing a
8 departure from the rest.

9 It was this very finding that has
10 prompted us to seek a review from our colleagues
11 at the North American Registry and at this point I
12 would like to thank Dr. Holmes and Dr. Hernandez-
13 Diaz for their thoughtful review. The objective
14 of their review was to determine if the UCB AED
15 Pregnancy Registry Birth Defects would have been
16 included in the North American Registry based on
17 their ALCM definitions. And their review
18 concluded that approximately 50% of the birth
19 defects in the UCB AED Pregnancy Registry would
20 have been excluded from the North American
21 Registry.

22 The interpretation of the results from

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1 the UCB AED Pregnancy Registry is further
2 challenged by the absence of an internal
3 comparator. In fact for the European Registry and
4 the North American Registry where an internal
5 comparator is available there are no notable
6 differences in the malformation rates for
7 Levetiracetam compared to Lamotrigine. And it is
8 for this very reason that UCB considers that
9 registries with an appropriate internal comparator
10 provide the optimal benefit risk insight.

11 So in conclusion variations in
12 malformation rates observed across the pregnancy
13 registry are difficult to interpret due to these
14 methodological differences. And in fact
15 publications often don't present substantial
16 enough information to assess these methodological
17 differences making the evaluation of the potential
18 impact of these differences on malformation rate
19 estimations challenging. An appropriate internal
20 comparator is important in assessing benefit risk.

21 Also these results highlight the rule of
22 large multi sponsored registries and the need for

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1 methodological harmonization for broader
2 contextualization of finding.

3 And lastly pregnancy registries should
4 not be the sole source of pregnancy related
5 benefit risk information. They should be viewed
6 in the context of other pharmacovigilance and
7 other external data sources.

8 I would like to acknowledge once again
9 the patients and physicians who are contributing,
10 the expert panel members and the CAR colleagues at
11 the North American Registry for their great
12 further review.

13 Thank you.

14 DR. SAHIN: Thank you. And will Speaker
15 Number Four please step up to the podium and
16 introduce yourself.

17 DR. DOAMEKPOR: Good afternoon. My name
18 is Dr. Lauren Doamekpor and I am a Senior Fellow
19 as the National Center for Health Research. Thank
20 you for the option to speak today at this
21 important meeting. Our non-profit center assesses
22 scientific and medical data and provides objective

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1 health information to providers, patients, and
2 policymakers.

3 We recognize the vital importance of
4 requiring post-market pregnancy registries. These
5 registries will clearly provide information,
6 important information to improve product labeling
7 and also enable health care providers to better
8 inform women about drugs or prescription drug use
9 during pregnancy. Even when risks are uncertain
10 data from these registries can provide valuable
11 insight into the potential risks from exposure to
12 drugs or biologics. It is incredibly important
13 that pregnancy registries use a rigorous
14 methodology and protocol to insure that the data
15 is scientifically sound.

16 Our comments today address the need to
17 insure an adequate sample size that is
18 sufficiently diverse and also the need for a
19 surveillance system for all marketed drugs used by
20 women of child bearing age.

21 Pregnancy Exposure Registries tend to be
22 too small and often have not included sufficient

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1 numbers of racial and ethnic minorities. This
2 lack of diversity is a problem for many studies
3 submitted to the FDA but for pregnancy registries
4 this problem may be particularly pronounced
5 because of the way that women are recruited and
6 enrolled. Enrolling women through physician
7 offices for example may limit the number of
8 participants from ethnic minority groups because
9 some minority groups are less likely to have
10 health insurance or to have regular prenatal care.
11 The physicians that they see in emergency rooms or
12 clinics may be less likely to participate in
13 registries.

14 Successful recruitment of women of color
15 will require new and creative strategies for
16 recruiting patients. A carefully created plan is
17 needed to recruit in community centers and urgent
18 care centers; a continued partnership with Text
19 for Baby and other social media platforms used by
20 a diverse group of patients is also essential.
21 Whenever possible enrolling women directly into
22 registries independent of physicians may be

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1 encouraged, this may allow for the inclusion of
2 women earlier in pregnancy and may also facilitate
3 follow up.

4 The biggest challenge is really
5 obtaining information on a drug safety during
6 pregnancy as quickly as possible after a new drug
7 has been approved and is already on the market.

8 However registries are not required for
9 all new drugs. The FDA should require pregnancy
10 registries for all newly marketed drugs used by
11 women of child bearing age. And the agency should
12 also consider requiring pregnancy registries for
13 some older drugs that are widely used during
14 pregnancy where safety data may be lacking.

15 So conclusion it is really essential for
16 pregnancy registries be founded on
17 methodologically sound protocols in order to
18 produce scientifically sound data for the safety
19 of drug use during pregnancy. This will
20 definitely help patients decide whether to take
21 medication during pregnancy or not.

22 Thank you.

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1 DR. SAHIN: Thank you. Will Speaker
2 Number Five please step up to the podium and
3 introduce yourself.

4 DR. ECKER: Good afternoon. My name is
5 Jeff Ecker. And I'm a Maternal-Fetal Medicine
6 Physician. Like Mike Green I practice high risk
7 obstetrics at Massachusetts General Hospital in
8 Boston where I am also a professor at Harvard
9 Medical School.

10 But I am here today neither representing
11 myself nor either of those institutions. Instead
12 I offer comments on behalf of the American College
13 of Obstetricians and Gynecologists representing
14 over 50,000 members who provide health care for
15 women. I am a fellow of ACOG and I serve as chair
16 of the committee of obstetric practice in which
17 role I have the pleasure of serving with liaisons
18 from the drug and the device divisions of the FDA.

19 We enthusiastically support the agency's
20 efforts to evaluate and advance efforts to
21 determine the safety of drugs and biological
22 products in pregnant women. And look forward to

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1 updated guidance from this group.

2 Our support is founded in the dual
3 beliefs that more research is needed regarding the
4 effects of drugs in women and on women's health
5 and that such research can be appropriately
6 conducted.

7 Our committee on ethics of which I am a
8 former chair supports the position that pregnancy
9 and/or its possibility should be neither barriers
10 nor excuses preventing these important studies.

11 My comments today will be focused on how
12 to make these registries workable for frontline
13 obstetricians.

14 Counseling women regarding the safety of
15 medication in pregnancy is not an unusual task for
16 folks like me. For 50% of women use at least one
17 prescription medicine at some point during
18 pregnancy. Both rising rates of chronic disease
19 and rising average maternal age at conception
20 argue that the use of prescription medicines
21 during pregnancy will only increase in the years
22 ahead. And yet less information is available to

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1 guide women and their physicians than we would
2 like.

3 Too often I search available databases
4 only to find that data to inform an evaluation of
5 risk is limited or missing. Not surprising given
6 the fact that pregnant women are often
7 specifically excluded from trials looking at the
8 safety of drugs before approval.

9 To fill these gaps as already noted by
10 this group, registries are of vital importance
11 because they record the experiences of women who
12 have either used medications before recognizing
13 they were pregnant or who have used medications
14 after they and their providers have deemed it best
15 for a safe and healthy outcome to a pregnancy.

16 I want to emphasize as in concordance
17 with ACOG's immunization expert working group that
18 obtaining information of vaccines is a vital
19 addition to information about medications and want
20 to be sure that all our conversations going
21 forward focus on a broad definition of medications
22 and biologic materials.

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1 Yet while pregnancy registries are
2 important, an important first step, they have as
3 this group has already acknowledged important
4 limitations. It is imperative that as many
5 pregnant women that are exposed to a particular
6 drug or vaccine enroll in available registries and
7 enroll as early as possible in pregnancy.

8 And yet another limitation of registries
9 is that all too often in my experience women and
10 providers either don't know that a particular
11 registry exists or find their process for
12 enrollment too cumbersome.

13 Having a readily accessible online
14 clearing house for open registries will be a great
15 help to busy clinicians who find their time
16 occupied with many tasks. How embarrassing that
17 until preparing these remarks I didn't know that
18 such a clearinghouse in fact exists albeit buried
19 deeply within the FDA website.

20 ACOG for its part will commit to
21 featuring a link to this in its resources to
22 members but we hope that the FDA in particular can

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1 play an important role in promoting registries to
2 those who prescribe for pregnant women who are not
3 obstetricians: primary care physicians, midwives,
4 family practitioners, and others.

5 All including the FDA should do more,
6 however, to connect providers and patients with
7 registries. Connections to registries could be
8 made and should be encouraged both when drugs are
9 prescribed and dispensed. Increasingly, of
10 course, prescriptions are not written but
11 transmitted and meaningful use is encouraged by
12 the Affordable Care Act places a premium on
13 electronic prescribing systems. Such systems
14 will often recognize that the patient for whom a
15 particular medicine is prescribed is pregnant
16 either because she is receiving a prenatal vitamin
17 or because the prescription is generated from
18 within an integrated electronic medical record in
19 which such a diagnosis is already flagged or
20 noted.

21 ACOG and FDA should encourage those who
22 use these systems to prescribe or to dispense

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1 medications to include notification when a
2 pregnancy registry is open for a medication in
3 question.

4 Ease of use also includes ease of
5 access. And when prompted patients access
6 registries their interface should be easy and
7 online and not paper.

8 Thank you for letting us speak today on
9 behalf of ACOG. We look forward to partnering
10 with the FDA and promoting progress in this
11 important matter.

12 Thanks.

13 DR. SAHIN: Thank you. Will Speaker
14 Number Six please step up to the podium and
15 introduce yourself?

16 MS. DUFFY: Good afternoon. My name is
17 Siobhan Duffy. I am research scientist with
18 United BioSource Corporation. Today I'd like to
19 talk about recruitment strategies to improve
20 location enrollment. Based on my working
21 experience at United BioSource UBC has been
22 designing and executing pregnancy exposure

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1 registries for a number of years now.

2 These are the recruitment strategies
3 described in the FDA's 2002 guidance document:
4 announcements, personal mailings,
5 exhibits at professional meetings and sponsors
6 working together with FDA and other organizations.

7 I'll provide an overview of the
8 advantages and disadvantages of each.

9 Prescribing information or product
10 labeling is the foundation of educational
11 initiatives. In fact 29 of the 58 medications
12 listed on the FDA website have information about
13 their registry within their prescribing
14 information.

15 These educational materials such as
16 brochures are a good method for direct health care
17 professional awareness and patient recruitment.
18 We've also seen these used in clinical studies.
19 But there can be a hesitancy on the part of the
20 sponsor because of the perception that you are
21 promoting use of the drug in pregnancy and/or
22 there is a misconception that there is a known

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1 risk about use for the drug during pregnancy.

2 Use of the internet and the website is
3 another method of direct prescriber awareness and
4 patient recruitment; it provides educational
5 material, registration information and registry
6 contact information. But this seems like it's for
7 a number of products a missed opportunity for
8 patient recruitment for the reasons that I have
9 described up here. Many are not written in lay
10 person terms. They are difficult to navigate;
11 difficult to find. They seem directed for health
12 care professionals. And many of them don't have
13 recognizable product or sponsor branding.

14 Journals and magazines provide general
15 distribution of prescriber awareness information
16 recruitment but they can be costly and there is no
17 certainty that you are going to get to your
18 targeted audience.

19 The health care professional letters are
20 an option to reach out to a targeted audience of
21 known prescribers or likely to prescribe. In our
22 experience at United BioSource the letters have

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1 resulted in almost a fourfold increase in calls to
2 the registry center and a noticeable increase in
3 the short amount of time in patient enrollment.

4 Exhibits at professional meetings
5 provide an opportunity for face to face
6 conversations with health care professionals but
7 the clinician is away from their practice and they
8 may be less likely to identify an appropriate
9 patient when they return to their practice.

10 Collaborating with the FDA and other
11 agencies may allow for greater access to targeted
12 patient populations, facilitating enrollment of
13 the comparator group and this can also lead to
14 multi- sponsor registries. 23 of the products
15 listed on the FDA website are part of a shared
16 registry. One of the challenges with multi-
17 sponsor registry is when there is a conflicting
18 interest in the registry whether it is an FDA
19 mandate or strictly researched based or otherwise.

20 Most pregnancy registry information
21 tends to be focused on health care provider
22 awareness but in UBC experience direct patient

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1 recruitment is more effective. As discussed
2 earlier today approximately half of the
3 pregnancies in the United States are unintended.
4 So there is also most likely a high amount of
5 unintended exposures and the patient may or may
6 not share with the prescribing physician that they
7 became pregnant while they took the medication or
8 share with the obstetrician that they were taking
9 the medication when they became pregnant.

10 There is a need for more general public
11 information about pregnancy exposure registries
12 and their purpose. Increased understanding of
13 pregnancy exposure registries may increase
14 recognition and interest in specific pregnancy
15 registries that use direct patient recruitment.

16 Thank you.

17 DR. SAHIN: Thank you. Will Speaker
18 Number Seven please introduce yourself?

19 DR. ALLEN: Albert J. Allen, Ely Lilly &
20 Company. And I am senior medical fellow for
21 Bioethics in Pediatrics.

22 I want to start by thanking the FDA for

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1 holding this meeting and for the work that you are
2 doing on guidance. I think that it is important.

3 My focus as a child psychiatrist is
4 often dealing with patients who have obviously
5 been born to mothers and in some cases those
6 mothers may have used medications. And I think it
7 is important to recognize that pregnant women have
8 health care needs like everyone else and so we
9 really do value the opportunity to try and learn
10 more about how can they use medications and
11 hopefully have an appropriate benefit risk. So
12 this is an important meeting.

13 Next slide. Sorry. I am not going to
14 talk too much about design challenges because I
15 think there has been a lot of discussion about
16 this already. Concerns that we have at Lilly and
17 these slides are based on information from a
18 number of our drugs where we've had registries or
19 attempted registries. The issue of registries
20 introducing bias into the population that you are
21 studying is one that has been noted and this is a
22 concern in a number of different areas.

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1 The issue in terms of limited ability to
2 enroll women early in pregnancy can be
3 particularly problematic especially for
4 teratogenic factors as was noted in the first
5 trimester challenges.

6 We will get to the limitations on
7 patient enrollment in just a minute but one of the
8 things that we have found is that because of the
9 design in enrollment challenges it can often take
10 decades to reach an adequate sample size to be
11 able to draw any sort of conclusions. And this
12 has been noted by a number of speakers is a
13 problem in terms of being prepared for how to
14 treat patients that are in front of you today.
15 Having data 30 years from now doesn't help a whole
16 lot.

17 So for us probably one of the major
18 issues is the enrollment challenge. We are
19 dealing with drugs that in some cases the medical
20 conditions that the pregnant women suffer from are
21 ones that they may be sensitive about making
22 others aware of whether through a registry or

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1 other situations.

2 As a psychiatrist in particular I have
3 dealt with a number of women who putting their
4 data or the fact that they are being treated for a
5 psychiatric illness into a database is a concern
6 for them. And that is an obvious barrier to
7 recruitment.

8 There are limited incentives that are
9 available for health care providers to participate
10 in these; in many instances the desire to add to
11 knowledge. But again you've got a long lag time
12 before they actually see any results at the
13 registries. So there is some question about how
14 useful this is as an incentive to say that they
15 are contributing to the knowledge that will help
16 other patients that they may treat.

17 We have legal limits on the risk that
18 impact health care provider participation. In
19 some cases they're concerned about potential
20 liabilities to themselves by participating in a
21 registry. We have challenges in terms of the role
22 that the industry or the company can do in terms

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1 of making people aware of the registry. Again
2 this is particularly an issue where we are
3 concerned often about are we somehow promoting the
4 drug off label or doing something that would
5 infringe upon the promotional practices. And I
6 would just echo the comment that was made earlier
7 about the value of having some sort of guidance
8 around those sorts of materials. What is
9 appropriate material; what is not?

10 We have as noted limited recruitment
11 incentives for the patient population and in some
12 cases we have got a small patient population to
13 begin with.

14 So there are alternative methods with
15 registries. You could have a government approach
16 such as the Danish Registry in Europe. EUROCAT is
17 another approach. A disease state registry or
18 multi-drug registry has a lot of attractiveness
19 because it means not one company is making people
20 aware of it so that you may have less promotional
21 concerns. Hybrid registries are another option
22 and then integrated health care system or hospital

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1 system approach.

2 So we think that this is something that
3 it is important to have cooperation and
4 collaboration. We would encourage more incentives.

5 Thank you.

6 DR. SAHIN: Thank you. Will Speaker
7 Number Eight please step up to the podium and
8 introduce yourself?

9 MS. JONES: Good afternoon. My name is
10 Cynthia Jones. I'm a pharmacoepidemiologist at
11 Biogen Idec working in drug safety and benefit
12 risk assessment.

13 Biogen Idec has several approved
14 therapeutics for multiple sclerosis. For those of
15 you who don't know multiple sclerosis is a disease
16 that disproportionately affects women of child
17 bearing age.

18 As a result of our work in multiple
19 sclerosis we have extensive experience in
20 pregnancy registries.

21 We have recently and successfully
22 completed pregnancy registries for Avonex and

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1 Tysabri and we are now enrolling patients for a
2 pregnancy registry for Tecfidera. Additional
3 pregnancy registries are planned for other
4 products that are currently in filing or in review
5 globally.

6 Because of this experience and lessons
7 that we've learned we have two recommendations.

8 First we recommend that the FDA allow
9 greater flexibility in pregnancy registry
10 protocols and not be specifying a comparative
11 population. Better comparative population data
12 than that which was pre-specified will become
13 available over the life of the registry; for
14 example the aforementioned Tecfidera registry
15 which is currently enrolling is scheduled to be
16 completed in approximately eight years. The
17 availability of population based MS background
18 rates and other informative external sources may
19 greatly evolve over the course of those eight
20 years. It could also be considered premature to a
21 priori select external comparison groups prior to
22 knowing the demographic composition of the

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1 registry patients.

2 Therefore we recommend that the FDA in
3 the guidance allow flexibility in the protocol and
4 not be specifying a comparative population.

5 Second we would like to see the FDA
6 facilitate birth outcome data. We find great
7 potential value in the use of data such as that
8 provided by the Medication Exposure in Pregnancy
9 Risk Evaluation Program (MEPREP). We believe that coupled
10 with existing background data, programs such as
11 MEPREP could provide another source of comparative
12 data on many different disease states and medicine
13 use patterns.

14 In summary based on our extensive
15 experience in pregnancy registries and
16 anticipation of more registries into the future we
17 have two recommendations: One, flexibility in FDA
18 guidance regarding protocol design and not forcing
19 a priori comparative populations; and two, FDA
20 facilitated availability of additional comparator
21 data.

22 Thank you.

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1 DR. SAHIN: Thank you. Will Speaker
2 Number Nine please step up to the podium and
3 introduce yourself?

4 MS. RYAN: Hi. I am Kate Ryan. I am
5 with the National Women's Health Network. It is
6 an advocacy organization networks to improve the
7 health of all women. We bring the voices of women
8 consumers to policy and regulatory decision making
9 bodies. And we are a membership based
10 organization. And do not take financial
11 contributions from drug companies, medical device
12 manufacturers, insurance companies or any other
13 entity with a financial stake in women's health
14 decision making.

15 The network has long advocated for the
16 FDA to provide better information for women about
17 the safety of drugs used during pregnancy both
18 provider recommended and guided as well as
19 accidental exposure. So we are very pleased that
20 the FDA and the FDA Office of Women's Health in
21 particular has convened this meeting to discuss
22 how to evaluate the safety of drugs and biological

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1 products used during pregnancy.

2 I am going to bring the patient
3 perspective today as I said we are a membership
4 based organization and let the trial design of
5 registries, leave that up to researchers.

6 What I want to say for women, so
7 pregnant women have historically been excluded
8 from most research trials due to the concern that
9 trial participation could harm the fetus even from
10 research that would advance our knowledge of
11 medical conditions and treatments intended to be
12 used during pregnancy. As a result we don't have
13 nearly enough information to provide women with
14 accurate information which is particularly
15 disturbing when you consider that more than half
16 the pregnant women take at least one prescription
17 drug during pregnancy.

18 I am not going to go into detail today
19 about this particular topic. But I do want to
20 find a way to include pregnant women in more
21 research because it is an important part of this
22 larger conversation kind of with the exception of

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1 what we've already seen so recently a drug
2 approved for nausea and vomiting during pregnancy
3 that actually did the type of thing we want to see
4 which is to study the women it is going to be used
5 in.

6 As a national membership based
7 organization the network hears women across the
8 country looking for information about drugs and
9 medical devices and procedures. We believe that
10 with the right information every woman could make
11 a good decision about their health care.

12 Our Women's Health Voice which is a
13 health information clearinghouse that we have
14 hosted since the '70s provides women with evidence
15 based information about medical products and
16 procedures so that they have the tools they need
17 to be an active participant in their health care
18 with their provider.

19 We strongly support the inclusion of
20 women in more clinical trials and post market
21 studies including pregnant women.

22 Without an adequate research

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1 infrastructure that can provide this type of
2 evidence based information we really can't give
3 women the information they want and need. About a
4 year and a half ago I spoke at an FDA Advisory
5 Committee Meeting about the use of Teratogenic
6 drugs by women of reproductive age and potential
7 pregnancy exposures, a topic with obvious
8 connections to the focus of today's meeting. As I
9 had said then the network believes that the FDA
10 should not restrict access to an effective
11 medication because of women's reproductive
12 capacity but at the same time we have to support
13 the collection of data through registries to track
14 what happens in the event of a medication exposure
15 during pregnancy. The long term data collected
16 from registries and other long term studies can
17 provide important additional information about the
18 safety of a drug beyond what we can get from a
19 short term pre-market clinical trial.

20 I know they can be difficult to enroll
21 women and we've heard today that it can be
22 difficult to enroll women in pregnancy registries.

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1 You know there are typically high dropout rates
2 and poor follow-up. However, we have learned from
3 a successful community based participatory
4 research in other areas that people and women in
5 particular are more likely to enroll in and remain
6 in engaged in a trial or research if they feel
7 engaged in the research. And somebody had spoken
8 to that earlier today, one of the panelists. But
9 it essentially means that health care providers
10 with patients who become pregnant while taking a
11 drug should be having conversations with their
12 patients about the purpose and public health value
13 of the research to insure they understand the
14 option of enrollment as well as the benefits of
15 enrollment not just to themselves but to the
16 public at large.

17 And additionally what we've seen is when
18 the FDA research and providers share the study
19 results when they become available women feel more
20 positively towards their participation in the
21 research. It is not enough to conduct the
22 research. However, women and providers do depend

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1 on the FDA to provide them with clear, accurate,
2 and timely information about what has been learned
3 from the research of affects of drug used during
4 pregnancy.

5 But until the agency follows through
6 with the commitment to release the guidance for
7 industry on drug labeling pregnancy categories we
8 are going to have a bit of a disconnect. We
9 really urge the FDA to finalize and release this
10 long awaited update to the guidance on pregnancy
11 and lactation labeling.

12 We also recommend the FDA work with
13 women's health organizations and women's health
14 providers to insure the information is
15 communicated in consumer friendly language so that
16 when women get the information they can understand
17 it and use it to make a decision that is based on
18 their own priorities, concerns, and values.

19 Thank you very much.

20 DR. SAHIN: Thank you. Will Speaker
21 Number Eleven please step up to the podium and
22 introduce yourself?

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1 DR. CLOWSE: I am number 10.

2 DR. SAHIN: Okay. Sorry. Ten.

3 DR. CLOWSE: I am going to keep going.

4 I am Dr. Megan Clowse and I am Rheumatologist at
5 Duke University Medical Center. I am also the
6 Director of the Duke Autoimmunity and Pregnancy
7 Registry which includes now about 300 patients
8 with various Rheumatologic ailments in pregnancy.

9 I wanted to raise what I think is an
10 important topic that has not been discussed yet
11 today much which is the impact that disease
12 activity has on pregnancy outcomes and how that
13 can particularly influence how we interpret the
14 data about pregnancy outcomes with medications.

15 So we know that in many diseases in my
16 world certainly Lupus in other world's things like
17 diabetes and inflammatory bowel disease that
18 having more disease activity during pregnancy
19 leads to worse pregnancy outcomes including more
20 preterm birth, more pregnancy loss, lower birth
21 weights, et cetera.

22 And so it is important that when we look

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1 at the medications that these patients are taking
2 they really take into account how much disease
3 activity they have and how that is leading to
4 their medication use. So for example in Lupus our
5 patients who have a history or active Lupus during
6 pregnancy will be on more drugs than our patients
7 with Quiescent Lupus and, therefore, will likely
8 have more pregnancy outcome problems potentially
9 because of their disease activity or potentially
10 because of the medications and it really makes it
11 difficult to kind of tease out those two problems.

12 I think that it's particularly important
13 when we look at what control groups we use. So we
14 need to have some control groups that are probably
15 matched in their disease activity level to the
16 patients who are on the medications. And I think
17 it makes healthy controls often not a great
18 control group for our patients with chronic
19 diseases. So a patient with Lupus who comes into
20 a pregnancy is just at much higher risk for
21 pregnancy complications than a healthy woman. And
22 that doesn't necessarily have anything to do with

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1 the medications that she takes. It is just who
2 she is. And we can't modify that she has Lupus or
3 not. What we can do is with the medications.

4 So I just want to add that I think that
5 it is really important that disease activity
6 measures be included in these registries figuring
7 out how to collect that information I think is a
8 significant challenge. Getting that data from
9 physicians I think would be probably the most
10 valuable but also probably the most technically
11 difficult. And I think that we all know that
12 physicians, myself included, are often not the
13 most receptive and responsive to more
14 questionnaires. But I think that there are new
15 and evolving patient reported outcomes as well
16 that can be useful and might be able to at least
17 give the investigators a general idea about a
18 patient's disease activity and, therefore, be able
19 to use that as I understand medication toxicities.

20 Thank you.

21 DR. SAHIN: Thank you. This concludes
22 our open public comment session. Thank you for

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1 everybody's participation.

2 MS. MOYER: So we are ready to start our
3 next topic. And Pamela Scott will lead us through
4 the afternoon.

5 DR. SCOTT: Welcome to the afternoon
6 session. And we are going to start with some
7 introductions since we have two new panelists
8 joining us. So we are going to start by asking
9 Kim Thomas and Julia Beck to do a brief
10 introduction. So we will start with Kim Thomas.

11 MS. THOMAS: Hi. My name is Kimberly
12 Thomas. I am a Senior Public Health Advisor in
13 the Office of Women's Health and I focus on health
14 communication and outreach activities.

15 MS. BECK: Hi. My name is Julia Beck.
16 I am here as a lay person. My day job actually is
17 running an organization called Forty Weeks where
18 we focus on helping brands to connect with new and
19 expectant parents. Our clients include Madilla,
20 Bravado and others focused on helping make that
21 transition a positive one. But today I am here as
22 a patient, as somebody who participated twice in

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1 pregnancy registries, one in each century

2 actually.

3 [Laughter.]

4 MS. BECK: Tah-dah.

5 DR. SCOTT: Thank you. And welcome.

6 So the afternoon session is going to
7 focus on issues related to enrollment, retention
8 and communication of pregnancy registries. In the
9 morning sessions we learned that pregnancy
10 registries are a valuable tool to collect data to
11 examine the risks of medical product exposures
12 during pregnancy. As we discussed in the morning
13 presentations pregnancy registry data can inform
14 product labeling and clinical practice guidelines.

15 During the course of the meeting today
16 we discussed the challenges related to data
17 collection analysis and briefly touched upon
18 issues related to enrollment, retention and
19 communication.

20 Now for this afternoon session we want
21 to shift gears a little bit and have a more in
22 depth discussion as it relates to these issues.

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1 And our first speaker today is going to
2 be Kimberly Thomas. And she is going to talk
3 about the use of digital outreach and innovative
4 partnerships to raise awareness about the
5 pregnancy exposure registries.

6 MS. THOMAS: I am short so I need to
7 lower the microphone. I am just going to share
8 with you today some of the digital outreach and
9 educational partnership strategies that we've used
10 in the Office of Women's Health to help to raise
11 awareness about pregnancy exposure registries
12 amongst women as well as amongst health
13 professionals.

14 First let me just give you a brief
15 overview of the Office of Women's Health. The
16 office was established in '94 with a mission to
17 protect and advance the health of women through
18 policy, science and outreach. And in support of
19 our mission one of our main focuses is to
20 translate and disseminate FDA information to the
21 public. And that is the role that we take in
22 terms of pregnancy registries.

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1 Now our outreach program really centers
2 around our Take Time to Care Program which is an
3 umbrella initiative for all of our consumer
4 outreach activities. We target consumers directly
5 but we also go through health professionals and
6 other community decision makers and advocates who
7 reach women in a variety of roles that they have
8 in their lives.

9 We do partnerships with a variety of
10 different types of organizations. And we conduct
11 outreach campaigns as well as digital outreach
12 including videos, website and social media, some
13 of which I'll talk about today.

14 Our outreach program uses five main
15 strategies or components to reach our target
16 audiences. We have consumer education, campaigns,
17 partnerships, conference exhibits, and
18 presentations to target the health professionals
19 as well as electronic outreach, everything from
20 social media to the FDA website and our technical
21 assistance.

22 Now our pregnancy initiatives really are

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1 in three main areas: the pregnancy registries
2 webpage which we've heard a lot about today, our
3 consumer education and outreach, and our health
4 professional outreach.

5 Now let me start with the pregnancy
6 registry page since we've already heard a lot
7 about the information that is on the page I am
8 going to talk a little bit more about why it was
9 created and what we've done to try to improve the
10 page over the years.

11 Now initially we heard from our
12 stakeholders that it was hard for women and
13 clinicians to find the contact information for
14 registries You had to go on an individual
15 basis, go from one site to another. They wanted a
16 one-stop shop. So the page was created about ten
17 years ago to connect consumers and health
18 professionals to the registry information and just
19 to raise general awareness about pregnancy
20 registries.

21 Now this is the website which you've
22 seen earlier today. In 2011 the Office of Women's

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1 Health conducted some usability testing in an
2 effort to learn more about how the public get
3 their feedback about the website and try to
4 improve its functionality. Now usability testing
5 provides an opportunity to use a small sample of
6 your potential website users to gain feedback
7 about how easy it is for individuals to find
8 information on the website and to get their
9 general feedback about the types of information
10 they are looking for.

11 Our testing, we were trying to figure
12 out how health care providers and consumers found
13 information on medication and pregnancy on the FDA
14 website and to identify the resources that they
15 use in addition to FDA to get information.

16 We used a sample of 16 participants,
17 eight consumers and eight health care
18 professionals and we were really trying to target
19 a representative sample, different ethnicities,
20 different professional backgrounds within the D.C.
21 area to get their feedback. And they conducted
22 some timed tests in trying to find basic

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1 information and they also gave us feedback on the
2 different sections of the site.

3 The first thing that we learned from the
4 usability testing was simple. Few people think to
5 go to FDA to our website. Most have never used
6 the site at all. And the providers were more
7 likely to go to other sources like other
8 government websites, the drug companies, clinical
9 studies, the literature, drug reference books;
10 everything but FDA.

11 The women really what we learned from
12 the conversations and from their tests was that
13 they were heavily influenced by their primary care
14 physician or their OB/GYN when it came to getting
15 information. But one of the things we also
16 learned was that women definitely used the
17 internet to search for information about the drugs
18 that we are taking.

19 In this testing we didn't go into detail
20 about the quality of the information but there is
21 a separate FDA paper that was done with some of
22 our external colleagues that talks about the lack

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1 of evidence for some of the sites that these women
2 go to.

3 One of the other things that we learned
4 was that something that we already kind of knew
5 about the website that both health care providers
6 and consumers had difficulty finding the
7 information about pregnancy and medication use.
8 Many of them had to go through many clicks before
9 they actually got to the site. Those who did put
10 pregnancy in the search box were able to find the
11 listing as well as find our other consumer
12 information.

13 And I just need to note that this
14 testing in 2011 was done before the FDA did the
15 latest round of upgrades to the website. So
16 things have changed considerably since the testing
17 was done.

18 When the women got to the pregnancy page
19 they found the information useful but they gave us
20 some insight into the problems that we may have in
21 terms of communicating with the public about
22 pregnancy registries. They didn't find the name

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1 intuitive and if they saw it, it wouldn't catch
2 their attention as something they would want to
3 click on.

4 We also found some interesting
5 information from the consumers about what they
6 were looking for. Many of the consumers wanted
7 more information on how the registries worked and
8 what they would need to do when they participate.
9 There was a link there but we decided to upgrade
10 the information to really try to allay some of
11 their fears.

12 And we also found that the health care
13 professionals wanted more direct information,
14 links to the drug label and that type of thing.

15 For us what we decided to do in 2011 was
16 to do more direct outreach related to pregnancy
17 registries. We wanted to promote the existence of
18 registries and the benefits of the registries not
19 only to the health care professionals but to the
20 women as well. And we wanted to provide more
21 general information to allay women's concerns and
22 fears about registries but just to also provide

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1 some general education.

2 Some of the challenges that we faced was
3 the feedback that we got kind of mirrored some of
4 the comments we had from earlier today about women
5 really wanting more definitive answers right now.
6 And being able to educate them that pregnancy
7 registries wouldn't provide that information but
8 it could be a valuable tool for them if they had
9 future pregnancies but also in their role to help
10 other women.

11 Our response was to develop some digital
12 outreach strategies as well as some partnerships
13 to increase our education related to pregnancy
14 registries. For our digital outreach we
15 definitely did some direct updates to the
16 pregnancy registry web pages, we added pages, we
17 tried to make the navigation more user friendly
18 and we also upgraded our pregnancy topics page
19 which includes links not just to the pregnancy
20 registries but to other FDA content for pregnant
21 women.

22 We started doing more website features

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1 and spotlights. And we also developed some new
2 tools, website cards as well as web buttons that
3 we could promote to our partners to try to raise
4 awareness about pregnancy registries and about the
5 website. And we also expanded our Twitter
6 outreach.

7 This is just a screen shot of the
8 pregnancy topics page that includes the links to
9 the registries as well as some of our other
10 information.

11 In addition to the digital outreach we
12 started some new partnerships. In 2012 text4baby came
13 to us because they had seen some of the
14 previous video outreach that we had done to
15 Hispanic women. They were interested in expanding
16 their outreach to African American and Latino
17 women. And we were interested in doing the same
18 in terms of pregnancy registries. So as a result
19 we joined forces to develop a short video in
20 English and Spanish that was launched in May of
21 last year to educate women about medicines in
22 pregnancy, about the resources available through

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1 our pregnancy website, and also to let them know
2 about the existence of pregnancy registries.

3 We did a lot of different types of
4 outreach including our stakeholder outreach, our
5 social media, and our YouTube Video ad campaigns.
6 All of these were successful and they are ongoing.
7 This was just the first step in our attempt to
8 really start reaching out to diverse audiences
9 about pregnancy registries.

10 This is screen shots to show you some of
11 the flyers that we used to promote the videos in
12 both English and in Spanish.

13 In addition we have a whole portfolio of
14 educational materials that are written in plain
15 language for women. We've been distributing our
16 materials for years. But in December of 2012 we
17 launched a special pregnancy publication promotion
18 to make available our materials on pregnancy
19 registries, our fact sheets on medicine in
20 pregnancy as well as some consumer updates from
21 the FDA Office of Communication that are designed
22 to educate the public about pregnancy registries

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1 and medicine in pregnancy.

2 Now we've distributed over 800,000
3 publications and these materials were made
4 available in bulk to health professionals to
5 community based organizations as well as national
6 associations.

7 And this slide shows some of the
8 materials that are available, our tear pads, the
9 website cards, and our fact sheets.

10 Some of our other partnerships were
11 designed to really raise awareness about the
12 website and to encourage both consumers and health
13 professionals to access our print and online
14 publications. We partnered with USDA to reach out
15 to over 4500 WIC agencies across the country to
16 make information about pregnancy registries and
17 our medicine in pregnancy fact sheets available.
18 We also work with the HHS minority health resource
19 center to distribute the medicine in pregnancy and
20 pregnancy registries materials through their call
21 center and through their preconception health
22 initiative.

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1 And lastly OWH provided funding to FDA's
2 public affairs specialist, our field staff, who do
3 local and regional outreach throughout the U.S.
4 and Puerto Rico to make the materials available in
5 those areas as well.

6 Our health professional outreach was
7 really in two different forms. We did our
8 traditional conference outreach in stakeholder
9 meetings where we tried to raise awareness about
10 the website and about the materials that are
11 available for health professionals. But also as a
12 part of a partnership that was already ongoing in
13 the Office of Women's Health to develop a woman's
14 health curriculum and tool kit for schools of
15 pharmacy, we made sure that information on the
16 pregnancy registries was included in the resources
17 so that those training students would have access
18 to that information early and would begin to
19 incorporate in their practicum training and in
20 their future practice.

21 And lastly we make the materials
22 available to health professionals through our

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1 interagency projects such as the partnership that
2 we sponsored for several years with HRSA in their
3 clinical pharmacy services collaborative that
4 provided clinical pharmacy services to women at
5 HRSA funded clinics and community health centers
6 across the country.

7 This last slide is just to show you a
8 little bit of some of the outcomes. These are
9 some of the milestones in terms of our web
10 traffic. It is just the beginning. We are the
11 FDA so we don't have millions of visitors the way
12 some other websites would. But we are hoping that
13 the feedback that we get from this meeting will
14 help us to ramp up our outreach digitally and in
15 terms of our partnerships.

16 And I will just end with a slide that
17 shows you some of our resources that we have
18 available.

19 And that is it. Thank you.

20 [Applause.]

21 DR. SCOTT: So we are going to open it
22 now to questions from the panel to Kim. Are there

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1 any questions from the panel?

2 Okay. So we will go on to the next
3 speaker. The next speaker is Dr. Cristina Chambers
4 and she is going to give her perspective from the
5 Teratogen Information Service. Dr. Chambers is a
6 professor of pediatrics from the University of
7 California, San Diego and also a member of the
8 Organization of Teratology Information Specialists
9 Collaborative Research Group.

10 MS. CHAMBERS: Thank you. So I am going
11 to talk about recruitment, retention and
12 communication from the OTIS Mother to Baby
13 Pregnancy Studies perspective.

14 And this is the various companies which
15 we receive research funding from for the studies
16 that we do.

17 For those -- I think most of you in the
18 room probably know something about the
19 Organization of Teratology Information
20 Specialists. Now with our more consumer-friendly
21 name Mother to Baby Services. The first service
22 was established in the late '70s. And in the mid

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1 '80s we formed a network of these services that
2 covers the U.S. and Canada with about 13 active
3 sites in the U.S. and Canada that are part of the
4 network for providing service.

5 We provide toll free typically telephone
6 information to pregnant women and health care
7 providers regarding the safety of medications and
8 other exposures, vaccines and chemicals and
9 occupational exposures and infections and so on
10 during pregnancy and breast feeding. And this is
11 done on a national routing system basis so that a
12 woman who lives in a state where there isn't a
13 service can be routed to a service where she can
14 get that information or a provider as well. We
15 respond to approximately 80,000 to 100,000
16 contacts via phone or other methods each year in
17 English, Spanish or French.

18 The newest service was just added last
19 year in 2013 so we are happy to see the group
20 growing and this is the Mother to Baby Georgia
21 services that opened in Atlanta at Emory
22 University and provides service to the State of

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1 Georgia.

2 Mother to Baby pregnancy registries
3 conducted by the Organization of Teratology
4 Information Specialists are conducted in one way
5 through the OTIS research center, a collaborative
6 research center that was established at UC San
7 Diego in 1998 initially with the ARAVA Pregnancy
8 Registry and we currently conduct U.S. and Canada
9 wide cohort studies that meet pregnancy registry
10 commitments or requirements.

11 And we also conduct the cohort arm of
12 the Vaccines and Medications in Pregnancy
13 Surveillance System or VAMPSS in collaboration with
14 the American Academy of Allergy, Asthma and
15 Immunology and the Slone Epidemiology Center of
16 Boston University. And you will hear some more
17 about that tomorrow from Alan Mitchell.

18 The basic design of the Mother to Baby
19 Pregnancy Registries is shown on this slide. So
20 in terms of recruitment what we do is have
21 individuals or services or sponsors or other
22 methods whereby a provider or a pregnant patient

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1 or a person planning pregnancy is referred into
2 the OTIS research center. And those -- a variety
3 of referral sources hear about the studies that we
4 are conducting and if a patient or provider has a
5 patient who might qualify or be interested in
6 participating in the study we require that the
7 mother herself be the person who is ultimately
8 routed to the research center. And at that point
9 she is screened by trained interviewers who
10 determine if she qualifies for one or more studies
11 that we're conducting. And then in turn
12 determines if she is willing to participate in
13 that study.

14 And if she agrees to participate she can
15 be recruited typically into one of three cohorts,
16 a group of women who have taken the medication or
17 received the vaccine of interest some time during
18 pregnancy and meet the recruitment criteria for
19 that cohort. If it is a medication used to treat
20 a disease we typically have a disease matched
21 comparison cohort where women are recruited who
22 have the same underlying disease or diseases but

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1 have not taken the medication of interest. And then
2 we typically have a healthy comparison group of
3 women who contact, typically these come through
4 the Mother to Baby Services so women who don't
5 have the disease or haven't taken the medication
6 or haven't received the vaccine but are recruited
7 in the same manner followed in the same manner as
8 the other two groups throughout pregnancy.

9 Women in all three groups participate in
10 multiple maternal interviews that take place up to
11 four times during pregnancy. If there are
12 underlying diseases involved we typically do have
13 an assessment at least two time points during
14 pregnancy of disease activity or disease severity.

15 And then all women in each of the groups
16 are followed through the outcome of pregnancy and
17 an outcome interview is conducted. Medical
18 records are requested and reviewed. And the
19 standard is that the children, live-born infants,
20 are followed up to one year. For some studies the
21 follow up is as long as five years. And for many
22 of the studies depending on the drug or disease we

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1 also have incorporated a specialized physical
2 examination by one of the study pediatricians,
3 geneticists, who actually travel to see the live-
4 born children wherever they live in the U.S.

5 or Canada and infant photographs are
6 taken in those cases as well.

7 The recruitment strategies that we've
8 used, many of these have already been mentioned,
9 ones that target both patients and providers are,
10 and of course we rely heavily on spontaneous
11 callers to Mother to Baby Services. And we also
12 ask those services to do outreach in their
13 catchment areas so that they contact providers,
14 clinics, locations where potential participants
15 might be identified and referred who might not
16 otherwise contact a service.

17 And we have identified some additional
18 clinical referral sites that aren't locations of
19 Mother to Baby Services where pregnant women are
20 seen, either high risk or routine OB care and they
21 proactively refer to us as well.

22 We ask Pharma sponsors for various

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1 studies if they receive contacts from pregnant
2 patients or providers with the exposure of
3 interest through medical information or safety or
4 through their medical liaisons that they refer to
5 us as well.

6 We recruit through our website, through
7 the FDA Office of Women's Health website,
8 Clinicaltrials.gov, and we provide marketing
9 materials, brochures and so on for providers but
10 also posters and brochures that appeal directly to
11 consumers that providers can distribute in their
12 offices.

13 And we are using, and I will talk about
14 this in the next slide or two, on a pilot basis an
15 electronic medical record best practice alert
16 mechanism for obtaining and facilitating referrals
17 from obstetricians.

18 We also recruit through Mother to Baby
19 fact sheets which are simple two-page two-sided
20 question and answer descriptions of what is known
21 about a particular drug or a disease in pregnancy.
22 And we produce those across the network and post

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1 them on the website. And make sure when we have a
2 new drug under study that we produce a fact sheet
3 for that drug and those are heavily downloaded
4 from the website. And each one of those has the
5 contact information for the pregnancy registry.

6 We also receive contacts from providers
7 and patients where the patient is not yet pregnant
8 so maybe planning pregnancy or considering
9 pregnancy and she may wish to enroll in a future
10 pregnancy and so as part of the Mother to Baby
11 Registry those patients are tracked and if they give
12 permission we re-contact them to see if they do
13 become pregnant.

14 I mentioned the fact sheets. This is
15 just a screen shot of the website that shows the
16 beginning of the list of fact sheets that are
17 available in English and Spanish and some in
18 French and as I said are heavily downloaded in our
19 source of recruitment for pregnancy registries.

20 And then I mentioned our pilot basically
21 because we are doing this at UCSD through the
22 electronic medical records system that exists

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1 there in reproductive medicine. And what we did
2 was initiate a best practice alert in the EMR so
3 that when the obstetrician sees a patient for a
4 prenatal care visit he or she gets a best practice
5 alert saying this patient may benefit from
6 receiving counseling about the medications or
7 other exposures that they have had or may have in
8 pregnancy. And if the physician accepts then we
9 automatically get that referral to our Mother to
10 Baby Service. And the patient also on the patient
11 visit summary gets a printout that indicates that
12 they have been referred to the Mother to Baby
13 Service. And the clinician has an opportunity to
14 explain to the patient why they have made this
15 referral.

16 We then in turn contact the patient so
17 that gives us permission to contact the patient
18 without having to wait for them to contact us to
19 provide them information about any exposures that
20 they may have had and also to determine if they
21 would be interested in or qualify for
22 participating in a study. And the information

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1 that's provided to the patient is then summarized
2 and put back in to the EMR so that the provider
3 when they next see the patient can see what the
4 summary of that encounter was.

5 And we've expanded this a little bit in
6 the last year to see if this sort of mechanism
7 would work with women of reproductive age who are
8 not pregnant but who have the potential to become
9 pregnant. So we have piloted this in Family
10 Medicine, expanding it to Internal Medicine and
11 Adolescent Medicine where the best practice alert
12 comes up on the basis of a prescription that is
13 being written or refilled for a woman of
14 reproductive age where the drug is a known human
15 Teratogen but certainly has the potential for
16 being more broadly instituted for medications or
17 vaccines that are under study for pregnancy
18 registry. And that has been successful in our
19 local setting as well.

20 So the variety of types of locations
21 where Mother to Baby Services are located and our
22 active referral sites includes primarily OB/GYN,

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1 pediatrics and genetics departments in university
2 or hospital or department of health settings. The
3 active clinical referral sites that are not Mother
4 to Baby Service locations are Georgetown
5 University, University of New Mexico, Kaiser
6 Southern California and we are just establishing a
7 new clinical referral site at University of
8 British Columbia.

9 Recruitment strategies that are
10 specifically targeted to providers over and above
11 the ones I just mentioned include professional
12 print media which we think is pretty much a waste
13 of time and money. We do professional
14 organization emails to members of these
15 professional organizations and website
16 information. And this is particularly facilitated
17 by the American Academy of Allergy, Asthma and
18 Immunology to their professional members.

19 We do quite frequently direct mailings
20 to physicians and other providers who see the
21 patients that we are targeting for recruitment to
22 give them updates on the study, provide them with

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1 brochures and let them know that we are still
2 interested in referrals of patients.

3 We do the exhibits at multiple
4 professional meetings and present abstracts as
5 appropriate. The contact information, of course,
6 is typically in the pregnancy label. And then
7 resources that professionals use like Briggs,
8 Drugs in Pregnancy and Lactation and Reprotox
9 will typically list the pregnancy contact
10 information for the registry in that drug
11 monograph.

12 And then the Mother to Baby website is
13 also used or provides an opportunity for providers
14 to refer via the website a patient without having
15 to try to find the phone number and try to contact
16 us. They can do this using a secure referral
17 mechanism via the web.

18 For patients over and above the
19 strategies I just described we also do extensive
20 paid print, web and radio advertising on heavily
21 used sites like Babycenter.com, advertise in
22 Pregnancy and Newborn Magazine, we get some unpaid

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1 media coverage through distributing press releases
2 and other types of coverage. We partner with
3 agencies such as WIC to disseminate information
4 about pregnancy registries. And we partner with
5 patient supported advocacy groups and professional
6 practice groups, so the Crohn's and Colitis
7 Foundation is in an active partnership with us now
8 to proactively recruit through their database,
9 National Psoriasis Foundation and so on.

10 We also do direct to consumer
11 recruitment through the Mother to Baby website and
12 through social media such as Facebook, Pinterest,
13 Google ads and so on. And this is an example of
14 the website that is patient focused that describes
15 the studies that we are doing and includes a page
16 that also tells the potential participant what it
17 means to participate in the pregnancy registry and
18 what the benefit might be and how it might help
19 others in the future.

20 And this is a screen shot of the
21 Facebook page with about 10,000 fans and this is
22 our newly launched Pinterest page.

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1 The challenges and barriers to
2 recruitment, some of these have already been
3 mentioned. Certainly for providers we think the
4 biggest barrier is knowing and remembering when,
5 where and how to make a referral. So specialty
6 physicians may not often see a pregnant patient
7 and OB/GYNs may not often see a patient who is
8 exposed to the target medication or the vaccine.
9 So playing both sides of those barriers is a
10 challenge.

11 For patients it is the same thing;
12 knowing that the study exists is the major barrier
13 if their provider tells them or not or if they
14 hear about it on the internet. And certainly as
15 we have heard before this certainly can affect
16 diversity and may contribute to a selection bias
17 in terms of those who do know that the study does
18 exist and then in turn enroll.

19 Following through on a referral if the
20 provider does make the referral is an issue as
21 well, a barrier to recruitment because we know
22 that there is a big gap between the referral being

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1 made and the woman actually taking the initiative
2 to make the phone call and contact the registry.
3 So we do everything we can to try to encourage
4 that the provider obtains permission for us to
5 contact the patient rather than asking the patient
6 to initiate the contact.

7 We survey women who come to us who have
8 qualified for the study or appear to qualify but
9 decline to participate and ask them if they will
10 provide us the reasons why. And the two top
11 reasons are time needed to participate and
12 reluctance to release medical records which we
13 heard earlier today.

14 The time needed to participate I think
15 we need to learn a little bit more about that
16 because it is not a defined response. So we don't
17 know whether the objection is that over the course
18 of pregnancy this is going to take three hours of
19 their time and they would be okay if it took 90
20 minutes of their time or if it is just that it
21 seems like it is an overwhelming thing to take on
22 when you are already dealing with a pregnancy and

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1 everything else in life.

2 The reluctance to release medical
3 records I think is a real concern and is something
4 that we have seen I think increase over the years
5 in terms of that being stated as a reason for not
6 wanting to participate.

7 In terms of retention, the second topic,
8 I think we are lucky that once we get a person
9 enrolled in the study that we've had really great
10 experience of all the various studies that we've
11 enrolled participants in through this process over
12 the years. Our losses to follow up have averaged
13 five percent or less. It certainly varies from
14 study to study and varies depending on which group
15 the woman is in but overall our loss to follow up
16 rates have been quite low.

17 And we attribute this to a number of
18 different factors but the primary thing we think
19 as has been mentioned before is that mothers are
20 always the enrolled registry participants and that
21 is important for scientific reasons in terms of
22 getting accurate exposure information. But we

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1 think that having the mothers as the individual
2 who is enrolled in the registry makes a huge
3 difference in terms of retention.

4 As we mentioned we do up to four
5 telephone interviews during pregnancy and so there
6 is a relatively short interval between participant
7 contacts. So we develop sort of a frequent
8 interaction with the participants which we think
9 aids in retention. Women who are enrolled with us
10 have ready access to Mother to Baby counseling
11 services. So as their pregnancy progresses if they
12 have a question about an antibiotic they have to
13 take or they just you know sprayed their house for
14 fleas or whatever they know they can call and get
15 information about that exposure and have sort of
16 their personal counselor available.

17 We think that rapport does develop
18 between the participant and the study interviewer
19 over the course of the pregnancy and in the at
20 least one year follow up. And we try to make it
21 as easy as possible for participants so not
22 hounding them with phone calls to set up a

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1 telephone interview. We try to offer alternative
2 methods of contacting them via email or text to
3 set up appointments to call.

4 Other retention strategies ones that are
5 used in epidemiologic studies all the time that we
6 have tried to get multiple other family and
7 friends contact information in case the
8 participant can't be located.

9 We staff to allow as best we can
10 interviewers to contact participants outside of
11 regular business hours, evenings or sometimes even
12 weekends. And we are testing opportunities to
13 offer alternative methods for some data
14 collection. So our interviews sometimes can be
15 depending on how many exposures the woman has in
16 her history can be 45 minutes long. So we are
17 testing in one situation now doing an additional
18 asthma survey where the mother is offered the
19 opportunity to be able to complete the survey at
20 the tail end of the telephone interview or she can
21 opt to do it via secure web process. And so we
22 will look to see what's the uptake in terms of

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1 opting for the secure web survey and then how many
2 of those are completed from among those who accept
3 them.

4 The physical examination of live-born
5 infants although it certainly has some important
6 scientific advantages it is labor intensive and
7 expensive but we think it serves as a retention
8 strategy as well that patient's families really
9 look forward to this and anticipate it when it
10 takes place in the first year of life and they
11 look forward to the feedback that they receive
12 from the exam.

13 And a much more remote retention
14 strategy is study results which as we all know
15 don't come around as quickly as we would like but
16 publications are sent to participants as sort of a
17 concrete evidence of what their participation
18 produced.

19 Challenges and barriers to retention
20 primarily the time burden for pregnant women and
21 new mothers to complete all the parts of a study.
22 And this is true on one end of the spectrum for

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1 very complicated pregnancies where the women are
2 just overwhelmed. And then I think on the other
3 end of the spectrum too for very uncomplicated
4 pregnancies for example unexposed healthy
5 comparison pregnancies where maybe the motivation
6 wanes over time to complete study participation.

7 I don't know whether this plays a role
8 in retention but we have not typically used
9 participant monetary incentives. The rationale
10 for women enrolling in the study is altruistic by
11 and large. But it is something that is worth
12 testing.

13 Communication strategies and this has
14 been discussed a lot earlier today that
15 communication to providers is greatly simplified
16 if the registry design is disease based. So even
17 though we really don't have a disease based
18 registry for example for autoimmune diseases we
19 have a series of pregnancy registries that really
20 as a group comprise a multiple disease based
21 registry.

22 We try to spin this so that providers

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1 see it as a disease based registry and so rather
2 than them having to think does my patient take
3 this drug or that drug for this disease that they
4 are encouraged to refer patients who have the
5 disease regardless of the medications that they
6 are using to treat that condition. And this
7 simplifies greatly knowing who to refer. It
8 certainly encourages referral of patients who
9 qualify for that disease match comparison group.
10 And as a side benefit of this it adds important
11 knowledge about the contribution of the disease to
12 pregnancy outcomes as was mentioned by one of
13 those who made public comments.

14 In terms of communications to patients
15 and providers about the existence of the registry
16 we think this is facilitated by the use of one
17 contact number. It certainly would be optimum if
18 pregnancy registries involved one contact number
19 period. But certainly for the ones that we do we
20 utilize the same toll free number since 1998 and
21 we think that that helps with communication.

22 Just as an example of one of the side

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1 benefits of doing something that is ultimately a
2 disease based registry we've been able to produce
3 some information about factors that contribute to
4 adverse pregnancy outcomes in women with an
5 underlying condition for which we are studying
6 multiple medications used to treat that condition.

7 Challenges and barriers to communication
8 this again has been discussed. We struggled with
9 this issue but for scientific reasons generally
10 speaking the release of data in Mother to Baby
11 studies with consultation of the advisors is
12 typically held until the end of the study or time
13 point at which a formal analysis can be conducted.
14 And this is driven of course by sample size either
15 requirements or having met a sample size that the
16 advisors and the investigators agree meets the
17 objectives of the study to the extent that they
18 can be met and allows adjusted analyses. So this
19 in turn, of course, can lead to time delay in
20 availability of final results for some registries
21 depending on how often the product is used and if
22 it is infrequently used by pregnant women it can

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1 delay release of information of the final study
2 results for a longer period of time.

3 So in terms of future directions I
4 wanted to mention a couple of things about
5 addressing recruitment challenges which I think
6 are the major issue at least for our pregnancy
7 registries. We think that this facilitated
8 referrals through electronic medical records best
9 practice alerts our experience has been that this
10 works and that its I believe a huge benefit for
11 clinicians and could certainly be expanded across
12 many, many settings where EMR regardless of what
13 the proprietary product is can easily be adapted
14 to do this.

15 In terms of women who decline because of
16 lack of time or reluctance to release medical
17 records we've considered the possibility of
18 offering a two tiered level of participation so
19 that women who would not enroll because they don't
20 want to spend the time or release medical records
21 but might be willing to enroll if they could do
22 one interview and one outcome interview and didn't

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1 have to release medical records; would that be
2 worthwhile? So is that information gained that we
3 would otherwise miss certainly introduces
4 complexities into the analysis and the sample
5 size.

6 And then we are testing the impact of
7 monetary incentives in a new study that we are
8 taking on to see if there is evidence for an
9 increased participation rate; is there evidence
10 for increased diversity in women who enroll in the
11 study based on the incentives. An important flip
12 side of that is does it negatively impact
13 retention. So if women would not otherwise enroll
14 if they didn't have the incentive; does the
15 incentive keep them in the study as well?

16 And then finally we would like to
17 increase electronic patient driven collection of
18 selected data that we think can be reliably
19 collected and validly collected using methods such
20 as a participant's personal web portal for some
21 information that we now spend time on the
22 telephone collecting or we ask the participant to

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1 complete on paper such as the pregnancy diary.

2 We'll end there. Thank you.

3 [Applause.]

4 DR. SCOTT: So are there any clarifying
5 questions from the panel for Dr. Chambers?

6 Trinkka.

7 MS. COSTER: Yeah. Listening to this I
8 was just you know all of a sudden I became aware
9 of actually holding records and I haven't heard
10 anybody say like and then when do you destroy
11 them. And then the second question I presume you
12 have all the HIPAA requirements so if you release
13 or if you are hacked in then you have to notify
14 everybody and tell them about that that their
15 personal information has been released. So same
16 rules and --

17 MS. CHAMBERS: Right. Right. Diana
18 could tell you way more the specifics but yes
19 medical records, we consent participants to the
20 retention of medical records indefinitely and we
21 have a whole separate HIPAA consent process that
22 goes along with consenting into the study for both

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1 the mother and the child. And yes the set of
2 rules that go along with that about protection of
3 privacy.

4 MS. BELINER: Can you explain more about
5 the EMR thing that you are doing. So I think I
6 heard you say that the doctor asks the patient if
7 they want counseling. And then if a patient
8 agrees then you transfer the patient's information
9 so is that all HIPPA compliant. And then also
10 well answer that one.

11 MS. CHAMBERS: Yes. And it is partly
12 because we are in the same institution that that
13 was easier to do. So we are in the same covered
14 entity. And the consultation that the provider is
15 asking for is for us to provide information to
16 their patient about any of the exposures that
17 their patient has had. So the trouble we have with
18 clinicians is you know they go through the list
19 and they say well maybe she needs to know about
20 this or maybe she needs to know about that. So I
21 think that they are thrilled with having the
22 opportunity to just say you talk to them to figure

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1 out what it is that they need to hear about,
2 provide us back with the information because they
3 don't want to be left out of the loop. They want
4 to know what we told them so they can then act on
5 it or follow up on it. But that also works well
6 for us just like it does if somebody comes in from
7 a provider referred over the telephone from
8 another institution; it works well for us to then
9 be able to say after we've provided the
10 counseling, would you be interested in hearing
11 about some of the research projects that we do.

12 That system doesn't necessarily have to
13 work that way. And actually the way that I
14 described it for non-pregnant women but who have
15 the potential to become pregnant, it can be set up
16 so it specifically targets you know the 50 drugs
17 that you are interested in looking at and the
18 alert only comes up for those. And then that alert
19 can make the referral specifically to hear about a
20 pregnancy study if the patient accepts; and if the
21 patient accepts, then it is a done deal. So it
22 works beautifully. And there really isn't any

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1 reason other than getting beyond whatever the
2 firewalls are and doing this with Kaiser or doing
3 it elsewhere that it couldn't work other places at
4 least in my opinion.

5 MS. BERLINER: No I think it is
6 interesting because one of the public commenters
7 also mentioned something about linking the
8 registries to the EMR systems. And so do you know
9 how many of your referrals come through that way
10 versus all the other ways that you've talked
11 about?

12 MS. CHAMBERS: It works beautifully for
13 common exposures like vaccines; so lovely if you
14 know 20 to 50% of women are receiving a vaccine.
15 It works for less common exposures. For something
16 that is an extremely rare exposure say for example
17 at our institution if there are 5,000 pregnancies
18 a year, the likelihood that we are going to come
19 up with very many exposures to one category X drug
20 that is used by .001 percent of pregnant women is
21 low. But for something that falls in the mid like
22 for psychiatric medications, for things, asthma

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1 medications it works quite beautifully.

2 DR. SAHIN: So this morning Dr. Holmes
3 had presented data where he showed that when there
4 is a physical examination done by one physician
5 that the outcome -- that the malformation rates
6 are different than when you look at medical
7 records. So have you had the same experience with
8 your dysmorphologist doing the examinations of all
9 the infants compared to your studies where you get
10 medical records?

11 MS. CHAMBERS: So that is a really good
12 question. And I think Lou Holmes is the inventor
13 of that topic. I think and Diana can speak to
14 this. The major value and why we include the
15 physical examination is with small sample sizes to
16 be able to say that we've had this careful
17 evaluation of children to look at whether or not
18 there is a specific pattern of minor malformations
19 which are completely unreliably abstracted or
20 recorded in medical records. And so to do that
21 requires the physical examination in a blinded
22 fashion by a study trained pediatrician; and that

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1 is the major purpose of it.

2 As a an additional benefit it certainly
3 is a mechanism whereby we can validate that if the
4 child does have a major malformation that is the
5 one that the pediatrician or whoever the health
6 care provider is says that the baby has.

7 And there is and Diana can say -- I mean
8 there is the odd situation where it turns out that
9 the diagnosis was wrong by the local pediatrician
10 and that is part of the engagement with the parent
11 that the pediatrician then goes over this with the
12 parent, says what were you told by your doctor,
13 and then they give permission to contact the
14 physician and it all gets squared away. So there
15 is a benefit to the parent of having this extra
16 specialist see the child.

17 In terms of it increasing the number of
18 birth defects I don't know -- I don't think,
19 Diana, that that is the case. Diana is the one
20 who looks at these things day in and day out that
21 there are not very many situations where the
22 specialist exam picks up a birth defect that

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1 wasn't already noted as some kind of birth defect
2 previously by either maternal report of the
3 medical records. Do you think that is fair to
4 say, Diana?

5 MS. JOHNSON: Yes. It's happened a few
6 times but it is not something that frequently
7 happens. And our study physician reviews all of
8 the medical records for coding purposes of the
9 major malformations. So that helps as well.

10 MR. IYASU: Could you comment on the
11 different groups in your study for example, there
12 is exposed group, you have the disease matched,
13 and then you have also the healthy comparison. So
14 if you are looking at recruitment strategies and
15 all the other parameters in terms of retention,
16 your loss to follow-up; can you comment on what the
17 drivers have been for enrollment for the different
18 groups and if there is differences as to
19 retention. I mean you talked about the 5% or
20 less than 5% loss to follow up.

21 MS. CHAMBERS: Uh-huh.

22 MR. IYASU: So how do you balance out

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1 all this and --

2 MS. CHAMBERS: Good question. So
3 clearly there are different drivers for different
4 people. But as I think was mentioned previously
5 by Elise that women may be anxious about the
6 medication that they are taking but I think they
7 do understand that they are not going to help
8 change the outcome of their pregnancy by
9 participating in the pregnancy registry. What they
10 are going to change is the outcome -- or the level
11 of anxiety that women, their sister or their
12 friend, or the next person down the line who
13 becomes pregnant and either has to take this
14 medication or has inadvertently become pregnant
15 what they have to deal with and their clinician
16 has to deal with in trying to understand what is
17 the best thing to do. And that is palpable at the
18 time that they enroll; that that is so important
19 to them that they be able to make that better for
20 the next person who comes along.

21 And I think that is true in the disease
22 matched group as well because the way that it is

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1 presented to them is we need to learn more not
2 only about drug X, Y, and Z but about the disease
3 that you have in pregnancy. And it is true I
4 think for multiple sclerosis and for many diseases
5 that when you scour the literature not a whole lot
6 is known about the disease itself and disease
7 activity and how that contributes to pregnancy
8 outcome. So I think the level of motivation maybe
9 for a little different reason may be different in
10 the two groups but the exposed and disease matched
11 group pretty similar reasons for participation.

12 The people in the healthy comparison
13 group are just the golden people of the world
14 because they are willing to do this to help other
15 women because they don't have the condition. They
16 don't have a very complicated pregnancy but they
17 can appreciate the anxiety that people feel and
18 they are likely will have to take a few
19 medications in pregnancy as well and so do it for
20 altruistic reasons.

21 In terms of how that affect retention I
22 think there is a little bit higher loss to follow

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1 up in the healthy comparison group and that is I
2 think sort of to be expected. But certainly not -
3 - we are never in the 20% range, we can be down in
4 the 8% range for healthy comparison women. And in
5 the exposed and disease matched group once they
6 are enrolled the retention rates are just
7 excellent.

8 DR. SCOTT: Thank you. So we are going
9 to move on to the next presenter. The next
10 presenter is Dr. Michael Greene. He is going to
11 give an Obstetricians' prospective. And Dr. Greene
12 is professor of Obstetrics, Gynecology and
13 Reproductive Biology at Harvard Medical School.
14 Thank you.

15 DR. GREENE: Thank you. Thank you very
16 much Dr. Sahin especially for this invitation. My
17 credentials here come from --. So these are my
18 disclosures.

19 My reason for being here is that I'm an
20 actively practicing obstetrician. I see pregnant
21 women every week. And I'm trying to bring you the
22 perspective from, if you will, the obstetrical

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1 trenches to the Food and Drug Administration.

2 These are my disclosures.

3 The next several slides are just a quick
4 run through of the electronic medical record
5 screens that we complete as we see a new patient.
6 First establishing a current pregnancy dating, how
7 did the patient become pregnant? Was it regular
8 pregnancy? Was it an assisted reproductive
9 technology, et cetera?

10 This is her past obstetrical history if
11 she has one or if she is a primigravida we skip
12 that page.

13 This is a review of the patient's past
14 medical history which is fairly extensive and when
15 we create an electronic medical record like this
16 we have to balance having a lot of blank pages
17 versus prompting functions. So we try to make the
18 menus that appear for each of these disease
19 classifications or disorders that are specific to
20 not only women but also women of the pregnancy age
21 group.

22 This is information that is unique to a

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1 prenatal record. Some of the other information
2 that you are going to see is generic for any
3 electronic medical record whether a patient is a
4 male or a female, pregnant or not. But this is
5 more specific for pregnant women; that information
6 that an obstetrician needs to accumulate to
7 provide proper care for the patient.

8 Family history is generic, history of
9 past procedures, surgeries and other procedures
10 that are germane.

11 A physical examination needs to be
12 completed. Complete physical exam.

13 And then finally the care and feeding of
14 a problem list which providers can use to keep
15 track of a patient's problems to make sure that
16 they are addressed appropriately during the course
17 of prenatal care.

18 The content of the first visit and these
19 slides are borrowed very heavily from the
20 guidelines for perinatal care which is a joint
21 publication produced collaboratively by the
22 American College of Obstetricians and

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1 Gynecologists as well as the
2 American Academy of Pediatrics. The
3 most recent edition is the 7th and was published
4 in 2012. But this specifies the scope of care
5 that is a part of prenatal care for every patient:
6 that at the first visit the doctor should discuss
7 the scope of care or a midwife, whoever the
8 provider is; laboratory studies and their
9 indications; the expected course of the pregnancy;
10 signs and symptoms to be reported; roles of the
11 members of the health care provider team;
12 anticipated schedule of visits; whether the MD. or
13 a certified nurse midwife will be scheduled for
14 labor and delivery and what that coverage
15 entails; the cost to the patient of prenatal care
16 and delivery which is as we are learning more and
17 more every day is almost an unknowable number;
18 practices to promote health care and health
19 maintenance; psycho-social topics in pregnancy and
20 post-partum period; the content of the psycho-
21 social risks screening; and counseling includes
22 assessing the desire for pregnancy, wantedness for

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1 pregnancy has been well known as an important
2 determinate of ultimate pregnancy outcome; issues
3 with respect to substance use and abuse, tobacco,
4 of course, being the only substance that when used
5 according to direction leads to death, but as well
6 as alcohol, mood altering drugs et cetera; issue
7 of clinical depression; and intimate partner
8 violence. This is from AHRQ. There was a credit to
9 AHRQ on the original slide as submitted. I see it
10 is missing from this slide but anyway but anyway
11 this is from AHRQ about counseling with respect to
12 tobacco.

13 This is a slide lent to me by my
14 pediatric colleague, Dr. Leslie Kerzner, which is
15 simply a collection of recent front page articles
16 from the Boston Globe about issues with respect to
17 neonatal abstinence syndrome and the increasing
18 frequency of neonatal abstinence syndrome. The
19 Department of Children and Families in
20 Massachusetts has been under tremendous scrutiny
21 recently for some very high profile deaths of
22 children supposedly under protection of DCF but

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1 who were with parents and did not do well or died.
2 Neonatal abstinence syndrome is increasing. This
3 is data through 2009 and this rate has continued
4 to rise. This was a recent article from the
5 Boston Globe again on the incidences of neonatal
6 abstinence syndrome and babies "born with drugs in
7 their system" at one of our local hospitals. This
8 is a community hospital where most people would
9 not expect large numbers of babies to be born with
10 "drugs in their systems". But it is a common
11 problem and all of these issues need to be
12 addressed. This is a very high profile case in
13 Massachusetts which actually was just resolved
14 yesterday with a guilty plea. Intimate partner
15 violence is a serious issue. All of these issues
16 are important. None of them can be dismissed.

17 In addition to the issues with respect
18 to counseling at the initial visit all of these
19 laboratory studies need to be ordered. And they
20 need to be discussed with the patient after they
21 have returned. Yet more laboratory testing
22 recommended for all or most patients.

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1 Indications for first trimester
2 ultrasound examination need to be reviewed by the
3 provider. And if appropriately indicated to be
4 ordered and obtained.

5 There is rapidly expanding indications
6 for screening for diabetes. The latest
7 recommendations if taken literally according to
8 some of the agencies that have made these
9 recommendations could lead up to 17 or 18% of all
10 pregnant women being diagnosed with gestational
11 diabetes.

12 In addition first trimester counseling
13 should include information about nutrition and
14 weight gain, avoidance of food borne infections
15 such as Listeria and Toxin, exercise, dental care,
16 nausea and vomiting of pregnancy, obviously a very
17 common symptom, vitamin and mineral toxicity
18 including mercury and fish intake, avoidance of
19 teratogens, air travel, prenatal diagnosis.

20 This is from the Food and Drug
21 Administration's own website about issues with
22 respect to mercury in fish including a list of

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1 fish to be avoided that the health care provider
2 should review with the patient.

3 These are the ethnic background issues
4 that should be kept in mind with respect to
5 screening for a variety of genetic disorders and
6 women who should be screened. The American
7 College some years ago crossed the river and
8 recommended that all pregnant women regardless of
9 age should be offered screening for Down syndrome
10 and that process of screening for Down syndrome is
11 one that has changed very rapidly in recent years.
12 This has been a case of fasten your seatbelts
13 because the technology for screening has advanced
14 way quicker than most obstetricians knowledge and
15 understanding of the technology.

16 So this was a paper in Nature in 2012
17 discussing the fact that fetal genes can be
18 detected in maternal blood using cell-free DNA
19 technologies and seemingly overnight no less than
20 four companies appeared in the United States
21 offering this cell-free fetal DNA technology which
22 has been a leap in prenatal diagnosis.

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1 And this is the inevitable slide that I
2 always get out of order but this is Institute of
3 Medicine Guidelines for weight gain which was
4 pertinent to one of the previous slides. And I
5 apologize it is out of order.

6 And just a couple of months ago the lead
7 article in the New England Journal of Medicine was
8 about the new DNA sequencing versus Standard
9 Prenatal Aneuploidy Screening demonstrating
10 superiority with respect to the number of false
11 positives and false negatives with modern prenatal
12 screening using cell- free fetal DNA in the
13 maternal circulation which is non-invasive and
14 something that encourages many more women to
15 request prenatal diagnosis.

16 So the point of presenting the preceding
17 slides is to help you appreciate that obstetrical
18 health care providers are under constant pressure
19 to provide an increasingly wider array of health
20 care services within the context of obstetrical
21 care while simultaneously holding the line on or
22 reducing health care expenses.

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1 The consequences of this expanded
2 definition of routine obstetrical care include a
3 rapid expansion of the knowledge base needed to
4 practice obstetrics and hence as Tina was saying
5 their obstetricians are only too eager to enlist
6 the help of any ancillary personnel, genetics
7 counselors and others, people from Teratogen
8 Information Services to assist with counseling for
9 their patients and decreasing time available to
10 address each of the individual elements of care.

11 In my time as the chair of the committee
12 on OB practice some years ago before my colleague
13 Dr. Ecker, it was a common occurrence for various
14 interest groups who had legitimate concerns about
15 things that we needed to bring to the attention of
16 our patients, about things that we needed to
17 attend to for and on behalf of our patients, to
18 bring these issues to our attention. And each one
19 of them was worthy and important and couldn't be
20 dismissed. And each one only took four or five
21 minutes. But that gobbles up an hour pretty
22 quickly.

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1 Any system I think that depends entirely
2 on obstetrical clinical care providers to identify
3 women taking medications for which there are
4 active registries and pair those patients up with
5 the appropriate registries is likely to result in
6 poor ascertainment and poor patient accrual.
7 Supplementary methods are needed.

8 So some potential solutions. So by my
9 count so far today I am the fourth person to
10 mention electronic medical records and their
11 potential utility in assisting with registration
12 for registries. This is a screen shot of several
13 medications that when we attempt to prescribe in
14 our electronic medical records system come with
15 some sort of warning that if this patient is
16 pregnant or is potentially pregnant think twice
17 about whether you ought to prescribe the
18 medication. As Dr. Ecker mentioned a few minutes
19 ago the electronic medical record is smart enough
20 to recognize when patients are pregnant, if there
21 is a positive blood pregnancy test in the
22 electronic medical record system and in the

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1 laboratory reporting system it knows that. And
2 these warnings are even stronger than you see here
3 which are generic for any person to whom this
4 medication is potentially being prescribed. These
5 are just some representative warning screens.
6 They are yellow lights. They are not red lights.
7 You can still pass them. But they are warnings
8 that there may be issues with respect to these
9 medications and their use during pregnancy.

10 This is the FDA's screen shot from the
11 FDA's website list of pregnancy exposure
12 registries and when I counted the number of
13 registries that were listed on the site at the
14 beginning of May when I prepared this slide I
15 counted about 58 registries that were listed. That
16 is not as you have learned today that is not 58
17 medications because many of those registries
18 include multiple medications. But there are only
19 58 registries and I would guess that if all the
20 medications were counted up amongst those 58
21 registries there is probably not more than 200 or
22 300 would be my guess although I haven't done a

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1 formal count.

2 This is the first page -- oh there is
3 the number 58, I knew I wrote it someplace. This
4 was the first page of the pregnancy registry list,
5 starting, it is alphabetical order, Abilify is A-B
6 and that leads the list and I just scrolled down
7 real quickly and cut and pasted the Ribavirin
8 Pregnancy Registry for which I serve on the
9 advisory committee. This is the first page that
10 you get when you go to the Ribavirin Pregnancy
11 Registry.

12 So what potential solutions might there
13 be. Well as already suggested again by others
14 there could be a link in the electronic medical
15 record to notify the provider if a registry is
16 available for a prescribed medication. It is not
17 too much of a leap I think to envision a situation
18 where the electronic medical record links to the
19 FDA's registry for registry sites and provides
20 information to the health care provider
21 immediately at the time of prescription of the
22 medication, often with the patient sitting right

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1 in front of him or her that provides information
2 with respect to a website.

3 A lot of things can be imagined. The
4 patient could be asked if she would like to be
5 contacted. We could put in the patient's email
6 address. We could give her an 800 number
7 depending upon how the patient would prefer to be
8 contacted; whether she would like to make the
9 initial contact or whether she would be willing to
10 have the registry make the initial contact. I
11 don't think that is too far- fetched and with
12 meaningful use as mentioned earlier again
13 everybody is going to need to be using an
14 electronic medical record. And everybody is going
15 to be doing electronic prescribing.

16 At our institution paper and pen
17 prescriptions disappeared years ago. And as also
18 many of you are probably familiar the system for
19 encouraging meaningful use will rapidly transfer
20 from a carrot to a stick. So previously you were
21 getting a bonus if you were using it. In the
22 future you will be penalized if you don't use it.

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1 And then finally as I mentioned earlier
2 and Alan pioneered this I think with the Accutane
3 Registry is that through prescription benefits
4 providers will notify patients directly when they
5 fill prescriptions. The large prescription benefit
6 providers will be able to notify patients directly
7 when they fill a prescription for a medication for
8 which there is a registry.

9 So those are a few of my thoughts.
10 Thank you for your attention.

11 [Applause.]

12 DR. SCOTT: Okay. We are going to move
13 on. And we will have clarifying questions for you
14 in a little while.

15 So the next presenter is going to be
16 Julia Beck who is going to give a patient
17 perspective on pregnancy exposure registries.

18 MS. BECK: Hi there. My name is Julia
19 Beck. And as noted I am a person who spends my
20 days at a company called Forty Weeks that I
21 founded specifically to help brands find ways to
22 develop creative strategies to connect with known

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1 expectant parents. So I spend my days engaging
2 expectant women. So you guys go lucky today, you
3 got a twofer.

4 But the story actually is a more
5 important one and that is one of being a patient.
6 And that is one of being a woman who had secondary
7 epilepsy as the result of a near death bout with
8 viral encephalitis, found herself in her mid 20's.
9 I really wanted to have children and it was scary.
10 It was a very scary time. There was not a lot of
11 information. This was the '90s, the late '90s.
12 Dr. Holmes I think I was one of the first people
13 on your registry in '98 I first got on that
14 registry. But it was scary and I was very much in
15 need of information. There was not a lot to be
16 had.

17 And so I basically vowed that once I
18 figured out how this was going to happen, how
19 information was going to be collected and shared
20 and how communities would be built to support
21 women like me who needed a solution I would
22 support all the way through. I have been.

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1 I have been participating as a media
2 voice and as counsel as best I can.

3 But to go back to how I ended up on a
4 registry in the first place; it was because I was
5 digging around and there was nothing there. And I
6 think that is a really important bit of
7 information. This was sort of early. Again think
8 of now as sort of registry 2.0. This was way back
9 when when there was hardly information to be
10 found. And I dug and I dug until I did find out
11 about the registry at Mass. General.

12 I wasn't told by an OB and I wasn't
13 certainly told by my neurologist. But I
14 participated. So the first one I registered for in
15 January when I was pregnant with my daughter who
16 is turning 16, the first one was January 1998 and
17 I participated in that.

18 I later participated in a second one
19 with my son who is turning 12 so that was 2002. I
20 think the important bit was that it really felt
21 important to try to find a way to connect with
22 other people who had the same situation, the same

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1 challenges. I think the hardest part was there
2 wasn't a lot of data yet to be given back. So it
3 felt a little less fulfilling that I had hoped in
4 the sense that there was not much for me to learn
5 from it. I don't think I got my first report
6 until -- or information shared I guess until I was
7 already pregnant with my second child.

8 But it appears to be really getting
9 pithier. It doesn't seem that there is the same
10 dearth of information. It seems that there is
11 more out there.

12 I have tried to with moderate success to
13 share the importance of this registry. I have to
14 be honest; I didn't know about the others. So you
15 got all my benefit. But I have done my best to
16 share this information with the clients that I
17 work with because really my specialty is bringing
18 my private sector clients, my for-profit clients
19 to make social responsibility and public health
20 agendas part of their marketing initiatives.

21 And, of course, this is not quite as
22 widely embraced as challenges such as work that I

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1 am doing at Ronald McDonald House or work that I
2 am doing with regard to issues of back to work and
3 breast feeding but still I share it with all the
4 magazines that I can connect with. I do what I
5 can.

6 I think though what might be interesting
7 to think about is and again, I am moving a little
8 bit away from my patient hat, a little bit over to
9 my professional hat, thinking a bit about where
10 these silos are of concentration. There is not a
11 huge concentration of young women with epilepsy
12 who are trying to conceive. You see more of a
13 concentration with anxiety and mood and depression
14 for example where there is more of a community
15 that is already openly sharing and openly engaged
16 with a conversation about concerns about staying
17 on or off meds during pregnancy and what that
18 might net.

19 With epilepsy I had no choice. It was a
20 secondary epilepsy. I had just recovered from an
21 illness. I certainly wasn't going to take a
22 chance of getting off of a med.

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1 One comment though about these
2 registries. You are all talking about something
3 that was very very important which was would there
4 be a malformation of my child. These children are
5 now older. They are teenagers and there are
6 things that they have that who knows where the
7 correlation was. And maybe that is not relevant
8 to this conversation. But I have one kid who had
9 a sensory integration disorder. I don't know. But
10 maybe it is a conversation worth extending if you
11 are able to engage these women for longer, follow
12 them for longer.

13 I am not anywhere near as qualified as
14 any of you but I do know that there is a question
15 that happens. It is a long season raising
16 children and you just -- I don't know. I don't
17 know. But they both turned out quite healthy to
18 start. So how is that?

19 I think the opportunity though to engage
20 and to share is really your opportunity. I think
21 it was Kate Ryan who spoke about the opportunity
22 for engagement and I couldn't agree with that

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1 more. I think that you are reaching people at a
2 place where they are desirous of information, they
3 are desirous of community and they are looking for
4 a way to feel connected with other individuals.
5 And that is engagement. And with that engagement
6 comes an understanding. There is almost a quid
7 pro quo they will be more willing to share with
8 you for longer period of time if you will do the
9 same with them.

10 As somebody who has been on a registry
11 and I will be forever be in support of these I
12 guess that is my biggest take away.

13 [Applause.]

14 DR. SCOTT: We have some time for some
15 clarifying questions from the panel to the
16 presenters. And let's start with questions from
17 the panel for Dr. Greene and then Julia and then
18 it can just be general. Okay.

19 Any questions --

20 MS. ANDRADE: Hi. This is Susan
21 Andrade. Dr. Greene I just had one comment. I
22 know you mentioned having an alert to identify

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1 women who might be eligible for pregnancy registry
2 and I know there is always a lot of concern that
3 there's alert overload in a lot of these systems.
4 And I am not sure if this is a question for you or
5 the group. Is there some way that these alerts
6 can kind of rise to the top so that people just
7 won't skip over them because they have already
8 seen like the fifth alert for this one patient
9 within two minutes?

10 DR. GREENE: Yes. Mike Greene. That
11 is an important issue. You are absolutely
12 correct. There is alert overload and electronic
13 medical records make it easy and foster alert
14 overloads.

15 The flip side of that, however, of
16 course, is that you know how many medications are
17 in the PDR and there are what 1200, 1600
18 medications in the Physician's Desk Reference.
19 And there are only maybe 200, maybe 300 for which
20 there are pregnancy registries so that the
21 majority of medications that a physician or
22 midwife, whoever, is going to prescribe in the

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1 normal course of events for which one of these
2 alerts will come up is going to be hopefully
3 pretty small.

4 And the other issue that I will mention,
5 the flip side is that many of the alerts are
6 inappropriate. They are false positives. And that
7 fosters ignoring alerts. Okay. Hopefully if
8 people realize that the match is good that when it
9 says Valproate and Valproate in the registry it is
10 the same thing and that is a real concern, not
11 just a close or near miss that should be
12 dismissed. So yeah there has got to be a good
13 both sensitivity and specificity of the alerting
14 system.

15 DR. SCOTT: Any other questions for Dr.
16 Greene? Any questions for Julia Beck from the
17 panel?

18 Okay. So I will just open it up for
19 general questions to any of the presenters from
20 the panel?

21 Are there any questions from the phone?

22 MS. TASSINARI: I am not sure where this

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1 question lies in all of this but we've talked a
2 lot about electronic health records. And I have
3 the sense that there are electronic health records
4 that are in UC San Diego and there are some in
5 Mass. General and there are some in all sorts of
6 different places. Is there a standard? Where is
7 the complication in us, meaning FDA, thinking
8 about encouraging a best practice for example of
9 using electronic health records and running into a
10 situation where there is the inability to cross
11 talk or the inability to expect that we are
12 getting the same standards across all of this. I
13 am not invested enough in the EHR to know where we
14 are in standardization and harmonization. I
15 wonder if you could comment.

16 DR. GEENE: This is Mike Greene. I
17 don't pretend to be an expert on the overall
18 electronic medical recordization of the United
19 States. However, there are a relatively small
20 number of commercial providers of electronic
21 health records that are coming to the surface that
22 will control the vast majority of the electronic

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1 medical record market. The degree to which they
2 are compatible is to paraphrase another public
3 official what do you mean by compatible. So most
4 of the electronic medical records will -- their
5 output will be as basically pdf files. So human
6 beings can read them. Okay. But they are not
7 necessarily defined fields that will transfer over
8 from one record to the next; so that a human being
9 reading the record will understand the record from
10 one university or one medical center to another.

11 Now the other advance that is already
12 here and getting better every day is what is
13 called natural language processing; so that
14 computers will very soon be able to read English
15 and understand it as well as or better than you
16 and me. And they will understand that what one
17 health care provider calls this and another health
18 care provider calls that are actually the same
19 thing. So that is advancing.

20 But in terms of a controlled vocabulary
21 and defined fields in electronic medical records
22 no I don't think that there is going to be a

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1 compatibility standard at least initially so that
2 an electronic medical record at UC San Diego can
3 be imported into our electronic medical record in
4 Boston and all the data is going to find itself to
5 the right places.

6 I don't think that is going to happen
7 any time soon. But it will be readable by human
8 beings.

9 DR. CHAMBERS: I can add to that a
10 little bit because we are expanding the
11 preconception one to UCLA. And so the program we
12 are trying to write the smartset for that is
13 negligible that they think they can just take what
14 has been done and they have a different system.
15 What has been done at our institution and write it
16 to fit theirs. So and I agree with Michael that
17 there is not an infinite number of types of
18 software that are used for this that potentially
19 could be done so that it applied to all of them.

20 DR. GREENE: Just one skeptical note is
21 that until it's done it isn't done. Okay. And
22 they think it is negligible but until it's done we

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1 have a lot of experience with programmers who say
2 oh this is going to be easy and two years later
3 they are still working on it. So --

4 MS. COSTER: Trinka Coster. On the part
5 about -- I guess I have a concern with the health
6 records being transferred to so many registries
7 and then kept indefinitely. And I would suspect a
8 lot of patients have problems with that just
9 because there is constantly so much loss of
10 identity.

11 And with new technology I mean why not
12 leave the records behind the firewalls where they
13 belong and use other methods to verify your
14 diagnosis such as like you are saying you could
15 put in that they had to have this exam, this exam,
16 this exam and essentially use the technologies
17 since everything is electronic anyway to gather
18 your data that way and then you are only passing
19 aggregated information rather than down to the
20 specific of birth date, social security numbers,
21 all that kind of stuff. And I was just wondering
22 if as you move forward if you would look at

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1 technology that would leave the medical records
2 behind the firewalls and just take aggregated
3 information so that you are maintaining the
4 privacy of the patients.

5 And I think if you considered that you'd
6 probably have a lot more participation because I
7 think people are concerned not only for themselves
8 but possibly for their children to have their
9 records indefinitely held could upset a lot of
10 mothers. But that is just what I am thinking.

11 MS. CHAMBERS: I think that addresses
12 the issue that we are not -- we don't really
13 understand what the barriers are. So is the
14 concern that it is something will happen five
15 years from now. Is the concern that there is
16 going to be something in the record that states
17 something about genetic disease or something that
18 wasn't part of what they agreed to release and so
19 on. So I think a better understanding of what are
20 the barriers to doing that.

21 From the standpoint of getting aggregate
22 data what we do with medical records at least the

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1 way we do it is we are abstracting very specific
2 information from those records, not just the
3 diagnosis of the birth defect but prenatal tests
4 and so on that ultimately go into the individual
5 analysis of potential confounding and exposure and
6 outcome for that patient. So being able to link
7 it to a specific patient is important which is not
8 to say that ultimately to the extent that it could
9 be de- identified, the record could be de-
10 identified once that linkage is made. So if that
11 is what you are thinking of yes I think that is
12 possible.

13 DR. GREENE: Mike Greene: One comment
14 I'd just like to make with respect to de-
15 identifying records is that Dr. Octo Barnett was
16 one of the pioneers of electronic medical records
17 starting almost 40 years ago. And he taught me
18 quite a bit. And one of the things that he always
19 said was that with five or six key pieces of
20 demographic information you can identify pretty
21 much anybody. Okay. So if you know that the sex
22 of the mother is female, you know her date of

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1 birth because you need that as an essential piece
2 of information, you know the date of birth of the
3 child, you know the sex of the child and you know
4 what the birth defect; it is very easy to identify
5 people even with de-identified data.

6 MS. COSTER: I agree with that but you
7 have to then ask do you need the exact -- can you
8 start looking at ranges or putting in algorithms
9 that switch that. And I think we certainly have
10 looked at that where you just basically put in an
11 algorithm that changes all the dates by one year
12 but it keeps all the relationships of every visit.
13 So you can do things that better anonymize. And
14 then you have to ask does it matter if I am 50 or
15 51 so you start thinking about age ranges so that
16 you are not exactly -- so I think there are things
17 we can do that actually benefit the patients
18 rather than having kind of the way we've always
19 thought just having a birth date.

20 DR. SCOTT: I have a question for Dr.
21 Chambers. In one of the morning's presentations
22 we saw data that showed that the women who

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1 participate in pregnancy registries are generally
2 well educated. And so I was curious what impact,
3 if any, did you think that the increased use of
4 these electronic data collection methods such as
5 the personal web portal that you mentioned will
6 have on the "representativeness" of the people
7 participating in the registries?

8 MS. CHAMBERS: So I think that the
9 primary goal of those kinds of approaches would be
10 to increase completion of data collection but a
11 secondary goal certainly could be to increase
12 diversity. So whatever the barriers are to
13 diversity and that is as I think Lew Holmes is the
14 one that presented some data about who
15 participates in a registry tends to be higher
16 social economic status more prevalently, not women
17 of color, and that is true for us as well. It
18 does vary by exposure. So we get more diversity
19 for some patients than others but I think that
20 exploring ways and that might be one of them that
21 might improve diversity is a goal of ours to be
22 able to do that. Because clearly not that the

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1 necessary result of the fact that these tend to be
2 higher social economic status better educated
3 women leads to false conclusions from what the
4 comparisons are that we are making but that we
5 would like to be able to make this as
6 generalizable as possible as well as increase the
7 sample size by drawing on a broader group of
8 people who might be eligible to enroll.

9 MS. TASSINARI: If we have time for one
10 last question I have one for Ms. Beck. Reflecting
11 on your commentary about your experiences trying
12 to find information and getting yourself enrolled
13 in the registry. And now in your conversations
14 with people telling them about your experiences
15 are they having the same difficulty finding out
16 about registries or have you found that it is a
17 little easier for them to get that support that
18 they need?

19 MS. BECK: Well first of all there has
20 been such a just a growth of information targeting
21 new and expectant women; right. And so the idea
22 of targeting new and expectant parents is

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1 completely in a new place than it was -- remember
2 we are talking about 1998. That is a long time
3 ago.

4 The information connection is a much
5 different currency than it was then and so women
6 are willing to work harder to find those
7 communities and again willing to be more loyal.
8 Are they still having an issue finding this
9 particular, the IDF registry? Yes. Yes, because
10 it is not aligned with other parts of the way that
11 pregnant women are being communicated to. So
12 there is an excitement to it. There is an
13 exuberance to it. There is a lot of stuff that is
14 sort of an easy way in as opposed to the rougher
15 way in. So there are a lot of opportunities to
16 connect. I talk about this all the time. Start
17 with baby names and nursery decor and you are
18 golden; right. Because there is no way to really
19 fall down there; there is no sad scary outcome
20 there. And so that is what I would tell for
21 example somebody trying to talk about nursing,
22 don't start with something hard, start with

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1 something easy.

2 But the same thing might apply to
3 talking about registry. Just on a checklist of
4 what it is you need to be thinking about as an
5 expectant woman; something as simple as that would
6 open a dialogue.

7 Does that answer the question? Yes.

8 DR. SCOTT: We have time for one more
9 question before the break.

10 Okay.

11 MS. MOYER: We are just on exact
12 schedule which is fantastic. We are going to
13 break for 15 minutes and we will resume at 3:35.

14 At that time we will start our panel
15 discussion and question and answer.

16 Thank you.

17 (WHEREUPON, a break was taken.)

18 MS. MOYER: If the panelists can please
19 take your seats.

20 DR. SCOTT: Welcome back. Can everyone
21 please take their seats? We are getting ready to
22 get started.

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1 So we are going to start the Topic 2
2 panel discussion. And we are going to focus in on
3 three questions related to enrollment, retention
4 and communication. But this time period is also a
5 time period in which the panel members can also
6 ask questions or comment on any of the materials
7 that were presented this afternoon including
8 presentations made during the public comment
9 period.

10 So let's get started with our first
11 question which is: How can enrollment retention
12 and pregnancy registries be improved? And in
13 answering or discussing this question we want you
14 to consider how do we overcome barriers to
15 enrollment; the use of enrollment and study
16 participant incentives; and then also how do we
17 minimize the loss to follow up.

18 So I would like to open up the panel
19 discussion with this question.

20 DR. HOLMES: Lewis Holmes from the North
21 American AED Pregnancy Registry. A comment on
22 informed consent as it related to enrollment. We

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1 had the same problem when we mailed a consent form
2 to women, they had great difficulty signing that
3 and sending it back which seems hard to believe.
4 But they did. So the good news was the IRB
5 allowed us to do a verbal consent. And I think
6 for pregnancy registries if you are setting one up
7 it is really the way to go because even though it
8 might seem logical that the easy, the women are
9 still pregnant, they are not involved in taking
10 care of a child, they ought to be able to receive
11 a consent form, sign it, send it back, it just
12 doesn't work. So that is an issue to help with
13 enrollment.

14 MS. BERLINER: I just want to comment on
15 Tina's presentation that the system that you
16 described it has a lot of synergy with stuff we
17 talk about at AHRQ which is really building a
18 patient centered research infrastructure. So a
19 lot of the things that Tina talked about about
20 like being a center of information for patients;
21 really considering the patients to be partners in
22 the research. I think those are all things that I

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1 think are really helpful and it shows in having
2 only a five percent loss to follow up.

3 DR. SCOTT: Dr. Greene.

4 DR. GREENE: Mike Greene. Lew can I
5 just ask you how many pages long was your consent
6 form that you sent to the patients?

7 [Laughter.]

8 MR. HOLMES: Since you work at the same
9 institution you know it is going to be eight,
10 nine, ten pages long with all these mandatory
11 paragraphs that would scare anybody to death.

12 [Laughter.]

13 MR. HOLMES: But we were running about a
14 50% sign and return rate and -- your point is well
15 taken, yes.

16 DR. SCOTT: Yes.

17 MR. MITCHELL: A couple of comments. I
18 am not sure a shorter consent would do any better
19 because then it would actually get read.

20 [Laughter.]

21 MR. MITCHELL: And there is one subset
22 of people that do read the entire --

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1 DR. GREENE: They are called lawyers.

2 MR. MITCHELL: Yes.

3 [Laughter.]

4 MR. MITCHELL: A couple of things.

5 First I got an email from Peg Honein so I am going
6 to channel Peg Honein because her cell phone or
7 whatever phone she was using was not very clear.
8 And the NBDPS study that CDC has orchestrated did
9 do -- we're involved with that as well, did do a
10 test of an incentive, a financial incentive for
11 participation in the study. And I can't remember
12 the dollar amounts, I can get them. But it turned
13 out that there was a disproportionate benefit on
14 enrollment for minority, lower SES. So there is
15 some evidence to suggest that a financial
16 incentive could actually not only benefit some
17 aspect of enrollment but could target the
18 populations that are typically underserved.

19 And then to switch gears in the
20 presentation about some focus groups for Office of
21 Women's Health which was really fascinating. One
22 of the things that struck me was one of the women

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1 said something about the word registry having a
2 negative connotation and it really made me wonder.
3 And I just throw it open to others on the panel.
4 When I think of registry independent of a
5 pregnancy registry I think of Registry of Motor
6 Vehicles, I think of people mentioned cancer
7 registries, you think of NSA; need I say more? So
8 I wonder if the word registry itself is a turnoff.
9 And has anyone explored that. I can't answer the
10 question.

11 MS. THOMAS: I know what we found in the
12 usability testing was not so much that it was
13 negative that people just would not click on it.
14 What resonated was medicine and pregnancy and
15 having those words caught people's attention and
16 that is what they were interested in. But when
17 they saw the word pregnancy registry, it wasn't so
18 much that they were turned off, it was just that
19 if you are faced with a lot of different ads, a
20 lot of different pop-ups on your computer screen
21 that might not be one that would catch their
22 attention. But I think if you package registry

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1 with terminology that would be of interest to
2 women then they would be interested. They would
3 click on it.

4 MR. MITCHELL: Well I am just thinking
5 in the shorthand and I'd really like to hear what
6 you have to say as well but in the shorthand that
7 a physician or health care provider necessarily
8 has to use if they are going to encourage women to
9 participate they are not going to -- I don't think
10 they are going to have the time to go into some of
11 these subtle distinctions. And the word group or
12 something that suggests that you are one of a
13 group of like people who can make a contribution
14 and benefit because I agree with you. I agree
15 with the other comments in our own studies as well
16 altruism is the main driver. It is remarkable how
17 altruistic people are when presented the
18 opportunity. But again I just wonder if some
19 marketing person came up with a different label.
20 And Julia --

21 MS. BECK: So the word registry actually
22 in pregnancy has to do with that wonderful gift

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1 registry that you sign up for at Babies R Us and
2 it has a whole different connotation than what you
3 are intending. And I think what Kimberly is saying
4 is right. They are clicking -- it is a
5 disconnect. And I think you are right a re-
6 labeling or a repositioning to put it in the
7 category of this is a community that I belong to,
8 there is information here for me, and there is a
9 way for me to help. I mean you could connect it
10 to Babies R Us Registry, there is a lot of
11 population there, there is no question about that.
12 But I think it is a disconnect name wise.

13 DR. SCOTT: I have a general question to
14 the panel. We talked about incentives in terms of
15 financial incentives. What other kinds of
16 incentives do you think would be helpful in terms
17 of retaining participants in pregnancy exposure
18 registries?

19 MS. BECK: So it almost circles right
20 back to what we were just talking about with
21 regard to gear. All populations regardless of
22 economics it is a whole new universe of things you

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1 need to purchase at a point of pregnancy. And
2 what would be interesting about partnering with
3 somebody to give gear instead of cash is then you
4 would benefit from their advertising, their
5 marketing, their PR.

6 They could proudly say they are
7 supporting the growth of this registry by giving a
8 diaper bag; I am making this up, a diaper bag as
9 an incentive for being a part of it. So not only
10 did you get the exposure to an incentive but you
11 also got the exposure to somebody else's marketing
12 amplification potential.

13 DR. SCOTT: Dr. Hernandez-Diaz?

14 DR. HERNANDEZ-DIAZ: I think I also hear
15 from the participants that if perhaps we were to
16 give women back more information, more access to
17 the findings that that might make them feel more a
18 part of the registry rather than just only giving
19 and not getting anything in return.

20 DR. SCOTT: Okay.

21 MS. BERLINER: Yeah. I think even like
22 having a newsletter that says here are the

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1 findings, you helped make this possible.

2

3 DR. SCOTT: Dr. Holmes?

4 DR. HOLMES: Two things. We've used a
5 raffle as a way of rewarding people. So if a
6 woman refers a friend or a family member as a
7 comparison group participant she's -- her name is
8 entered into a raffle as well as the comparison
9 person. And it is like \$400 I think they are gift
10 cards. And the odds of her actually winning this
11 are probably in the one percent range. It is like
12 after 100 women enroll then we have the raffle and
13 somebody gets that \$400 gift certificate.

14 The other issue is the newsletter.
15 We've been sending out a newsletter once a year
16 for quite some time and we see in the enrollment
17 it always ticks up significantly for both the
18 unexposed and the exposed. So and it has turned
19 out to be an effective way of keeping people aware
20 the registry exists because a lot of people if it
21 is too long an interval they will say we wondered
22 if you were still operational. So is that

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1 helpful.

2 DR. SCOTT: Thank you.

3 MS. YAO: I don't want to shift topics
4 completely but I think I have heard a lot this
5 afternoon about again the need to engage a
6 pregnant woman directly. I haven't completely
7 given up the notion; I hope not, that there is a
8 way to engage the health care providers a little
9 bit more to participate in this endeavor.

10 So this one concept has been percolating
11 in my mind for a while and I would love to hear
12 the panel's opinion on tying in some way now that
13 we have all these requirements to maintain board
14 certification with our own specialties this
15 concept of maintenance of certification or MOC
16 that I know many of us are dealing with to
17 maintain certification. And I do wonder do you
18 think there is a way to tie in the need to collect
19 these data to encourage professionals to enroll
20 them in registries with a maintenance of
21 certification because it seems like a way to
22 incentivize or encourage people to participate in

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1 the public health of their specialties. And use
2 that to allow them to maintain certification. So
3 I am throwing it out there because I would love to
4 hear what the panel thinks and whether or not we
5 should be engaging the various professional
6 boards.

7 MS. CHAMBERS: I don't get certification
8 so I can't comment from a physician's standpoint
9 but I do think that it is wrong to ignore the
10 providers. And when it comes to the provider
11 playing a role that I think our experience has
12 been that if a pregnant woman is encouraged by her
13 provider to enroll that is a huge leap up; that
14 they will do it because the provider says this is
15 a good thing to do. So it is incredibly important
16 for the provider to think that it is a good thing
17 to do. And part of that is getting -- giving
18 something back to the provider.

19 So whether it is the incentive of a
20 certification perk or it is that they get feedback
21 on what happened with their patient or they get
22 feedback on what is happening with the whole

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1 study. And maybe it goes back to the newsletter
2 thing that it is really important to make the
3 provider feel as valued as possible for the really
4 important impact they can have on getting a woman
5 to enroll.

6 DR. SCOTT: Are there any other
7 suggestions for incentives for health care
8 providers?

9 Dr. Hernandez-Diaz?

10 DR. HERNANDEZ-DIAZ: On the same point
11 some information that may help the discussion I
12 was asked this morning about the proportion of
13 women from the North American Anti-Epileptic
14 Pregnancy Registry that report us to enroll
15 because their provider referred them versus the
16 website versus other sources like the label. And
17 Kathleen Smith the study coordinator sent me the
18 data and overall over the years around 85% of
19 women enrolled because they enrolled or their
20 prescribers refer them to the registry. Not that
21 they enroll the women but let the women know about
22 it and so I think the providers are key and I

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1 agree that they have to be part of it. And I
2 don't know if the grates would work but certainly
3 I think after they receive the information and
4 then enroll in epilepsy meetings, they get to the
5 information that the registry has and I think they
6 appreciate being able to see the updated
7 information on the newsletter. So yes, I
8 definitely think they are an important part of it.

9 And just one more comment that perhaps
10 the enrollment has two parts of it: one is women
11 being aware of the existence of the registry and
12 then a second step, they enroll. And perhaps the
13 website have more of a role in that enrollment
14 part once somebody tells them about the registry,
15 they go to the website and then depending on how
16 appealing it is, that might influence the
17 likelihood to enroll and click.

18 MS. BERLINER: I am wondering which
19 provider really has ownership because it is like
20 if you have a woman with a co-morbid medical
21 condition and it is like the obstetrician is in
22 charge of the pregnancy and the other physician is

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1 in charge of the woman's medical condition so who
2 is really in charge of the interaction. And again
3 one of the things that Tina said that just really
4 resonated with me is the idea of having someone to
5 consult with; right. So if you are an
6 obstetrician with a patient with epilepsy and you
7 only have a handful of patients with epilepsy it
8 is not really your expertise but who can you --
9 who can help that patient and if you're a doctor
10 treating epilepsy how many of your patients are
11 pregnant. So it is really having a place to go to
12 send the patient to get more information on the
13 interaction.

14 MS. THOMAS: I'd like to add something.
15 One of the things that we've seen is that the free
16 continuing education courses are a good tool to
17 raise awareness among a variety of different types
18 of health care providers. And they are very
19 receptive to being able to: one, get credits that
20 can help them with whatever certifications or
21 things that they need but also they are getting
22 the information. So that it may not necessarily

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1 be tied to them signing up someone for a registry
2 at that moment but you're are bringing it to the
3 forefront of their mind. You're talking about the
4 resources, you're talking about the information
5 that we have available so that it is there for
6 them and they may be more likely to refer someone
7 later on. So I think a continuing -- a free
8 continuing education course for not just for
9 physician but for nurses and pharmacists would be
10 a very helpful way to raise awareness among health
11 care providers.

12 MR. MITCHELL: Yeah. I guess one thing
13 that I wouldn't want to get lost in the shuffle
14 here is -- has already been touched on but I think
15 it is generally accepted that patients find their
16 physicians the most trusted source for medical
17 information. And the alternative is a patient God
18 forbid going on Google. Julia you said you didn't
19 have any resources. Now we've got too many.

20 MS. BECK: That is true.

21 MR. MITCHELL: And the ability to sort
22 the real from the imagined is beyond the canon of

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1 most lay people, most professionals.

2 So I think one of the things that a
3 provider can do in the context that Tina described
4 is by directing their patient to a Teratogen
5 Information Service or Mother to Baby to answer
6 questions that not only provides them a vetted
7 source of information and avoids misinformation
8 but it also opens the door to participation and
9 research. So in a sense the provider can kill two
10 birds with one stone. They can refer the patient
11 to a trusted source for information about
12 medications they might be taking and at the same
13 time it could enhance enrollment because there are
14 that many more people calling. And they are
15 calling because their provider suggested it.

16 MS. ALBANO: One of the things, this is
17 Jessica Albano, that the APR does when they
18 publish their semi-annual interim reports is to
19 recognize some of the physicians who have reported
20 cases. And we have some minimum criteria of cases
21 that need to be reported, specific quality et
22 cetera. But as a way that that can take some

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1 ownership that they have contributed to the data
2 that is being reported.

3 DR. SCOTT: Do you have any comments for
4 those on the phone?

5 Okay. We are going to move on to the --
6 I am sorry. Yes.

7 MS. DANA: It is Adrian Dana. I just
8 wanted to say that in our registries you know we
9 work really hand in hand with the providers and we
10 do as a requirement of enrollment we do need to
11 have a provider involved and one of the things
12 that we do do and one of the reasons that we
13 actually do prepare periodic, usually annual
14 reports is that when a provider calls they are
15 actually most of the time looking for information
16 more than enrolling into the registry. And so at
17 that point we have a contact where we are able to
18 ask them to enroll the patient that has been
19 exposed that they have. And then we are able to
20 provide for them the most recent annual report
21 which gives them whatever information we as a
22 company have, good information. It forms a basis

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1 for counseling and informing their patient. And
2 so we do feel that we work hand in hand and we
3 take this obligation to provide that information
4 to the providers very seriously so that they can
5 use that information. And so I do think that is
6 one real advantage for the preparation of routine
7 periodic reports so that we can provide that to
8 people for counseling purposes.

9 DR. SCOTT: Thank you.

10 Leyla?

11 DR. SAHIN: I have a question for Diana.
12 So can you talk a little bit about when patients
13 call the Teratogens Information Service and then
14 they get their genetic counseling regarding their
15 exposure to a medication; and then what is the
16 process to get them into a study and what are
17 their perceived barriers? How open are they to the
18 idea? You know they have come here for some
19 information but then all of a sudden they are
20 talked to about recruitment into a study. So
21 could you provide some comments please?

22 MS. JOHNSON: Sure. So typically the

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1 counseling takes place and the counselor will let
2 the woman know that they may qualify to
3 participate in a research study and would the
4 woman be willing and interested in hearing more
5 about the participation. And if she says yes, she
6 is asked if she would like to be transferred or if
7 she would like a call back. And then our
8 interviewers will give a call back if that is the
9 case or transfer over to an interviewer and
10 discuss some basic elements of participation. Go
11 through just a brief screening. And if she is
12 agreeable then we go through a screening consent
13 to find out if she qualifies and go through a list
14 of questions in terms of whether or not she is
15 willing to take part. And if she is, then we will
16 go through the informed consent.

17 So most of the time as Tina mentioned
18 women who decline participation either say that
19 they don't feel that they have the time to
20 participate or they are reluctant to release
21 medical records after their pregnancy has
22 completed.

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1 DR. IYASU: Actually I just wanted to
2 ask a question. Maybe Dr. Sahin if you are
3 familiar with the strategies that have been
4 employed by the National Children's Study. I know
5 that there has been some evaluation of different
6 strategies for recruiting pregnant women into the
7 study. And if I recall they were sort of
8 evaluating the tradeoffs between direct patient or
9 pregnant women outreach versus a facility or
10 provider based and I think ultimately they found
11 that the best strategy is really a hybrid. But I
12 don't know if you are familiar with what they
13 decided.

14 DR. SAHIN: This is for the National
15 Children's Study? It has been a while since I
16 have been involved in anything related to that.
17 Tina do you know?

18 MS. CHAMBERS: I think the current
19 status is yes a hybrid of provider based
20 recruitment versus direct patient recruitment.
21 And at least as the publications are starting to
22 come out now if it's direct patient recruitment

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1 one of the original strategies was going household
2 to household, the biggest barrier to recruitment
3 was the first person being a male that you
4 contacted.

5 [Laughter.]

6 MS. CHAMBERS: Instead of a female.

7 DR. SCOTT: So we are going to move on
8 to the next question. Question 2 is: How can
9 overall awareness of pregnancy registries as well
10 as the existence of available registries be
11 increased for patients and health care providers?
12 I want to open that up to the panel.

13 MS. BERLINER: So I heard some criticism
14 before of patients looking at Google but I think
15 that is where patients are going to go and so I
16 just did a little quick search of epilepsy and
17 pregnancy to see what came up. And the first
18 three sites were the Mayo Clinic, the Epilepsy
19 Foundation and WebMD. And they have these nice
20 little sites saying are you thinking of getting
21 pregnant? Here are some things to think about and
22 some information about medication. But not really

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1 very detailed. But is that something that the FDA
2 could make partnerships with those sites so that
3 there could be a link on those sites that say need
4 more information on medication and pregnancy and
5 epilepsy or whatever the condition is then go to
6 the FDA website. Then have more detailed
7 information from the FDA on what is known and not
8 known about the risks of different medications and
9 then an invitation to look at the registries.

10 So it is just like you know patients are
11 going to be seeking information so how can we
12 leverage that to get them to consider the
13 registries.

14 MS. THOMAS: Well I think what we've --
15 this is Kimberly Thomas. I think what we've done
16 is a hybrid of that in the past. We've done some
17 paid Google ads, some in places where our target
18 population is going. So if they are looking at
19 certain videos that have nothing to do with FDA or
20 medicine on YouTube but it is baby related or
21 pregnancy related then we have done ads to have
22 our things pop up there. They watch the video and

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1 it directs them to our website. We've also done
2 ads, just the headline ads to direct people back
3 to the website. And we've done outreach to some
4 of our stakeholders to get them to add links on
5 their website to where we are going. So I think
6 we've done it but it is something we can do more
7 of really going to where people are and making
8 sure we are putting accurate information or links
9 to accurate information even in some of those chat
10 rooms where we know people are talking about
11 things that are incorrect; directing people to the
12 correct information and to the website.

13 DR. SCOTT: So my question is to Julia.
14 Do you have any suggestions for us in terms of
15 increasing awareness about pregnancy registries
16 among patients?

17 MS. BECK: I'm thinking about what
18 Kimberly just said and I think there is a
19 difference between availing yourself and
20 establishing yourself as the ultimate resource.
21 And I think that that is again, I am hearing a lot
22 of amazing things today, but then sometimes these

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1 disconnects come up and so this is really the hub
2 of all of this data yet somehow it isn't owned.

3 And so I am thinking a bit about I think
4 the idea of partnering not just saying we're here
5 but partnering with the assumed places to go for
6 information saying glad you are here because we
7 are the resource, we are the definitive source and
8 we are partnered with them. So the idea that you
9 really put on this hat and say this is the right
10 place. Maybe that is the wrong metaphor, maybe it
11 is more like Lucy's sign but the idea that it is
12 sort of like if you can't beat Google you are
13 going to join Google. You are going to think about
14 how to use it most effectively for you. And
15 whether you like it or not thinking about
16 pregnancy is private or between, if it is planned,
17 it is a very Googled act, it is what it is. So I
18 think there has got to be a way to really then put
19 yourself in the middle of the conversation as
20 opposed to seeing if they show up. Does that
21 answer the question?

22 DR. SCOTT: Uh-huh.

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1 Do we have any comments from those on
2 the phone?

3 What about --

4 DR. CONLON: This is Dr. Conlon at the
5 Naval Health Research Center in San Diego. Again
6 our experience is a little unique I think. But
7 what we've seen as far as referrals from providers
8 working with our vaccine registries is their
9 electronic medical record is now designed to ask
10 about the recommended vaccines in pregnancy to
11 include influenza and Tdap and that seems to alert
12 them to check about those vaccines. But there is
13 nothing in the electronic health record asking if
14 a woman has been exposed to say smallpox vaccine
15 or anthrax vaccine. So maybe those triggers could
16 be helpful.

17 In our setting too we have the allergy
18 and immunology vaccination clinic that are another
19 somewhat ancillary provider that are good to reach
20 out to because they are seeing these patients,
21 providing the vaccine, and then often when a woman
22 finds out she is pregnant they go back to that

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1 vaccination clinic for the various forms to be
2 followed. So for them to have awareness is
3 helpful.

4 And I would think that could translate
5 in the medication world to working more closely
6 with pharmacists who are ultimately dispensing the
7 medication to insure that women at that point of
8 care are aware that there might be a registry for
9 the medication that they are picking up at that
10 time.

11 DR. TASSINARI: So I guess I want to
12 swing back to Lynne's question from earlier
13 because
14 it strikes me as I am listening to this and some
15 of the suggestions which I think are really
16 requiring us to think about using current media to
17 do the job that we want to do for patients. But
18 what do we do about the health care providers?

19 I am beginning to think there are two
20 streams we have got to get moving here. And what
21 would be your recommendations if we are focused on
22 health care providers here to increase awareness?

23 DR. HOLMES: This is Lewis Holmes with

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1 North American AED Pregnancy Registry. Melissa we
2 don't have the answer to that but we know from our
3 many years of doing this that this group of
4 cheerleaders has really made the difference. And
5 so I would rephrase your question to say how do
6 you find at a medical meeting or whatever when you
7 are giving the information to 100 people, 500
8 people, 1,000, how do you identify that subset who
9 is turned on by that information and says hey, I
10 want to help because that is what really matters.

11 The women will tell me that my doctor's
12 enthusiasm for me calling this toll free number
13 was a key factor in my deciding to do that. And I
14 don't know the answer to this. But getting to
15 those people, not everybody, but that subset who
16 really is interested is what we are talking about.
17 And that made all the difference for us; I am sure
18 other registries as well.

19 DR. TASSINARI: So I would take that to
20 say it is not that we should be looking at health
21 care providers in general but we should be
22 focusing in on those folks, cheerleaders as you

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1 were calling them, to really help us make sure
2 this awareness grows and do it that way?

3 DR. HOLMES: I just don't know why if
4 you present something to 100 people only two or
5 three or whatever the number is really say hey, I
6 want to help with that. But that seems to be the
7 way it works. And that is the reality. And, of
8 course, we've targeted some of our follow up
9 marketing to those people. You know just look
10 through the system and say okay who has referred
11 more than three patients or four or whatever the
12 number is and then send information just to them
13 as a way of trying to increase whatever it was we
14 were trying to increase.

15 DR. SCOTT: Dr. Chambers?

16 DR. CHAMBERS: I was going to add to
17 what Lew said. I think that by going along with
18 that in any kind of specialty physician group
19 there probably is one or two people who consider
20 themselves the experts on pregnancy for that
21 specialty. And so to have them not on your side
22 is a big negative. So it is important I think to

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1 identify who are the opinion leaders in that
2 particular specialty regarding pregnancy and make
3 sure they understand what the pregnancy registries
4 are about and how it can benefit them.

5 And the other thing I wanted to say
6 going back to Julia's comment is who owns this and
7 kind of the disconnect. I think neurologists are
8 so familiar with anti-epileptic medications that
9 it spans teratogenicity that it is something that
10 has been on their radar screen for a long time.
11 But you take other specialty physicians and they
12 may not be thinking that very many of the
13 medications that they use have safety issues or
14 potentially could. And when they find out that a
15 patient is pregnant do they pass the
16 responsibility on to the obstetrician and is there
17 a disconnect between the two in terms of who is
18 responsible for making the patient aware of a
19 pregnancy registry existing. And I guess I would
20 say both, that the two need to be talking with
21 each other but the reason the specialty physician
22 really needs to be involved is they are going to

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1 know about it probably earlier than anyone and
2 that is the time when you want the person referred
3 is as early as possible in pregnancy.

4 DR. HOLMES: This is Lewis Holmes again.
5 That raises the question about trying to use
6 medical meetings of whatever this group is as a
7 way to do that. We benefit from the fact that
8 there is an American Epilepsy Society which is the
9 neurologists with an interest in epilepsy and all
10 aspects. And that organization has set up special
11 interest group meetings at the beginning of the
12 annual meeting and we've been invited along with
13 the other pregnancy registries interested in this
14 group of drugs to come every year and give a ten
15 minute, 12 minute summary of what their latest
16 information is. So that has worked for us in the
17 neurology community. And Mike could speak to or
18 anybody else to other organizations you know what
19 is the likelihood that an OB organization would
20 have a similar interest in having a focus on
21 specific things because that seems to be every
22 year the room is full. It is a room sometimes as

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1 big as this room and it is full and it is mainly
2 people that are going home wanting to know what is
3 the latest on Keppra or whatever because it is a
4 constant question they are asked; and would there
5 be an equivalent in OB and would there be other
6 specialties because that system has seemed to be a
7 great asset.

8 DR. IYASU: Yes it's Solomon. There
9 have been several comments about information
10 getting back to the provider from the registry and
11 also information gets back to the participants.
12 And I am wondering with respect to the patients
13 what kind of information is a motivator because
14 you wouldn't be able to get information that is
15 pertinent to the drug that they are exposed to
16 within the lifetime of the pregnancy duration and
17 it is long after that you will find some
18 information that is generalizable in a way to
19 women who might be interested in contributing
20 towards knowledge.

21 So how much of that is a disincentive
22 when you tell them that information may not be

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1 immediately available that would help other women
2 but it is three, five, six years down the road.
3 So in the meantime what do we do in terms of
4 providing information that pregnant women are
5 interested in; what kind of things are we doing to
6 sort of keep them in the registry and actually so
7 that there is follow-up, adequate follow- up. So
8 I am trying to understand what are the kinds of
9 thing that would work actually given that it takes
10 a long time to get that sort of motivator which is
11 what we call altruistic nature of human being to
12 contribute towards knowledge.

13 DR. COSTER: Or of disseminating
14 information. The Med Page, Medline, FDA alerts
15 that come automatically to physician's email box
16 is a way - - I don't know if the summary on the
17 patient registries hook in with those
18 organizations but you would get a lot of that
19 going right to the email boxes of physicians. And
20 usually what happens with those in large hospital
21 organizations, those are repackaged and sent. And
22 they are also discussed. Now we have the patient

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1 centered medical homes where you talked about a
2 champion usually all you need is one physician in
3 that medical home huddle that is bringing in to
4 their other five or six physicians that work in
5 that clinic that information. So we found it is a
6 pretty effective way of getting that kind of
7 information out -- physicians is like for the FDA
8 alerts that goes right to your email box, the
9 Medline, Med Page when there is announcements,
10 they repackage that and put it out and it goes to
11 people's email box you know hooking in with those
12 already, rather than having to specifically order
13 yours but having it announced so that it actually
14 goes out at a professional meeting. So it is
15 communicated in these kinds of services that most
16 clinicians kind of hook into could be an effective
17 way of getting that information out to your
18 clinicians and as you said you only need maybe one
19 in those patient centered medical homes that then
20 transfer that information.

21 DR. SCOTT: Do we have any -- I'm sorry.

22 MS. JOHNSON: I was just going to say

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1 and maybe you can speak to this a bit yourself but
2 in our case I think that most of our subjects
3 understand that it takes a while to gather the
4 information and they understand the period of time
5 that we are going to be taking to gather the
6 information and because they've gone through the
7 counseling and they realize that there isn't much
8 out there, that is why they want to contribute
9 even though they are not going to have the
10 information back in a month or six months or one
11 year. So I think when you go through the process
12 of explaining what is out there and how the
13 information is gathered and how long you are going
14 to take to gather that information. I think most
15 patients understand that and they want to be able
16 to help contribute in the future.

17 MS. BECK: Well I actually hear that
18 everybody is describing the same basic motivator
19 both physician and patient. It is somebody who
20 has the ability to really latch on to the problem
21 and a desire to be altruistic as you said and part
22 of the solution. And I wonder again, I understand

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1 there is HIPAA and there are other things but what
2 about some sort of content that could live on the
3 website for example that called out people who
4 have been exemplary; physicians who have done an
5 amazing job of sending patients to a registry and
6 highlighting patients, maybe coupled even with
7 that doctor showing the journey that they've gone
8 on together. And really somehow just giving
9 credit where credit is due in a way that might
10 inspire others. I mean this is from the
11 physician's side but it is a just a working
12 thought.

13 DR. MITCHELL: Alan Mitchell. One of
14 the things that may be helpful because it is of
15 course the case that the women who enroll in the
16 registry are not going to benefit directly from
17 the results of that unless they become pregnant
18 again but providing intermittent progress reports
19 in a global sense is a sort of self-reinforcing
20 process where the women now see themselves as part
21 of a larger whole and may be more motivated. I
22 think in a registry that is 95% retention it is

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1 not, there is not much margin to improve. But in
2 general I think the fact that women know that
3 there are X hundred other people, perhaps they are
4 in these stages of follow up and the participation
5 rates are such and so, that kind of feedback I
6 think, and we have done that in different kinds of
7 studies, seems to have some beneficial effect in
8 retention.

9 And I think when it comes to providers
10 just to restate what people have said I mean the
11 bottom line is if it is a clinically relevant
12 question as Lew said the epileptologists really
13 want to know the answers. And so if you can keep
14 them in the loop about we are working on it, we
15 are working on it and then identify by thank you
16 the high rollers or the champions I think that
17 also has a self-reinforcing effect.

18 DR. SCOTT: Okay. We are going to do
19 questions or comments from Dr. Chambers and then
20 Dr. Holmes and then we are going to move on to the
21 next question.

22 DR. CHAMBERS: I think this falls into

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1 this topic area but I was thinking of is there a
2 way that we can think out of the box about how the
3 FDA website could function and not just as a place
4 where people go and find out where a registry
5 exists. But actually to facilitate then getting
6 the person who goes to the website in contact with
7 that registry. So I am thinking of it could you
8 go in and enter a drug, a disease and be able to
9 search on the website a match to a potential
10 pregnancy registry and then actually have an email
11 go out that provides information to that registry
12 about that provider or that patient in some
13 fashion that was HIPAA compliant.

14 The CTSAs have a thing called
15 researchmatch.org that is run throughout the
16 United States that allows patients to register in
17 it with certain characteristics and then people
18 who have IRB approved protocols go in and enter
19 their information into researchmatch.org and if
20 the patient meets the criteria then they get an
21 email saying that you might qualify for this
22 study; would you be interested in hearing more.

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1 They open up the option of being contacted and
2 then the researcher gets that contact information
3 and can contact the patient to see about enrolling
4 them. And that works nationally. So I am
5 wondering if there could be a way that you could
6 maximize use of the FDA website.

7 We were talking earlier about FDA being
8 perceived as a trusted source without different
9 objectives in mind would that be sort of a one-
10 stop shop that at least a provider or a patient
11 can find out yes, I might qualify for this
12 particular registry and then give permission to be
13 able to be contacted.

14 MS. THOMAS: I am not sure about the
15 capabilities of the website but it does raise some
16 issues in terms of if you do search drugs at FDA
17 and get information about it is there something
18 that could be added there that says there is a
19 registry for this particular drug, I don't know if
20 they will have the capability of sending an email
21 but at least of having something there. But I
22 will definitely check into it.

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1 DR. SCOTT: Dr. Holmes?

2 Okay.

3 DR. GREENE: Just quickly, Mike Greene.

4 On the FDA's website now when you go to the
5 registry, the list of registries you can click
6 right through to the registry's website. And
7 there you can get whatever information and/or
8 supply any information to the registry depending
9 upon on how their website works. So the FDA is
10 sort of facilitating that already. So you can
11 click right through. The web address for the
12 registries are right on the FDA's website.

13 MS. THOMAS: Yeah. I think this was in
14 reference to if you go somewhere else on the FDA
15 website and you just search for something about a
16 drug if we could take you back to the registry
17 page and then connect you that way.

18 DR. SCOTT: Okay. So we are going to
19 move on to the next question which is: Discuss
20 the role of the FDA in communicating information
21 about pregnancy registry. We want you to consider
22 in your comments recommendations for the FDA's

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1 Office of Women's Health webpage and other methods
2 that FDA uses to communicate information about the
3 existence of a pregnancy registry.

4 And I want to start off by asking the
5 first question to the panel. I notice that in
6 some of the presentations people talked about how
7 they used the information that is currently on the
8 FDA's web page for pregnancy registry. Some
9 people mentioned that they used it as part of
10 their recruitment tools. Other people viewed it as
11 a FDA clearinghouse so to speak for pregnancy
12 registries. And so I just want to get more
13 information from the panel in terms of how you use
14 the information that is on the web page and what
15 your recommendations are for us to improve it
16 because as you saw from the presentations this
17 morning it is not a comprehensive list. And so we
18 want to make sure as we move forward we implement
19 changes so that it is more useful for you.

20 DR. GREENE: Mike Greene. So let me ask
21 a question in response to that question. How do
22 the registries get on to the FDA's list of

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1 registries now? Do the registries have to approach
2 the FDA? Does the FDA -- how does it happen?

3 DR. SCOTT: So the registries that are
4 listed come from two sources. Some of them are
5 post-market commitments and post-
6 market requirements so that we are aware of them
7 within FDA and then they are cleared and they are
8 put up. Others are voluntary in which the company
9 approaches us and say I have a pregnancy registry
10 and I would like you to post it on the website.
11 And we take that information and we consult with
12 our colleagues and CDER to see whether or not it
13 fits the definition of a pregnancy registry and
14 whether or not we should post it.

15 But that is an interesting question
16 because on the website we don't distinguish
17 whether it's post-market commitment, post-market
18 requirement or voluntary. So is that something
19 which would be useful for everyone to know how we
20 put things up there, what categories they fall in,
21 how do you want us to sort? Right now it is sorted
22 by

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1 disease and you could also sort by actual product
2 listing. What is the best way to communicate this
3 information to you?

4 DR. GREENE: This is Mike Greene again.
5 So with that then as background I think one of the
6 themes that has run through the discussion is who
7 is your audience okay. So is your audience
8 providers or is your audience patients or do you
9 need both and if you are going to do both can you
10 reach both with the same approach. And if your
11 audience, who are your customers, if your audience
12 is providers do you want it to be obstetricians or
13 do you want it to be the neurologists who are
14 prescribing anti-epileptic drugs or do you want it
15 to be gastroenterologists and infectious disease
16 docs who are prescribing the Ribavirin for HepC.
17 So and it is likely that one size is not going to
18 fit for all, okay. And that you may need
19 different ways to attract doctor's and provider's
20 eyeballs as compared to patient's eyeballs on your
21 website.

22 So I was struck by the fact when I saw

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1 the presentations today that there were two
2 different ways of finding your way to the
3 registry. One is just going to the FDA CDER site
4 which is the way I did it. And the other is to go
5 to the Office of Women's Health Site. And it
6 seemed to me there was slightly different content
7 on the two different sites.

8 DR. SCOTT: So that is something that we
9 can look into because I am not aware of the
10 differences between the information. I would
11 think that it should link to the same webpage.

12 MS. THOMAS: I am not sure what CDER
13 page you were referring to. If it is just that
14 you went through the drugs tab and it took you
15 back to our list. But the page that we show
16 basically there are three different pages that are
17 all within the same section. And the main page is
18 the page with the woman on it and then there is
19 the main list page and then there is some more --
20 a general information page. But they are all in
21 the same regardless of whether or not you come
22 through the drugs tab or you come through the

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1 Office of Women's Health tab it takes you to the
2 same place.

3 But one of the things that you did raise
4 is something that we are considering with the
5 restructuring or reorganization of the website is
6 that when you come to the main page having the
7 button that says for providers and a button that
8 says for patients and it takes you to slightly
9 different information. You still may end up on the
10 same list page but where you start off would be a
11 little bit different and the way the information
12 is framed will be different if it is for the
13 provider or the patient. But I think one of the
14 things that you raised in terms of the specificity
15 for the different types of providers we may not be
16 able to be that nuanced in that one website but at
17 least having a separate entrance point for
18 providers is something that we are considering.

19 DR. HERNANDEZ-DIAZ: Perhaps something
20 to keep in mind for who is the audience perhaps
21 neurologists or epileptologists or HIV infection
22 disease doctors know about the registries for this

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1 particular medications because they have been
2 around for a long time and they are known to have
3 potential toxicities that result in that. But
4 perhaps this FDA website will be particularly
5 useful for more of a general audience of OB/GYNs
6 or primary care providers that may have to
7 prescribe different medications occasionally to
8 pregnant women. And perhaps the alert we were
9 talking before that the represented having
10 electronic medical records give an alert, a yellow
11 light, that could include the link to the FDA
12 website where the provider could find and access
13 information about many registries in case these
14 prescribers have to prescribe many different
15 medications to different women with different
16 conditions. So just to keep in mind when
17 designing it.

18 DR. SCOTT: Any other comments?

19 So can anyone think of any other groups
20 or organizations that we could potentially target
21 to increase awareness of the web page?

22 DR. GREENE: Mike Greene. So I don't

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1 think that you will be able to find one group that
2 you can contact about the webpage for all of the
3 registries. I do think, however, that there are
4 patient groups that find -- that patients find
5 each other on the web as interest groups if you
6 will and those interest groups whether it is anti-
7 epileptic patients or whether it is patients with
8 cystic fibrosis or other disorders those patients
9 do find themselves and do have their websites and
10 chat rooms on the net. And you can target them
11 for their registry rather than all registries.

12 MS. BECK: I am curious about the
13 pregnancy media, both digital and traditional
14 print. I would assume that they would be very
15 interested in having information about a
16 centralized source and again I have done little
17 bits here and there but I am wondering if there is
18 an opportunity for a centralized effort with Fit
19 Pregnancy, The American Baby, you know the laundry
20 list.

21 MS. CHAMBERS: We had talked earlier
22 about the possibility of proactively sending out a

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1 text for baby message at the first contact when a
2 woman signs up in pregnancy that says go to the
3 FDA website and having a link there to see if you
4 qualify for a pregnancy registry.

5 MS. COSTER: Actually for other groups
6 you are asking about contacting is the P&T
7 committees. They are the ones that really own the
8 ability to change the electronic medical records
9 for drug warnings and vaccine warnings. So they
10 are a good organization as well as your patient
11 safety community because usually have a patient
12 safety officer at a hospital who kind of goes to
13 all the other specialties and can transmit
14 information; so insuring that patient safety
15 officer is aware that there are registries that
16 the P&T Committee is aware of the registries; it
17 helps them then decide as a hospital organization
18 how are they going to disseminate and warn
19 patients about information.

20 DR. SCOTT: A question that I have is
21 outside of the registry process, does the panel
22 have any recommendations on how we can encourage

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1 patients and prescribers to report information on
2 drug exposures during pregnancy. Outside of the
3 registry process, do you have any recommendations
4 on how we can encourage patients and prescribers
5 to report information on drug exposures during
6 pregnancy?

7 DR. MITCHELL: Are you talking about
8 just the fact of an exposure or link to an
9 outcome?

10 DR. SCOTT: Link to outcomes. So we
know

11 we have the Med Watch form and you report
12 information there. Is there anything else to
13 capture some information?

14 DR. MITCHELL: I guess I would pose the
15 question of whether does FDA want to do that? The
16 value of those spontaneous reports is minimal at
17 best. And I frankly would see that as a
18 distraction and perceived as competitive to the
19 registry effort which is interpretable.

20 DR. SCOTT: Thank you.

21 Dr. Holmes?

22 DR. HOLMES: Yeah, I think to echo what

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1 Alan said there are two well documented examples
2 of where studios review of the adverse event
3 reports has led to spurious publications of
4 alleged teratogenicity that required a lot of
5 effort to dispel. And so the FDA system not only
6 didn't work but it caused harm. So there is no
7 sense in encouraging it.

8 DR. SCOTT: Okay.

9 Any comment or questions from the people on the
phone.

10 DR. SAHIN: All right. So we discussed
11 a lot of topics today and I am just going to try
12 to do a high level recap of some of the key
13 messages that we received.

14 So quickly to go through some of the key
15 messages: We need to be clear about the
16 information that can reasonably be obtained from a
17 registry; taking into consideration issues like
18 the sample size, the power of the study, and the
19 outcomes that are being assessed. Marketing
20 efforts need to be established from the get-go of
21 the pregnancy registry and whatever resources and

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1 money are spent in terms of marketing, that it is
2 really money that is well worth spending to raise
3 the awareness of the pregnancy registry. There
4 was a lot of discussion about prospect of
5 enrollment and how the definition is changing as
6 prenatal diagnostic tools advance and so this
7 needs to be taken into consideration when data is
8 analyzed and submitted to the FDA. Inclusion and
9 exclusion criteria need to be clearly defined.
10 Comparison groups need to be appropriate for the
11 study population. And we also heard that FDA
12 needs to develop standards for specific
13 surveillance methods and increase its standards in
14 terms of what it asks for for a post-marketing
15 study.

16 This afternoon there was a lot of
17 discussion on the use of electronic media to raise
18 awareness and increase diversity in these studies.
19 Use of electronic medical records alerts; notify
20 health care providers of a pregnancy registry.
21 There was a lot of discussion regarding the need
22 to engage the patient to improve enrollment into a

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1 study and also keep them engaged and improve
2 retention in the study. And there was also
3 discussion about the importance of providing
4 feedback to the patients in terms of the study
5 findings because a lot of patients do participate
6 for altruistic reasons and for them it is
7 important to feel that they contributed to the
8 study. But there was also discussion about the
9 importance of the health care provider as well as
10 it is the health care provider who often refers
11 the patient and a health care provider's
12 encouragement or interest or support of a patient
13 to enroll into a registry has an important impact
14 on whether or not the patient will enroll into the
15 registry. And there was also discussion about the
16 importance of identifying health care provider
17 champions to spread the word about a registry.

18 So I may not have captured all the
19 points but those were some of the key messages
20 that we received. So it has been a great day; a
21 lot of stimulating discussion.

22 And thank you very much to everybody,

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1 all the panelists, and all the members in the
2 audience including all the people who made public
3 comments. And we really appreciate everybody's
4 participation.

5 Thank you very much.

6 And we look forward to seeing you
7 tomorrow morning.

8 MS. MOYER: Tomorrow morning we start at
9 eight o'clock.

10 (WHEREUPON, the meeting ended for
11 the day.)

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1 CERTIFICATE OF NOTARY PUBLIC

2 I, ERICK MCNAIR, the officer before whom the
3 foregoing deposition was taken, do hereby certify
4 that the witness whose testimony appears in the
5 foregoing deposition was duly sworn by me; that
6 the testimony of said witness was recorded by me
7 and thereafter reduced to typewriting under my
8 direction; that said deposition is a true record
9 of the testimony given by said witness; that I am
10 neither counsel for, related to, nor employed by
11 any of the parties to the action in which this
12 deposition was taken; and, further, that I am not
13 a relative or employee of any counsel or attorney
14 employed by the parties hereto, nor financially or
15 otherwise interested in the outcome of this
16 action.

17

18

19

20

ERICK MCNAIR
Notary Public in and for the
State of Maryland

21

22

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1 CERTIFICATE OF TRANSCRIPTION

2 I, CHERYL LaSELLE, hereby certify that I am not
3 the Court Reporter who reported the following
4 proceeding and that I have typed the transcript of
5 this proceeding using the Court Reporter's notes
6 and recordings. The foregoing/attached transcript
7 is a true, correct, and complete transcription of
8 said proceeding.

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CHERYL LaSELLE

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