

1 not life-threatening. For more serious and life-
2 threatening diseases, we're usually willing to go
3 into the pediatric population a little bit
4 earlier.

5 Also, another reason for deferral is
6 if there's another appropriate reason for
7 deferral. I can't give you an example of that off
8 of the top of my head. We've really relied on the
9 top two bullets for our criteria, but there is a
10 possibility that there could be another reason
11 that would come up and we would consider that.

12 Once we've decided that a deferral
13 can be granted, the applicant must submit a
14 certification for the grounds of the deferral, a
15 description of the planned studies, which is the
16 pediatric plan, and also evidence that the studies
17 are being conducted or will be conducted with due
18 diligence and at the earliest possible time. They
19 also have to provide a date for which time they
20 anticipate those studies will be finished and when
21 this all gets incorporated into a postmarketing
22 commitment, we have a due date that gets posted as

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1 well.

2 Under FDAAA, if studies are being
3 deferred for any of the criteria previously
4 stated, the sponsor does need to submit an annual
5 report about the status of those studies and that
6 information will be posted publicly.

7 We can also grant waivers for studies
8 under PREA. So, there are some circumstances
9 where we will tell a company that even though
10 their application triggered PREA, we don't want
11 them to study pediatric patients.

12 Those criteria are that studies,
13 necessary studies, are impossible or highly
14 impracticable. The example I would give you is if
15 the condition doesn't occur in pediatric patients
16 in a high enough number. Prostate cancer. We
17 clearly could not require studies of prostate
18 cancer in pediatric patients. So, we would waive
19 that product for that indication.

20 That brings up a good point. Under
21 PREA, unlike BPCA where we can ask for everything
22 on-label and off-label, under PREA, we can only

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1 ask for studies on that indication that comes in
2 that application. So, it's a very narrow
3 viewpoint rather than BPCA where it's very broad
4 and we can ask for everything.

5 Another reason for a waiver would be
6 there's strong evidence that suggests a drug or
7 biologic would be ineffective or unsafe. It
8 should be noted that if this is a criteria used
9 for waiver, this information has to be conveyed in
10 the labeling.

11 And then the third criteria for
12 waiver is that the drug or biologic does not
13 represent a meaningful therapeutic benefit over
14 existing therapies and it's not likely to be used
15 in a substantial number of pediatric patients.

16 As you can see, this is a double-
17 pronged criteria that makes it very difficult for
18 sponsors to use this criteria because even though
19 you might say there are already five other
20 products out there, so it wouldn't represent a
21 meaningful therapeutic benefit over existing
22 therapies, it's often hard to predict if your

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1 product is going to move up to the top of the
2 market and be used by a substantial number of
3 pediatric patients.

4 Partial waivers are actually waivers
5 that only cover a part of the pediatric population
6 by age. So, the criteria are the same, except for
7 one difference and one difference would be if you
8 can't develop a formulation that would be
9 appropriate for, say, the youngest portion of the
10 pediatric age range.

11 An example of this might be acne.
12 You probably wouldn't require acne studies in kids
13 less than 12 and another example may be if you
14 have a solid oral dosage form for the indication
15 of seizures and as hard as you try from a
16 chemistry standpoint, you couldn't get that tablet
17 into a liquid formulation, then you probably
18 wouldn't require studies under the age of 4 or 5.

19 If studies are deferred, the
20 applicant does have to submit the annual review.
21 As I said earlier, that's new. Also, if we do
22 waive a study based on the fact that they can't

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1 make the pediatric-friendly formulation, that data
2 has to be submitted to the agency and that gets
3 posted as well.

4 I just wanted to flash up a chart
5 that describes the differences between the old
6 labeling and the new physician labeling rule
7 because previously, we made labeling
8 recommendations mostly for the Pediatric Use
9 Section of labeling which is under Precautions and
10 now the Pediatric Information comes under 8.4
11 which is Use in Specific Populations, Pediatrics.

12 So, I'm going to talk a little bit
13 more about labeling and I'll be referring to the
14 Pediatric Section rather than the Pediatric Use
15 Section. I know, very FDA of me.

16 So, labeling changes again under the
17 Pediatric Research Equity Act. Pediatric study
18 information must be included in the product label
19 and that's whether the study demonstrates safety
20 and efficacy, does not demonstrate safety and
21 efficacy or is inconclusive, and the reason for
22 that is the same reason that the law was changed

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1 to require inclusion of information from BPCA
2 studies.

3 That is, that we usually only have
4 one shot at getting pediatric data and we want to
5 make sure that information is available to people
6 who have to use these medications to treat sick
7 children.

8 The Pediatric Advisory Committee
9 previously recommended a way for us to format our
10 labeling and I don't know. Some of the members
11 have been around long enough to remember that
12 discussion with Iris Masucci, but if the
13 indication is granted specific to the pediatric
14 population, that information is spread throughout
15 labeling and you've seen that in some of the
16 labels that you reviewed today.

17 If the indication is not granted,
18 then what we want to try and do is consolidate all
19 of that information under the Pediatric Section of
20 labeling and the important reason for doing that
21 is because you want to make sure that whoever's
22 reading the label reads information on the dose

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1 that was studied and what the safety and efficacy
2 findings were in the context of the fact that we
3 don't think that the drug works in the pediatric
4 population and maybe why we don't think that the
5 studies were positive.

6 There are a couple labels out there
7 that say the pediatric studies failed but it may
8 have been because they were inadequately powered
9 or the design was somehow flawed, and, of course,
10 under PREA, we now have a dispute resolution
11 process that is comparable to that that happened
12 under BPCA.

13 So, if at the time we're ready to
14 make a labeling change, the sponsor does not agree
15 to that labeling change, we do have the authority
16 to bring that labeling dispute to you guys, so we
17 can discuss the facts and then try and figure out
18 whether or not information should be included in
19 the labeling.

20 It should be noted that the law
21 actually requires us to comment in a 180 days, but
22 that's not really consistent with the time frame

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1 for a standard review of an NDA which would be 10
2 months. So, we'll come to you at the time that
3 the approval or not approval occurs.

4 Also, there's a greater transparency
5 under PREA in that the full medical, statistical
6 and clinical pharmacology reviews will be
7 available. Remember that previously only the
8 summaries of those studies submitted in response
9 to a written request under BPCA were available.
10 Now everything's going to be available.

11 And now the internal review committee
12 and this is a life labor of mine now. The
13 internal review committee is mandated by law.
14 We're called the Pediatric Review Committee or the
15 PeRC, and our role is to consult and review on all
16 mandated activities under both BPCA and PREA.

17 So, we provide quality and
18 consistency on helping divisions interface the
19 BPCA and PREA. We look at all pediatric plans,
20 assessments, waivers and deferrals and all written
21 requests prior to taking an action, prior to the
22 agency taking an action, and we really do try to

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1 provide some guidance to the divisions based on
2 the overall experience of the pediatric population
3 in all of these studies, our experiences that we
4 have here and all the experience from the research
5 community.

6 So, we provide consultation to
7 product divisions on all pediatric plans and
8 assessments. We give advice on granting of
9 deferrals and waivers. We make recommendations on
10 when submissions should receive priority review
11 and also all membership activities have to be
12 documented.

13 So these, as Dianne pointed out, we
14 spend three hours every Wednesday going over many
15 products. We have reviewed over 70 waivers,
16 deferrals, plans and assessments since October of
17 2007. So, you can see with that kind of a number
18 the workload that's going to be coming to you guys
19 from these new PREA activities.

20 The PeRC membership is actually
21 stated in the law and must include all of these
22 different expertise and so we have people from the

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1 Office of Pediatric Therapeutics as well as the
2 Review Divisions and we have lawyers and chemists
3 and statisticians. We've got everybody on the
4 board. It's a big group.

5 We do have a couple of deliverables.

6 Within 12 months, we have to conduct a review of
7 the studies that were submitted, deferrals and
8 waivers that were granted since PREA 2003, and
9 PREA 2003 was actually retroactive to April 1st of
10 1999. So, we have to go back and look at all the
11 waivers and deferrals that occurred since 1999 and
12 look at the quality and consistency and try and
13 make some recommendations to the Review Divisions
14 regarding waivers and deferrals.

15 It will actually give us a good
16 chance to go back and learn some lessons from what
17 we've done in the past.

18 We have a lot of tracking
19 responsibilities. I don't want to read all of
20 these for you because you will fall asleep, but
21 needless to say, we will be constantly updating
22 our web page with many details about the pediatric

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1 studies, both under PREA and BPCA, including
2 numbers and centers and center locations. So that
3 way people who are interested in pediatric
4 research have easy access to data that they may
5 find helpful.

6 More tracking and posting and even
7 more tracking and posting. I'll let you guys read
8 that on the airplane home.

9 We also have longer-term progress
10 reports. We do have an Institute of Medicine
11 report that we have to start within three years.
12 I know that Skip Nelson in the Office of Pediatric
13 Therapeutics is working a lot on that because
14 there's a big ethical piece.

15 We also have GAO reports on both BPCA
16 and PREA that are due by January 1st of 2011, and
17 of note, both BPCA and PREA do sunset October 1st,
18 2012. I hope that nobody in the AAP plans to
19 retire before then. They'll have to help us with
20 reauthorization.

21 And one of the biggest issues for you
22 guys, of course, is the annual safety review that

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1 has now been expanded to PREA. So, all adverse
2 event reports must be referred to FDA's Office of
3 Pediatric Therapeutics for the first year after
4 approved labeling changes and those reports will
5 be presented to the Pediatric Advisory Committee,
6 and, of course, additional reviews will occur
7 beyond the first year, as appropriate, and so now
8 you will be doing this on top of those reviews
9 from the Best Pharmaceuticals for Children Act
10 studies that are submitted in response to written
11 requests.

12 This is just a summary chart that
13 compares and contrasts our mandatory program with
14 our voluntary program and I think that the most
15 important change is that for both of these
16 programs, the studies do have to be labeled, the
17 information does get posted on the Web, and the
18 adverse events are presented to our Pediatric
19 Advisory Committee, and you'll be hearing more
20 about that from Dr. Cope who will be up here in
21 just a moment to cover that.

22 In conclusion, the new law's renewed

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1 many important provisions of BPCA 2002 and PREA
2 2003, and the new provisions really do increase
3 transparency in the process. The laws were
4 intended to work together and a new internal
5 review committee helps to provide consistency and
6 this really provides an opportunity for the FDA
7 and industry to work together to advance the
8 public health for children.

9 Thank you very much for your time. I
10 don't know. Should we stop for questions or do
11 you want to move on to Judith's presentation?

12 Okay. Yes. Any questions?

13 (No response.)

14 DR. MATHIS: All right. With that,
15 I'll introduce Judith Cope who's with the Office
16 of Pediatric Therapeutics, and she's going to go
17 over the safety reporting a little bit in more
18 detail.

19 Safety Update, Biologics and Devices

20 DR. COPE: So, everybody's tired,
21 right?

22 My name's Judy Cope, and I'm a

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1 pediatrician and epidemiologist with the Office of
2 Pediatric Therapeutics.

3 So, I'm going to be talking about
4 safety, so our focus is coming back to safety, and
5 as the subtitle, even though I'm going to be
6 talking mostly about drug products, reviewing a
7 lot of things for you, giving you some new things,
8 the biological and devices are going to be coming
9 your way. So, I know you've been hearing about
10 your growing workload, the challenges, but it
11 really is going to get more interesting as we get
12 into devices and the long-term effects of
13 biologics.

14 So briefly, I'm going to just very
15 briefly, I don't have a lot of regulatory slides,
16 I don't think, I'm going to give you an overview
17 of really the pediatric safety legislation, go
18 over the process for the pediatric focus reviews,
19 and I'm going to talk about our meetings, kind of
20 what you have done in the past, what we've
21 learned, what's coming ahead, and then how the new
22 legislation's going to be changing your work.

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1 So basically, 10 years ago, the FDA
2 Modernization Act or FDAMA really didn't have a
3 lot of safety requirements. So those came about
4 in 2002 with BPCA, and as you know that was the
5 law that then required for the one-year safety
6 reviews that you hear here at these committee
7 meetings, one year after exclusivity, and then in
8 2003, it was amended and this committee was born
9 basically.

10 It was earlier a subcommittee of the
11 Anti-Infective Drugs AC but then Congress made it
12 a full Pediatric Advisory Committee, and with the
13 new legislation that was passed September 27th,
14 last year, it's going to be expanding the
15 pediatric safety reviews then to biologics, not
16 just therapeutic biologics but all the other
17 biologics, and only a subset of the devices.

18 So, the devices that will be coming
19 for your review are what will be humanitarian
20 device exemption devices, we'll talk about that a
21 little later, with pediatric indication.

22 So, let's talk a little bit about the

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1 process. Actually, Dianne sort of introduced that
2 in the beginning, but I kind of think it's nice to
3 just, here you are in red and just wanted to point
4 out that you actually are tied right up to the
5 Office of the Commissioner.

6 So, the charter charges you to advise
7 and recommend on pediatric therapeutics, pediatric
8 research, and other issues that are pediatric, all
9 the way up, and on the right-hand side, the
10 reviews that you are presented, most of the
11 presenters come from the Pediatric and Maternal
12 Health staff.

13 All the Review Divisions, remember
14 people are sitting up at the end of the table,
15 those are from the divisions of the Drug
16 Evaluations, according to specialties, and they
17 are all under the Office of New Drugs, and then
18 on the postmarket side is the Office of
19 Surveillance and Epidemiology, and they're all
20 under CDER.

21 So, when we get into biologics and
22 devices now we're going to bring in two more

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1 centers and reviews will come from different
2 databases and we'll talk about that.

3 So briefly, again I think Dianne
4 opened it in reminding you what the process is a
5 little bit and we'll just review. We have a team,
6 the OSE, the Office of Surveillance and
7 Epidemiology, the Review Divisions with the
8 medical officers, pharmacologists, and
9 statisticians, and they're the ones then that know
10 the full pre-market history and the clinical
11 trials, the medical officers with pediatric
12 expertise from the Pediatric Office and then our
13 office that helps coordinate things, and our
14 process really goes over several months where we
15 have a series of meetings.

16 So, we get everybody together as a
17 team initially and people brainstorm, come
18 together with what they know and we try and
19 identify early what the known concerns are and
20 then in a very focused way, we go to the safety
21 evaluators, sometimes the epidemiologists may be
22 needed if there's more analysis, and these are the

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1 ones that are on the front lines, the receiving
2 lines, that analyze all these adverse event
3 reports all the time.

4 So, they will then come back with
5 their safety review. We meet a few more times.
6 Then we figure out what kind of questions we might
7 even think of asking you and let the data emerge.

8 So, if we have safety signals, you know, we need
9 to really ferret out, everybody really needs to
10 come as much as we can from our different areas to
11 decide what the issues are.

12 So, then your role, of course, I
13 counted, you had more than 600 pages that Carlos
14 sent out to you, but we send you all the
15 background materials which, of course, are
16 actually now on the Web and bring your expertise,
17 input, listen to all the presentations for -- this
18 wasn't too bad maybe today, but sometimes for a
19 couple days, and then your role is to advise and
20 make recommendations and based on that, then FDA
21 takes all your recommendations seriously into
22 consideration and may recommend to either go back

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1 to routine monitoring, labeling changes, safety
2 studies, continued monitoring, or have certain
3 risk minimization strategies that we may think are
4 important to get the word out to public health
5 care professionals, patients, and revise
6 medication guides which are called med guides.

7 So, we've talked a little bit about
8 AERS, and I'm going to try and go through this
9 quickly, but I think some of these things are
10 important to highlight, even though it's a bit of
11 a review, because a lot of what you hear is based
12 on these adverse events.

13 It is the chief tool for the FDA
14 postmarket surveillance. It's maintained by FDA.

15 Today, you heard some about Japanese reports and
16 certainly that was the case with Tamiflu.

17 The reports that the manufacturer has
18 to turn in are U.S. and foreign reports, and the
19 majority do come from the manufacturer. They are
20 required by law to report all the reports to the
21 FDA. Less than 10 percent and we'd certainly like
22 to up that a bit, but really about less than one

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1 out of 10 reports come from consumers, health care
2 professionals, and we try and make it easy on the
3 website. You go to MedWatch, you can fill it in
4 electronically, but, of course, there are a lot of
5 reasons that people may not report.

6 But I have a little personal bias,
7 but I think physicians give us a little more
8 detailed reports but anyway the system
9 accommodates electronic submission. Even though
10 it's close right now, the agency does not require
11 electronic submissions, but many or most companies
12 do.

13 There's more than four million
14 adverse events right now in the system and we use
15 MedDRA. I'm not sure if you're familiar with
16 MedDRA. It's a tool that basically uses
17 international codes that are accepted by all the
18 biopharmaceuticals and regulatory agencies around
19 the world, that basically you'll take an adverse
20 event report narrative and then based on that is
21 given certain codes.

22 So, blood pressure problem and then

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1 all the way down to lower terms, like hypertension
2 or hypertension no further diagnosis or secondary
3 to something else.

4 So, the importance of MedDRA is that
5 it helps search hundreds of documents and sort of
6 try and put likes and likes together to really
7 help in detecting safety signals.

8 And my colleagues from FDA and I,
9 they actually let me use this table, but we looked
10 at 17 years of AERS reports. So, these aren't the
11 serious ones now. These are all reports that come
12 in that had information on age. So, the pink part
13 of each bar for each year represents adults 18
14 years and older and the pediatric ones are showing
15 up white here.

16 So, it sort of shows over the last 17
17 years the pediatric reports are pretty steady
18 whereas if you look at the adults, it looks like
19 the trend is a little more that they're on the
20 increase, but the last 17 years, those with age
21 information are about 1.5 million adverse events,
22 that's through December '07, and 5 percent or

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1 about 75,000 are in the pediatric age group or
2 under age 18.

3 So, I just thought you might be
4 interested in -- I knew you'd need some pictures
5 here at the end.

6 The limitations, of course, with
7 these AERS, I think you had a lot of questions
8 about them today, is it is passive surveillance,
9 underreporting. I think several people have tried
10 to look at the FDA and, well, how many are we
11 missing, and I think the adverse events that are
12 coming in are about one out of 10.

13 There's, of course, lots of report
14 biases, including if there's something in the
15 press, last month about Tamiflu, people are going
16 to say we're getting a lot of Tamiflu adverse
17 events. So, sometimes publicity might change
18 things, for example.

19 The quality of the report is
20 variable. Many times complete. Missing age is
21 sometimes a problem and you can't necessarily even
22 figure out how old the individual might be by

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1 reading it, and usually, as you've seen with a lot
2 of the presentation, there's going to be
3 confounders. People are using other medications,
4 they have underlying disease.

5 So, sometimes it's not easy to always
6 see is this a signal or not in your
7 interpretation, and, of course, the reporting
8 rates are not incident rates. I know everybody
9 over and over would like us to give you
10 denominators. We do have use data, but again it
11 isn't perfect. It doesn't give you the
12 denominators and we don't even have perfect
13 numerators for you.

14 However, the strengths are it does
15 cover all U.S.-marketed drugs. It's simple. It's
16 inexpensive. We do uncover previously unknown
17 adverse drug events. You can find signals that
18 you're not going to find in the clinical trials
19 and adverse events too rare will come up.

20 Oh, for example, if you took aplastic
21 anemia with something like chloramphenicol, I mean
22 that might be one out of 20,000 and you might find

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1 that because doctors don't see it much and they'll
2 start reporting it and certainly we often see
3 greater seriousness than the adverse events in the
4 trials.

5 I think that was sort of evident in
6 some of the presentations today.

7 So, in general, clinical trials are
8 limited by their size. They're often too small,
9 too narrow, focusing on an indication. Study
10 population may be healthier or select, so you may
11 not really have a lot of generalizability. There
12 are a limited number of trials and in pediatrics,
13 things are even more limited and fewer in numbers.

14 So, I thank Lisa Mathis for this
15 slide. She suggested I might use it, and this
16 sometimes just highlights it visually, that if you
17 remember with the PK studies, you're going to get
18 more healthy volunteers maybe for those and
19 smaller groups, and then your Phase 2 trials are
20 sometimes based on what you learned with the Phase
21 1 and maybe you're much more controlled with not a
22 lot of patients and your pivotal and your

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1 continuing safety data Phase 3 trials, they often
2 will be hundreds of patients, up to a thousand or
3 so, maybe, but is that really going to pick up a
4 significant safety signal?

5 I give you something to think about.

6 It would take 3,000 patients at risk if you would
7 follow to detect one adverse event with an
8 incident rate of 1 in a 1,000. So, many times
9 you're not really going to pick these up till
10 later and the clinical trials are not, you know,
11 powered to really pick up the important safety
12 endpoints.

13 Now, I've actually added two
14 pictures. This is a very young infant and a
15 teenager mid-puberty and I did that to this slide
16 because I honestly think these are the most
17 vulnerable groups to safety. There's fewer
18 studies in these age groups and, importantly, in
19 utero and very early, you know, the first couple
20 months when the babies are doubling their size,
21 et. cetera, but this, of course, is the most
22 growth.

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1 It's the greatest amount of growth in
2 the lifetime is in utero and remember with these
3 teenagers, they're going to put six to 12 inches
4 on and totally transform in a period of a year,
5 and I think that the pharmacodynamics of drugs, we
6 really don't understand the effects of growth and
7 development on that, and I think that's one area
8 that needs to be much, much better studied,
9 especially long-term effects of all the different
10 exposures.

11 So, anyway, AERS does reveal adverse
12 events in the real world, for longer duration of
13 therapy, different use, and more vulnerable
14 subgroups are exposed.

15 I'm not going to spend a lot of time
16 on this, but actually I remember it came up this
17 afternoon. We did talk about causality and I list
18 for you nine elements that are important that, if
19 you had all of them or many of them, would suggest
20 that there was a cause of the adverse drug
21 reaction.

22 So, the time to onset, whether or not

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1 you give the drug, take it away, the reaction
2 comes or goes, dose response, whether the
3 biological plausibility, whether or not it goes
4 along with what we know about the clinical
5 pharmacology of the drug, and then these others.

6 So, just a couple slides.
7 Specifically, I wanted to go back -- let's see.
8 So, this committee has been going on since June
9 '03 up to now. So, a couple years after it had
10 been going, at this advisory committee on
11 Valentine's Day back in 2005, the committee was
12 asked how is this process going and what can we
13 do?

14 So, we did listen. The committee,
15 maybe some of you were here, that you didn't want
16 to hear all the adverse events, you just wanted the
17 deaths and the serious adverse events, and you
18 wanted to know, okay, so there were all these
19 pediatric deaths, but maybe I should know what's
20 going on with the adult population.

21 So, someone specifically said they
22 wanted to know the adult deaths. They wanted

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1 background information on the clinical trials.
2 They want the denominator which we have to keep
3 saying we just don't have with the system in place,
4 and then that even for the abbreviated
5 presentations, like you heard today, you wanted the
6 full package which we've given to you and if we
7 didn't think there was a signal, the committee back
8 then wanted to know a reasoning behind that.

9 So, the other -- I wanted to give you
10 one reg here because I know some of you are new to
11 the group and I think you need to understand what a
12 serious AE is and there's a specific regulation,
13 314.80, and it's defined as any adverse drug
14 experience occurring at any dose that results in
15 any of the outcomes, deaths, life-threatening,
16 hospitalization, prolonged hospitalization,
17 persistent or significant disability, congenital
18 anomaly or defect, and then any medical event that
19 could jeopardize the patient and possibly lead to
20 that. So, it is defined by the regulations and
21 that's what we bring to you.

22 So, in summary for the safety

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1 reporting to the committee, from June '03 to the
2 last meeting November '07, there were 12 PAC
3 meetings and 73 different drug products were
4 reviewed. That doesn't include the ones that you
5 had us bring back to you.

6 By the end of this year, our goal is
7 to complete all the BPCA safety reviews that are
8 triggered by the exclusivity date and then with the
9 new FDAAA legislation, and I think that Lisa really
10 hit that home, that the safety reviews are now
11 going to be triggered by labeling and will include
12 both the drugs by BPCA and PREA as well as all
13 biologics.

14 Negative studies mandated for
15 labeling is going to mean more products that need
16 to be reviewed and the adverse event and update
17 reports to the PAC will begin for the pediatric
18 HDEs or what I really want to say is HDEs with
19 pediatric indication.

20 So, I made a table here just to point
21 out there were 73 drugs then through the end of
22 last year and the numbers, according to specialty,

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1 I broke out. So, you'll see here there were 13
2 different drugs in hematology oncology products, 11
3 for cancer, one for anemia, one for
4 thrombocytopenia, and all the way down, and just
5 for your interest, we tallied them and all, but the
6 hematology oncology products that you reviewed, the
7 eye products which were drops for glaucoma
8 infections and the rheumatology products were all
9 returned to monitoring. So, none of those groups,
10 all of the ones in those groups, you returned to
11 routine monitoring. That was your recommendation.

12 When you broke it down to see what
13 you really did want, there were a total of 48,
14 which is about two-thirds of all the products that
15 were brought to you, you wanted to return to
16 routine monitoring, 14 led to changes of labeling
17 med guide or patient package insert, and 11 you
18 wanted continued reviews, and I just bring you a
19 couple of the revisions or med guide
20 recommendations that ended up making changes after
21 the PAC.

22 So, in 2006, for the selective

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1 seroton in reuptake inhibitors, there was the
2 stronger box warning and a med guide for all ages,
3 suicidality or increased risk of suicidal thinking
4 and behavior, and also the text talked about the
5 non-teratogenic effects of neonatal withdrawal
6 syndrome and the possible risk, rare risk, for
7 increased persistent pulmonary hypertension in the
8 newborn.

9 I know you all remember the Tamiflu
10 and it was this year, earlier this year, just the
11 last few months, that Tamiflu and other antiviral
12 products, such as Relenza, got the labeling
13 revisions with stronger warnings against the risks
14 of neuropsych events.

15 And then for Avandia, the data was
16 insufficient to recommend pediatric use of Avandia
17 and that was placed in the Pediatric Use Section.

18 When this product came, I think it
19 was about a year and a half ago, before your
20 committee, the data really didn't support efficacy
21 well in the pediatric age group and your committee
22 recommended that it be better spelled out for

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1 patients.

2 So, how are the new legislation going
3 to change things a little bit? So, I think we
4 talked quite a bit about how labeling is suddenly
5 going to dictate this now, and I just really don't
6 want to dwell on it too much, but I basically think
7 the key points are that labeling really is what's
8 going to be setting the time or triggering for our
9 safety reviews now, not the pediatric exclusivity
10 being granted, and this is an important point.

11 I don't think we brought this up
12 before, that when applicants come in for studies,
13 pediatric studies, even if it's been on the market
14 for a few years, the manufacturer's got to come in
15 and submit all AEs for pediatric submissions. So,
16 all of them are going to be required to do that.

17 The safety reviews now are going to
18 be biologics, too. So, they'll be coming
19 regularly, like the drug products are, and, of
20 course, now with devices, you're going to be seeing
21 a small set of HDEs with pediatric indication and
22 also brought to the committee, you'll be reviewing

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1 to decide or weigh in or recommend whether or not
2 you think this profit-making waiver that they were
3 given, that they can now make profit on these type
4 of devices, remains appropriate.

5 So, I just want to remind you,
6 because people forget, oh, okay, so a device is
7 like a heart valve, but actually those crutches
8 even I saw at the side of the room are devices.
9 This is a tanning booth, a stethoscope, insulin
10 pumps. I mean, it really covers the gamut. Some
11 are implanted devices, some are not. Some are
12 reusable, some are not.

13 The full definition is here. I think
14 I want to remind you that lab tests, so a strep
15 throat test would be classified as a device, as
16 would also an HIV test. HIV test because of
17 whether or not you were diagnosed to HIV would have
18 to have a lot more clinical data and come in for
19 approval on that, but those are PMAs, pre-market
20 applications, that have to come in with big full
21 clinical trials and the ones that will be coming to
22 you are the more challenging.

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1 They are humanitarian device-exempted
2 devices with pediatric indication. It's a little
3 different than orphan drugs, if you're familiar
4 with that, because it's a much more limited use,
5 less than 4,000 annually.

6 Also, devices are different. There's
7 pediatric guidance so that children are thought to
8 be all the way up to age 21. Manufacturers have to
9 think of it that way, and these HDEs are exempt
10 from effectiveness. So, they have to come in with
11 clinical data for assessment of and some benefit,
12 but they're required to meet the safety threshold.

13 So, here it is. Clinical data
14 relevant to the assessment of risk and probable
15 benefit and profit-making with the new legislation
16 is allowed if there's a pediatric indication.

17 Now, it's sort of like, well, what
18 kind of devices are these? So, if you go back,
19 there have actually only been nine or 10 devices in
20 the last 10 years that would fall into this
21 category. Most of them are like cardiovascular,
22 catheter or implanted devices. Few of them are

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1 fetal devices, urinary devices, but I bring you
2 this one just to kind of give you something
3 interesting.

4 This device is a vertical expandable
5 prosthetic titanium rib. So, it's a rib. It's
6 slightly curved. It's made out of titanium, and it
7 is to treat very rare pediatric scoliosis patients
8 who are in respiratory failure and when they grow,
9 it's only going to get worse. So, the device is --
10 the ribs are usually missing in these cases. Maybe
11 you could think of like achondroplasia in its
12 severe form would fall into this category.

13 It's called thoracic insufficiency
14 syndrome and they basically surgically implant a
15 rib in there that then they can expand every so
16 many months and the only thing -- this was approved
17 because the only thing that they had to do for
18 these young children who were operated on in the
19 first year of life would be to do spinal fusions,
20 take out some of the vertebra, and that, of course,
21 wouldn't allow the children to grow well. So, this
22 was meant to address that unmet need.

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1 So, then biologics. Here's the
2 regulatory definition, but again the products that
3 are going to be coming to you are not only vaccines
4 but things like monoclonal antibodies, proteins,
5 enzymes, human-derived tissues, like recombinant
6 bone morphogenic substances that may be used in
7 various surgical procedures, and both the devices
8 and the biologics have different databases, not
9 just the same AERS. So, I've covered these
10 different things.

11 In summary, I'd like you to visit our
12 home page and this is a brand-new home page that
13 just went live last week, so they changed the
14 colors and all that, but I wanted to point out to
15 you on the left here is the Pediatric Therapeutics
16 under Research and Science and there's the
17 MedWatch, if you want to send a report in, but if
18 you click on the Medical Therapeutics, it takes you
19 to our home and two things way on the right upper
20 corner is the New Legislation.

21 So, if you click on that, it'll take
22 you to your easy reading of a 156 pages for the New

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1 Legislation, and the Safety Reporting, if you click
2 that, you'll see all the work that's been done by
3 this committee. On the left are the drugs and so
4 we're up to, after this meeting today, we're up to
5 79 drugs that have been brought before you. The
6 date of exclusivity, the date it came to the
7 advisory committee, and then give us a few days but
8 the outcomes from the committee are summarized for
9 you for each and every drug. So, we hope that
10 you'll visit that.

11 I just want to thank everybody,
12 importantly the committee members for all their
13 expertise, their workload, going through the 600
14 pages, and there's only more to come, but I do
15 think it'll be more interesting, and I wanted to
16 thank all the FDA staff that's supported this whole
17 process.

18 Adjourn

19 DR. RAPPLEY: Thank you very much. Carlos had to
20 remind me to come back to the meeting because I'm
21 just reflecting on all of this that we've done over
22 this period of time and it's pretty amazing, but I

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1 think great thanks is owed to the diligent and
2 wonderful people who work in the agency and provide
3 all this material for us and review it so
4 completely and package it for us so well, as you've
5 done this time. Looks really good and we
6 appreciate that greatly.

7 It's sort of unsung heroes, I think
8 you all are, and I love it that there's a website
9 now that has Pediatric Therapeutics on it and we
10 can get the story out there, so that's great.

11 DR. MURPHY: We want you to tell
12 people to go there and look at both the summaries.

13 You can look at the -- they're no longer summaries
14 but also the full reports and you can look at the
15 safety reporting for yourself just to see.

16 I think, Judith, we had one of our
17 older versions up there because for the Tamiflu the
18 last time this committee knows, we actually changed
19 the label to talk about the impact of influenza
20 possibly and the CNS effects, too. But we really
21 have tried to summarize for you in a very concise
22 way all the different activities that this

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1 committee has recommended on that website,
2 particularly for the new people who haven't been
3 around, you can sort of flip through there, and
4 when you click on some of those links, it will
5 actually take you back to that meeting and you can
6 look at the minutes or look at some of the slides,
7 if you have any questions.

8 So again, thank you all very much.
9 Anybody have any questions about their future?

10 (No response.)

11 DR. MURPHY: Glad it's clear. We
12 hope not to frighten you away because we really do
13 need you. I hope we've made that clear, also. You
14 play a very important role.

15 DR. RAPPLEY: Well, thank you again
16 to the people who are rotating off. We will miss
17 you, and we hope to see you back at some other
18 point in time, and the meeting stands adjourned.

19 Thank you.

20 DR. MURPHY: Thank you all very much.
21 Safe trip home.

22 (Whereupon, the meeting adjourned at 4:07 p.m.)

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CERTIFICATE

This is to certify that the foregoing transcript
in the matter of: Pediatric Advisory Committee

Before: Marsha Rappley, MD

Date: March 25, 2008

Place: Gaithersburg, Maryland

represents the full and complete proceedings of the
aforementioned matter, as reported and reduced to
typewriting.


Eric Mollen