

FOOD AND DRUG ADMINISTRATION

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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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PUBLIC MEETING ON OTC SALE OF

HAND-HELD Doppler ULTRASOUND

PRENATAL LISTENING DEVICES

+ + + + +

WEDNESDAY,

MARCH 29, 2006

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The conference convened in Salons A and B of the Hilton Washington D.C. North, 620 Perry Parkway, Gaithersburg, Maryland, at 7:30 a.m., Mark Barnett, facilitator, presiding.

PANEL MEMBERS PRESENT:

MARK BARNETT Facilitator

GERALD HARRIS, Ph.D.

DANICA MARINAC-DABIC, Ph.D.

ROBERT A. PHILLIPS, Ph.D.

MELVIN STRATMAYER, Ph.D.

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FDA STAFF PRESENT:

LINDA KAHAN Deputy Director, CDRH

PRESENTERS:

JACQUES ABRAMOWICZ, M.D.American Institute of
Ultrasound in Medicine

JOSHUA COPEL, M.D.American Institute of Ultrasound in
Medicine

LENNARD GREENBAUM President, American Institute of
Ultrasound in Medicine

STACIE HANSEN BabyBeat, Inc.

TOM HANSEN BabyBeat, Inc.

DAVID JONES Summit Doppler Systems, Inc.

DENNIS NEWMAN For himself and on behalf of
Russel Thomsen, The Babydater
Co.

CAROL RUMACK, M.D.American College of Radiology

ALSO PRESENT:

SHARON HOGAN

SETH STABINSKY, M.D.

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P R O C E E D I N G S

(9:07 a.m.)

1
2
3 MR. BARNETT: Okay. I guess we should get
4 started. Can you all hear me? Are the microphones
5 working? Okay. Good.

6 Well, I want to welcome you to this
7 workshop on hand-held Doppler ultrasound prenatal
8 heart rate monitors. I'm Mark Barnett with the FDA
9 Center for Devices and Radiological Health, and I'm
10 going to be serving as your moderator today.

11 As everybody in this room knows, these
12 devices are designed to allow the user to hear a
13 fetus' heartbeat by transmitting and receiving
14 ultrasonic energy, and we're all, I think, also aware
15 in this room that at this point at least all of these
16 devices are prescription devices.

17 Now, over the past two years, FDA has
18 received three petitions asking that over-the-counter
19 sale be allowed for certain of these hand-held Doppler
20 ultrasound prenatal heart rate monitors. The FDA
21 denied the first two of these petitions because of
22 concerns about the safety of the fetus if these

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1 devices were to be sold without the order or
2 instructions of a physician.

3 Now, in responding to the third petition,
4 the FDA agreed to sponsor a public meeting to discuss
5 scientific data on the possible risks and benefits of
6 over-the-counter sale of these products, and of
7 course, that's why the FDA is here today, to listen
8 and to learn, to hear from a variety of interested
9 parties about the pros and cons of allowing over-the-
10 counter sale of these devices.

11 I want to stress that we're not here today
12 to talk about the legal or regulatory aspects of the
13 decision. Rather, what we're here today for is to
14 hear what you have to say about the science involved,
15 in other words, about the benefits and risks of over-
16 the-counter sale.

17 And so we're hoping that the people who
18 signed up to speak today are going to give us
19 scientific data that either supports or rejects the
20 idea of selling these devices over the counter. After
21 this meeting is over, the FDA is going to use what was
22 said today in helping to decide the question of over-

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1 the-counter sale.

2 So let me tell you a little bit about the
3 format of today's meeting. Up here in the front of
4 the room, we have a panel of FDA experts in this area,
5 and I think I'll introduce them now. And since you
6 guys out in the audience can't see these name cards,
7 I'm going to ask each person to raise their hand when
8 I introduce them so you can match a description with a
9 face.

10 Dr. Mel Stratmayer, hand up, is Deputy --

11 DR. STRATMAYER: Somebody already said I
12 don't listen very well.

13 MR. BARNETT: That's a bad thing for
14 today.

15 Dr. Mel Stratmayer is Deputy Director of
16 the Division of Biology, in the CDRH's Office of
17 Science and Engineering Laboratories. He has been
18 active in biological effect research and ultrasound
19 for over 30 years, and he's a Fellow of the American
20 Institute of Ultrasound in Medicine, or AIUM. He also
21 serves as the FDA's representative to several
22 international and national standards organizations in

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1 the area of ultrasound.

2 Dr. Jerry Harris is research engineer and
3 ultrasonic's laboratory leader in CDRH's Office of
4 Science and Engineering Laboratories. He has had over
5 30 years of experience in measuring and evaluating
6 exposure levels from medical ultrasound devices. He
7 holds fellowships in the American Institute of
8 Ultrasound in Medicine, the Acoustical Society of
9 America, the Institute of Electrical and Electronics
10 Engineers, and the American Institute of Medical and
11 Biological Engineering.

12 Dr. Danica Marinac-Dabic is Chief of
13 Epidemiology in CDRH's Office of Surveillance and
14 Biometrics. She's a physician and an epidemiologist
15 with a background in obstetrics and gynecology, and
16 she's an expert in epidemiologic studies of the
17 potential bioeffects of diagnostic ultrasound used
18 during pregnancy.

19 And Dr. Bob Phillips, Bob, yes? Okay. Is
20 Chief of the Radiological Devices Branch in the
21 Center's Office of Device Evaluation. He has had 28
22 years of experience as a radiation protection

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1 specialist in the FDA and ten years as a hospital
2 based radiological physicist. He is certified by the
3 American Board of Radiology as a diagnostic radiologic
4 physicist, and he serves on the Maryland State
5 Radiation Control Advisory Board.

6 Now, these folks are experts in this area,
7 but they're not going to be doing much talking today.

8 What they're here to do is to listen to you
9 presenting information on the scientific evidence that
10 can demonstrate either benefits or risks from over-
11 the-counter sale of these devices.

12 And the way they're going to hear that
13 information is through a series of presentations by
14 individuals and organizations who have signed up to
15 speak. We're going to call on each of them in turn to
16 discuss the potential risks and benefits associated
17 with over-the-counter sale of these devices.

18 By the way, we asked the speakers in
19 advance of the meeting to let us know how much time
20 they would need, and that's the time you'll see on
21 your agenda. So I'm going to ask each person to stay
22 within that time limit. I'm going to remind each

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1 speaker when there are two minutes remaining, and then
2 I'll ask them to finish up when the time is up.

3 After each presentation I'm going to ask
4 the FDA panels if they'd like to have any further
5 clarification from the speaker, and I'm also going to
6 give other people in the audience the opportunity to
7 ask the speaker for clarification, but I want to stay
8 within our time limit, and so I'm going to limit each
9 audience member to one question for the speaker and
10 then the speaker gets one answer back again.

11 After all the persons who have signed up
12 to speak have made their presentations, I'm going to
13 open the floor up to comments or presentations by
14 anyone else in the audience, and we'll have a time
15 limit of five minutes for those speakers, and again,
16 the FDA panelists and the audience will have the
17 opportunity to ask for clarification.

18 So that's the way the morning's meeting
19 looks and before we start I want to call on the deputy
20 director of FDA's Center for Devices and Radiological
21 Health Linda Kahan to say a few words of welcome.

22 Linda.

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1 MS. KAHAN: Thank you, Mark.

2 I do want to thank everybody for coming
3 out this morning. I'm really happy that we have
4 people here to talk to us, and I just want to
5 reiterate what Mark has said, that we're here to
6 listen today. We think that it's very important that
7 we make all of our decisions with as much information
8 as we could possibly get, and the idea of today is to
9 hear from all of you about what you have to say about
10 the science of the risks and the benefits of this
11 particular kind of device, and we really are here with
12 an open mind.

13 You've got very good listeners there, even
14 though they didn't raise their hands very well. They
15 really are good, and they are experts in their field,
16 and if you'll see in the back of the room, you have a
17 lot of FDA people who have come to also hear what you
18 have to say.

19 So we really look forward to a lot of
20 interesting presentations today. Thanks so much.

21 MR. BARNETT: Thank you, Linda.

22 Our first speaker is Patrick Martin from

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1 Sonosite (phonetic). Patrick Martin, is he here? I
2 know he was late.

3 Okay. What we will do then is we will
4 defer his talk and go on to our second speaker, Dennis
5 Newman. Is Dennis Newman here? Yes, okay. Good.

6 What I'm going to ask each speaker to do
7 when they come up is identify yourself in terms of
8 your name because we're having this transcribed so
9 that we have a record of it later. So identify
10 yourself by name and the organization you represent.
11 Okay?

12 Thank you.

13 MR. NEWMAN: Well, thank you.

14 Pleased to be here and start this meeting
15 off here, but I appreciate very much the opportunity
16 to speak both on behalf of myself, Dennis Newman, and
17 also on behalf of Dr. Thomsen. Unfortunately, Dr.
18 Thomsen cannot be here today, but given the
19 circumstances, I was pleased when he asked me to
20 present.

21 What he asked me to do was to read a cover
22 letter from his written comments that he submitted to

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1 the FDA here, and so I would like to do that. Dr.
2 Thomsen and I have been friends for many years, and I
3 really wish that he could be with us here in person
4 today, and I know that he really wishes that he could
5 be here today as well.

6 As many of you know, Dr. Thomsen has been
7 a real tireless crusader in the right of expectant
8 women to use a Doppler and now in home to listen to
9 their fetus' heartbeat, based on his understanding of
10 the safety and the benefits of these devices, and his
11 citizen's petitions to the FDA to grant OTC status to
12 these devices that are, I think, the major reason that
13 all of us are here today.

14 His passion for his cause, which goes back
15 over probably a couple decades has been a wonder to
16 many of us over the years, especially because he has
17 really never had any significant financial interest in
18 any company that would benefit from OTC status.

19 Dr. Thomsen is licensed physician in the
20 State of Washington and Board certified by the
21 American College of Obstetricians and Gynecologists.

22 Dr. Thomsen's letter begins, and I'll

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1 paraphrase some of it. It says:

2 I have had considerable wishes to
3 participate in this important public workshop dealing
4 with some of the issues surrounding the OTC sale of
5 low output, hand-held Doppler fetoscopes so that these
6 ingenious and useful and safe devices can be used in
7 the privacy of the American home in circumstances
8 chosen by American women.

9 Unfortunately, I am suffering from a
10 chronic illness which has chosen to worsen
11 significantly at this time, making my attendance and
12 presentation to this public workshop just not
13 possible.

14 This workshop is taking place through the
15 thoughtful consideration and work of professionals at
16 the FDA and specifically is held to address many of
17 the issues which I have presented to the FDA through
18 three citizen's petitions.

19 Because of my illness I have asked a long
20 time friend, Mr. Dennis Newman, to read this cover
21 letter into the record, and in doing so, also place
22 into the record a small portion of the supporting

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1 material, communications I have had with professionals
2 with the FDA about my view that certain Doppler
3 fetoscopes should be available to American women
4 through the OTC market.

5 In brief, I am an obstetrician-
6 gynecologist who had most of my clinical year spent as
7 a clinician in the U.S. Army Medical Corps. I've
8 delivered over 4,000 babies and was fortunate to
9 practice obstetrics during those years of tremendous
10 change for the good. For instance, it is realistic to
11 find that from the 1960s to the present, the most
12 significant advances in obstetrical care in all
13 recorded history took place. Ultrasound in many
14 applications was part of that great epoch of
15 improvement in women's pregnancy and newborn health
16 care.

17 I first met Dr. Lillian Yin as a colleague
18 in federal (phonetic) medicine in 1973 when it was my
19 privilege to present before an oversight committee of
20 Congress what I considered to be serious dangers in
21 the FDA's oversight of interuterine contraceptive
22 devices, IUDs, in general, and of the Dalcon Shield,

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1 in particular.

2 Those hearings, chaired by Senator Ted
3 Kennedy and others at the FDA, led inexorably to the
4 May 28th, 1976 enactment of the medical device
5 amendments to the Federal Food, Drug and Cosmetic Act.

6 With our 1973 meeting at the Dalcon Shield
7 hearings, Dr. Yin and I developed both a friendship
8 and a professional relationship which combined my
9 clinical observations with very strong feelings that
10 the FDA had a distinct obligation to safeguard the
11 pharmaceuticals and devices over which it had had
12 increasing regulatory obligations.

13 Our mutual interest, it seemed came
14 together over a seemingly small, little device
15 generally known as the hand-held Doppler fetoscope,
16 and the single most significant meeting of federal
17 minds on the subject of Doppler fetoscopes, regulatory
18 versus clinical, just happened to take place in front
19 of a display booth of a fledgling medical device
20 company, Imex Medical, at a national convention of the
21 American College of Obstetricians and Gynecologists
22 held in 1986 in the new convention center in New

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1 Orleans.

2 Billy and I excitedly brought Dr. Yin to
3 the Imex booth which featured a new model of the
4 company's expanding line of Doppler devices.

5 "I think that every expectant mother in
6 America should have the right to have one of these
7 Doppler fetoscopes in their home."

8 "Russ," Dr. Yin responded without missing
9 a beat, "what would happen if the woman could not hear
10 her unborn baby's heartbeat or thought that she heard
11 something wrong?"

12 "Dr. Yin," I responded immediately, "that
13 would be no problem. She would simply consult with
14 her doctor."

15 The Doppler fetoscope debates between Drs.
16 Yin and Thomsen started at that moment with Dennis
17 Newman interestingly listening in on that free-for-
18 all. Unfortunately, Dr. Yin, who passed away in 2000,
19 is not here to share her strongly held and rather
20 appealing views that she had an obligation to protect
21 American women from, shall I suggest, from Dr. Thomsen
22 and the little Doppler device.

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1 But I have never wavered in my views,
2 actually strengthening them as time, insight, and
3 thought have led to the following conclusions.

4 Number one, in addition to the numerous
5 studies demonstrating the amazing safety of ultrasound
6 in obstetrical care, a virtual mountain of clinical
7 experience refutes any lingering questions. Contrary
8 to some historical renditions, it should be realized
9 that portable Doppler ultrasound came to obstetrics in
10 1965 out of the University of Washington commercially
11 through SmithKline Instruments, and in 1966 with the
12 commercial sale of the Doptone by SmithKline
13 Instruments.

14 There are a little over four million live
15 births in the United States each year. Consider that
16 each pregnancy has about ten doctor ordered fetoscopes
17 clinical exams. That means in the two decades, 1968
18 to the present, since Dr. Yin and I debated the home
19 use of Doppler fetoscopes, there have been between 750
20 million to one billion clinical exams of pregnant
21 women, or in even more historical perspectives, since
22 the 1966 invention of the Doptone, there have been

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1 between one and two billion obstetrical exams with the
2 Doppler fetoscopes.

3 Complications of Doppler fetoscopes have
4 not been reported to the FDA by the use of a reporting
5 system that encourages, not discourages the reporting
6 of potential complications of use.

7 Number three, the massive use of Doppler
8 fetoscopes with the use of obstetrical evidence to the
9 contrary, an inescapable conclusion that Doppler
10 fetoscopes have not only saved fetal lives because of
11 early intervention when routine clinical visits had
12 turned into the discovery of severely ill unborn
13 babies.

14 If such incidental clinical encounters
15 have resulted in the saving of innumerable fetal
16 lives, it can only be concluded that beyond a
17 statistical certainty American women would save
18 hundreds of lives of their unborn babies each year if
19 OTC Doppler availability resulted in even periodic
20 use.

21 Five, and finally, with this possibly
22 being the first reference to such a possibility, it is

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1 likely that OTC Doppler fetoscopes would lead to live
2 births of hundreds of babies each year in the United
3 States because women have given further thought to
4 therapeutic termination of their pregnancies after
5 hearing the heart sounds of their unborn babies. That
6 this prevention of abortion would occur is within the
7 findings of any study of early pregnancy of mother and
8 fetus.

9 As this public workshop is being held, it
10 is most probable that U.S. personnel are, as my Black
11 Hawk pilot son and his wife in California are
12 listening to the heartbeats of their unborn babies
13 through the miracles of Doppler fetoscopes
14 transmitting via the Internet to front lines in
15 defense of freedom.

16 I do wish the success of this public
17 workshop as people with genuine interest in the well-
18 being of future generations of Americans through the
19 miracle which is OTC Doppler fetoscopes private home
20 use.

21 Most sincerely, Russel J. Thomsen, M.D.

22 And Dr. Thomsen has submitted quite a

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1 packet of additional written comments here for the
2 panel.

3 Now if I could also offer a few comments
4 of my own, sort of doubling up here today, but I have
5 been involved with the design and manufacturing and
6 marketing of these Doppler devices for virtually all
7 of my professional life, and that is getting to be a
8 long time these days. In the interest of full
9 disclosure, let me first summarize my background and
10 disclose all of my current relationships with
11 companies and organizations in this area.

12 I have an engineering background with
13 engineering degrees in electrical engineering from the
14 University of Colorado and Washington State
15 University. My ultrasound experience began in 1967 at
16 the Battelle Memorial Institute in Richland,
17 Washington.

18 I joined a small Denver firm called Metrix
19 in 1972, and Metrix was actually one of the first
20 companies to market diagnostic ultrasound products,
21 including an obstetrical Doppler. So I've been
22 involved with those Dopplers for a long time.

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1 In 1976, my wife and I started Imex
2 Medical Systems, and Imex went on to becoming the
3 leading manufacturer of obstetrical Dopplers in the
4 U.S. We sold the company a few years ago, in 1997, to
5 Nicolet Vascular after 21 years. I consulted with
6 Nicolet for about five years after that, but I have no
7 current relationship with them.

8 In 1998, I founded the Vascular Disease
9 Foundation, a nonprofit, public education foundation
10 that's now working with the National PAD Coalition and
11 the NHLBI on a public educational program for
12 peripheral arterial disease.

13 I'm a shareholder in Summit Doppler, and
14 you'll hear a presentation from Dave Jones
15 representing Summit later.

16 I'm a partner in the new company with my
17 son Spencer and others who are here today, and we are
18 developing a new medical device that is not yet on the
19 market.

20 And finally, I'm the father of Stacie
21 Hansen, who with her husband Tom, owns BabyBeat, and
22 they'll be making a presentation later today as well.

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1 I have no financial interest in that company, but I
2 would certainly like to see them succeed.

3 But I wanted to also say that I'm not
4 speaking on behalf of any of these companies or
5 organizations today. My remarks are strictly my own
6 personal remarks.

7 Just a little bit on the background of the
8 market for OBs. I realize this is a little bit of a
9 digression, but I think it does also pertain somewhat
10 to the question that's before us today about OTC
11 status.

12 Today this market for obstetrical Dopplers
13 is estimated to be in the range of only 15 to \$30
14 million per year worldwide. Contrast that to the
15 market for ultrasound imaging systems, which is about
16 200 times larger, about \$4 billion a year for imaging
17 systems.

18 What this means is that the companies in
19 this Doppler market are relatively very small or at
20 least small divisions within larger companies, and
21 unfortunately from my perspective, the small Dopplers
22 often get dragged into compliance and regulatory

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1 issues that are really more appropriate to the
2 marketplace. In fact, some of even the FDA guidelines
3 sometimes almost ignore the Doppler, the Doppler power
4 measurements and so on.

5 I shouldn't say that, but basically they
6 are much more focused on the imaging systems, I
7 believe, than the Dopplers, but at any rate, the
8 barriers to entry in this market are also relatively
9 small, and many new firms have popped up from time to
10 time over the years. Just sitting down for a minute,
11 it looked to me like there's probably over a dozen
12 firms that are currently manufacturing obstetrical
13 Dopplers for sale in the U.S., and I could also
14 predict that there's no consensus among those firms
15 relative to this OTC question before us today. Some
16 will benefit from this OTC status and others will not.

17 As far as my experience at Imex in the
18 more than 20 years that I was running that, Imex has
19 sold over 100,000 Dopplers over the years to OBs and
20 hospitals. Most were sold through basically hundreds
21 of medical distributors, none to pharmacies, to my
22 knowledge, probably more than a few ended up in the

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1 hands of patients either by sale from a distributor
2 that we were unaware of direct to a patient, again,
3 without our knowledge, or because the patients
4 borrowed them from the doctor's office.

5 Shortly after I sold Imex to Nicolet,
6 Nicolet actually applied for OTC use of a new Doppler
7 in 1997. Dr. Thomsen and I consulted with Nicolet on
8 that 510(k) application. The FDA respectfully denied
9 the OTC status of that Doppler, but did grant a
10 prescription home use status.

11 Kind of along the lines of some of the
12 comments that Dr. Thomsen made relative to how many
13 exams these Dopplers have been used with, if there are
14 about four million births each year in the U.S., I
15 would say that conservatively at least one million of
16 those are monitored each year using Imex Dopplers.
17 And since a Doppler exam is typically done on each
18 prenatal visit, this would be about ten million
19 examinations per year using Imex Dopplers.

20 And again, even with the FDA complaint
21 systems in place, I am not aware of any record of
22 complaint about any maternal or fetal injury or

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1 problem caused by the use of the Imex Dopplers, which
2 I think is a tremendous record of apparent safety.

3 I know that it's impossible to prove that
4 a product is safe, but, of course, it's very easy to
5 show that a product is unsafe. However, by concerns
6 raised here today and in other previous meetings, I am
7 unaware of any substantiated injuries or deaths
8 attributed to the OB Doppler.

9 I contrast that to proven problems for
10 many other products that are readily available over
11 the counter or even unregulated, aspirin, Tylenol,
12 even Coor's Light or especially Coor's Light, I
13 suppose, or fetal alcohol syndrome.

14 I think that the benefits of a Doppler
15 exam are real insignificant, as you'll hear later from
16 BabyBeat's presentation, but also by virtue of the
17 fact that nearly every obstetrical caregiver in this
18 country performs a Doppler exam at every prenatal
19 visit, obviously the obstetrical caregivers understand
20 the benefits of this product. So I hope they
21 understand the risks involved with that.

22 These are not keepsake ultrasound exams,

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1 but are testimony to the reassurance the Doppler
2 sounds give to the mother and the stress relief that
3 comes from hearing the fetal heart.

4 I think unfortunately in talking to our
5 customers, obstetricians, not all obstetrical
6 caregivers -- certainly many are, but not all are
7 aware or sensitive to some of these stress issues that
8 mothers present. Although they continue to perform
9 the exam on their own over time, they have remarked to
10 me that they believe mothers at home want to do this
11 just for fun, although you can see from BabyBeat or
12 will see from BabyBeat's presentation that there is
13 much more to it than that.

14 As a father and now grandfather, I can
15 attest to the enormous roller coaster of emotions that
16 accompany a typical pregnancy, and I have seen first
17 hand the devastation that accompanies a miscarriage
18 and the stress and worry that comes with follow-up
19 pregnancies, much relief by hearing the baby's
20 heartbeat.

21 Finally, to summarize my personal
22 feelings, it's really my strong belief that it's very

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1 possible to provide adequate directions for safe use
2 of this product. I obviously believe that it serves a
3 real need to many expectant mothers and has a real
4 place in home use.

5 I also believe that the best source of
6 information currently available to worried mothers is
7 through the best of the Doppler sales and rental
8 companies. Their trained staff can quickly and
9 accurately answer many questions about the use of
10 these devices. They are more knowledgeable and
11 helpful than the pharmacy is and complement the
12 obstetrical caregiver.

13 So that's my remarks, and I thank you. I
14 guess if we're taking questions or I'll turn it back
15 over to you.

16 MR. BARNETT: Thank you. Thank you, Mr.
17 Newman.

18 Does the panel have any questions or
19 clarifications?

20 DR. HARRIS: Yes. Jerry Harris.

21 Of course, we are sorry that Dr. Thomsen
22 couldn't make it, but I'm very glad that you could be

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1 here not only to make this presentation, but also I've
2 been familiar with your work, such as in the Schlearn
3 (phonetic) imaging of ultrasound fields for years. So
4 it's a pleasure to see you from that standpoint.

5 I did have one question about point number
6 four in Dr. Thomsen's letter.

7 MR. NEWMAN: I'm not sure that I can
8 answer for him.

9 MR. BARNETT: Why don't you read it?

10 DR. HARRIS: Yes, this is, "If such
11 incidental encounters have resulted in the savings of
12 innumerable fetal lives, it can only be concluded that
13 beyond a statistical certainty, American women would,"
14 and it's skipping, "save hundreds of lives of unborn
15 babies each year if OTC Doppler availability resulted
16 in even periodic use."

17 My question was about the phrase
18 "concluded that beyond a statistical certainty." Now,
19 in the materials that Dr. Thomsen provided, there was
20 a very brief paragraph about a professional
21 statistician being consulted who apparently did an
22 analysis. I did not find anymore details about that

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1 in the packet. So it would be helpful to us if either
2 you or Dr. Thomsen could provide some more details
3 about that statistical analysis.

4 MR. NEWMAN: I'll have to speak further
5 back to Thomsen on that one because I wasn't involved
6 in that actual calculation and so on. I basically
7 know that what he's talking about, of course, was just
8 if enough women were using these, basically found a
9 problem while listening to their babies' heartbeat
10 contacted their doctor that some of those babies might
11 be saved, but the actual statistical analysis, I
12 cannot help to answer that question.

13 DR. HARRIS: But if it would be possible
14 to get that, that would be helpful.

15 MR. BARNETT: All right. Anyone else?
16 Bob.

17 DR. PHILLIPS: You mentioned that the
18 Nicolet device had been cleared for marketing with
19 prescription home use status. That particular status
20 applies to all prescription devices.

21 My question is: what advantage to the
22 patient would ensue from changing from prescription

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1 home status or the device can be used at home under
2 the supervision of a physician, the obstetrician,
3 versus just having it over the counter.

4 MR. NEWMAN: Well, that's an excellent
5 question. I have given some thought to that. You
6 know, I think that from my personal perspective, I
7 think, some of the issues today with prescription
8 versus over-the-counter, some of those revolve around
9 basically the fact that many obstetricians, again, are
10 not -- I guess two major things.

11 First of all, many obstetricians are not
12 used to prescribing this. Many obstetricians actually
13 believe that this is already over the counter and that
14 you can buy this at Babies Are Us, and so on. I've
15 heard, again, Hannah and her daughter Lee say that
16 they tell their patients, "Just go to the Internet and
17 get one of these." They're not used to writing a
18 prescription. So that's one issue.

19 I think that the other one is depending on
20 how strict I guess you could call it the letter of the
21 law is applied to prescriptions, it could be very
22 difficult to provide these through prescriptions

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1 basically because, as you know, prescriptions are
2 regulated really on the state-by-state basis in terms
3 of what's actually required.

4 I've never seen a pharmacy, for example,
5 carry a Doppler. So my answer is basically just one
6 of access to these Dopplers. You know, that may be
7 just a factor that takes more information being
8 disseminated to the obstetrical carriers.

9 MR. BARNETT: Anyone else on the panel?

10 DR. MARINAC-DUBIC: Yes, I have another
11 question that actually is related to Jerry's question
12 about the statistical calculation, and I'm only
13 assuming that Dr. Thomsen had done something like
14 taking the total number of live births in this country
15 and added the late fetal deaths to that, and then
16 assuming that such-and-such number of the perinatal
17 death occurred in the same year, added to that the
18 late fetal deaths; so by dividing those two numbers,
19 he probably came up with something that was related to
20 several hundreds per 100,000 of potentially lives
21 saved, which means that those late fetal deaths could
22 be potentially safe had those women had access to

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1 these devices.

2 However, when you convey our concerns to
3 Dr. Thomsen, I would like him if he responds to think
4 about the fact that actually if this device is being
5 available, the general population will have to also
6 assume that 90 percent of the women in general
7 population are actually low risk women, and that those
8 fetal heart rate decelerations do not occur all the
9 time.

10 So just assuming that by giving an access
11 to all women at all times does not mean that those
12 women will be able to really detect that, especially a
13 small portion of the high risk women, and even if we
14 assume 100 percent of the detection rate, we still
15 have to decrease this number for several assumptions.

16 For example, there will be women who, you know, their
17 deceleration will result without an intervention.
18 There will be women for which we will send them to the
19 obstetrician, but then, you know, even with proper
20 care given, they will still end up having fetal death.

21 So these are the things, and also we
22 cannot assume that by giving availability to this

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1 device to everybody that all of the women will have
2 equal access to that.

3 So those are the things when he responds I
4 would like if he can really elaborate on these things
5 as well.

6 MR. BARNETT: Okay. Thank you.

7 MR. NEWMAN: I understand.

8 MR. BARNETT: Okay. Anybody else on the
9 panel?

10 (No response.)

11 MR. BARNETT: Okay. Is there anyone in
12 the audience that would like to ask for clarification
13 of any of this?

14 (No response.)

15 MR. BARNETT: Okay. If that's the case,
16 thank you, Mr. Newman.

17 MR. NEWMAN: Thank you.

18 MR. BARNETT: And now is Patrick Martin
19 here yet?

20 PARTICIPANT: It does not look like he
21 will be joining us today. I have not heard.

22 MR. BARNETT: Okay. We'll leave room at

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1 the end in case he shows up.

2 Okay. If that's the case, let's go on and
3 we have a series of presentations from AIUM, and I
4 assume that the AIUM folks want to go in the same
5 order that they are listed on the agenda, or you guys
6 can choose and just send up.

7 DR. GREENBAUM: Well, good morning, and
8 thank you for the opportunity to present. I'm Dr.
9 Leonard Greenbaum. I am president of the American
10 Institute of Ultrasound in Medicine, and my day job is
11 that of radiologist that exclusively does fetal
12 ultrasound, and I'm co-director of the Youth Center
13 for Fetal Diagnostics, which is part of Orlando
14 Regional Health Care.

15 And I have no conflicts of interest
16 regarding the subject before us today.

17 I'm just going to give you a brief
18 overview just for the record about the AIUM and its
19 activities. I have a little bit about regulatory that
20 I will leave out of the presentation, and then I have
21 two of my colleagues who will continue the
22 presentation.

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1 First of all, regarding the AIUM, we are a
2 multi-disciplinary association that's dedicated to
3 advancing the safe and effective use of ultrasound in
4 medicine through professional and public education,
5 research, development of guidelines, and
6 accreditation. We have about 7,500 members that
7 include physicians not from all specialties, but from
8 many specialties: stenographers, engineers,
9 physicists, veterinarians, technicians, manufacturers,
10 and medical students. We are a little over 50 years
11 old, and we're down the road a piece in Laurel,
12 Maryland.

13 What the objectives are of the AIUM is to
14 provide professional education, public education and
15 research initiatives, and promote the importance of
16 and uses of ultrasound; to increase the quality
17 practice of medical ultrasound by advocating standards
18 and accreditations to promote patient rights and
19 safety; to be a source of expertise in ultrasound, as
20 well as a resource for government agencies; and to
21 represent all forms of medical ultrasound.

22 As far as some of our recent activities,

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1 this past year we hosted two multi-disciplinary forums
2 to develop consensus over various issues, one being
3 dealing with ultrasound in obstetrics and gynecology
4 and another dealing with thermal and nonthermal
5 bioeffects from ultrasound.

6 And in 2004, we had another consensus
7 forum, multi-specialty forum dealing with the use of
8 hand-held or compact ultrasound systems.

9 We established Medical Ultrasound
10 Awareness Month back in 2001, and we have an ongoing
11 collaboration with several different societies in the
12 creation of joint clinical ultrasound practice
13 guidelines.

14 One of our more important activities is
15 our accreditation process where we have accredited
16 more than 1,500 ultrasound practice sites throughout
17 the United States and Canada.

18 And I will skip the regulatory stuff, but
19 the AIUM does have a prudent use statement, and we
20 feel that this applies in this area, too. And as far
21 as the underlying segments here, the AIUM strongly
22 discourages the nonmedical use of ultrasound, and

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1 although there are no confirmed biological effects on
2 patients caused by exposure from present diagnostic
3 ultrasound incidents, the possibility exists that such
4 biological effects may be identified in the future.
5 Thus, ultrasound should be used in a prudent manner to
6 provide medical benefits to the patient.

7 Now, I think all of this revolves around a
8 risk-benefit ratio that ultrasound certainly has
9 tremendously altered how obstetrics is practiced
10 throughout the world, and it's an absolutely wonderful
11 device, and, yes, we are fortunate that we are not
12 seeing biological effects, but with any instrument if
13 there's information that's important to be gained, it
14 should be used, and if it's really not medically
15 indicated, then it should not be used.

16 I have, as I said, two colleagues with me
17 who are quite qualified to talk about this subject.
18 The first presenter is going to be Dr. Jacque
19 Abramowicz, who is chair of our Bioeffects Committee
20 and is Professor of Obstetrics and Gynecology of Rush
21 University in Chicago, and Dr. Abramowicz will be
22 talking about hand-held Doppler: is it safe for my

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1 baby?

2 And following Dr. Abramowicz, Dr. Joshua
3 Copel, who is president-elect of the AIUM and is
4 Professor of Obstetrics, Gynecology, and Reproductive
5 Sciences, as well as Pediatrics, at Yale. And Dr.
6 Copel will be speaking on fetal heart rate and rhythm
7 and over-the-counter hand-held Doppler devices.

8 So I will turn it over to Dr. Abramowicz.

9 DR. ABRAMOWICZ: Thank you very much.
10 Thank you for inviting me to present this morning.

11 And what I will try to do is speak a
12 little bit about the safety of Doppler. This is who I
13 am. I'm a Board certified OB-GYN and a Fellow of the
14 American College of OB-GYN and a Fellow of the
15 American Gynecologic and Obstetric Society. I'm a
16 Professor of Obstetrics and Gynecology, and the last
17 line, I'm the Chair of the American Institute of
18 Ultrasound in Medicine's Bioeffects Committee.

19 I don't have any financial or other
20 interest in any Doppler manufacturer or distributor.

21 This is something that I found on eBay a
22 couple of weeks ago, and it says fetal Dopplers are

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1 regulated by the FDA and are approved for personal use
2 with the approval of your physician, and then the part
3 that is important, research has proven that the rays
4 from a Doppler will not harm an unborn baby. And it
5 says you should contact your physician, et cetera, et
6 cetera. This particular unit sells at \$449.

7 Let's look at some facts because research
8 has proven that the rays from a Doppler will not harm
9 an unborn baby is actually not a correct statement
10 because you cannot prove it.

11 So let's look at facts. Ultrasound is
12 energy, and this is true for any form of ultrasound.
13 Now, ultrasound is a weight form. So there's positive
14 and negative pressures, and the two major effects are
15 of a thermal energy, which is an indirect effect and
16 mechanical energy which is direct. The positive
17 pressure causes movement, and negative pressure can
18 induce medication, which is a reaction of bubbles in
19 the tissue to the ultrasound itself.

20 Now, it needs to be considered that in any
21 tissue that ultrasound traverses there will,
22 therefore, be an increase in heat. That's the one

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1 effect, and there will be oscillatory movements.
2 That's the mechanical effect, which could cause
3 certain reaction to the tissue including possibly
4 reduce of free radical.

5 Other facts, ultrasound, under certain
6 condition will heat tissues. Anybody who has had
7 therapeutic ultrasound could obviously have very
8 different frequency and power, but you could actually
9 feel the heat.

10 The other fact, the heating of tissue by
11 ultrasound is extremely fast, one to two minutes from
12 onset of exposure, and in fact, near bone, 30 seconds.
13 This is another number that is worth remembering.

14 Now, there are many, many measures of
15 intensity of ultrasound, and I'm not going to go into
16 details, but the peak of the intensity, you average it
17 or you do not average it with the cell on and off.
18 There are all of these essentially five possibilities
19 to vary the intensity of the beam itself.

20 Now, when one speaks about regular office,
21 not doctor office now, there was a limit in the past
22 of 94 milliwatts per centimeter squared, which was

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1 then early '90s and moved to 720 milliwatts per
2 centimeter squared for fetal use. Again, these are
3 numbers to keep in mind when we move forward.

4 Now, there are several studies looking at
5 actually acoustic power measurement of Doppler
6 ultrasound device, and here is a study from 1990, and
7 they tested four devices, and you can see that the
8 acoustic power varied from the lowest being 8.7
9 milliwatts to up to 96.8 milliwatts.

10 Here is another study, a survey of the
11 acoustic output of ultrasonic Doppler equipment, and
12 this is a study that looked at a variety of clinical
13 Doppler instruments, including continuous wave Doppler
14 units, which is what we're talking about here, but
15 also fetal monitors, stand alone pulse Doppler, and
16 Doppler that's found in ultrasound machines.

17 And this is a long sentence, but I would
18 bring your attention only to a few parts " . . .
19 Almost all the pulsed Doppler and duplex systems
20 investigated could generate temporal-average
21 intensities with a maximum of 825 milliwatts per
22 centimeter squared. So we're certainly above 94. It

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1 involves 720, and the next sentence says these
2 intensities were also reached by some continuous wave
3 Doppler system, and then continues by saying that
4 there is a wide variation in pulse length and a wider
5 range of pulse rate intensity than previously
6 reported.

7 The introduction of the Perinatal Doppler
8 Society came out with guidelines and recommendations
9 for safe use of Doppler, and again, the major part of
10 the sentence is that the acoustic outputs are
11 sufficient to produce obvious biological effects, not
12 necessarily harmful effects, but certainly biological
13 effects, such as the temperature increase.

14 Now, this is speaking about pulse Doppler,
15 which is different from continuous doppler.

16 And, again, another part of the sentence
17 saying thermal defect. The risk of thermal defect was
18 greater in the second and third trimester because
19 there's bone, and as I showed you, an increase in
20 temperature can occur very quickly, in less than 30
21 seconds, while non-thermal bioeffects may be more
22 significant in early gestation when the fetus is not

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1 born, but is made mostly of protein.

2 And the sentence which is very important,
3 to insure that continuous safe use of ultrasound in
4 obstetrics, et cetera, et cetera, et cetera, and the
5 issue of risk-benefit, which is very important, and
6 therefore, the practical implementation of ALARA,
7 which is as low as reasonably achievable principle.
8 That is, you need to use ultrasound when it is an
9 official benefit that's higher than the risk, and when
10 you do that, use it for the lowest time available at
11 the lowest power available.

12 Now, there was an area of study in the
13 Lancet which deals with ultrasound and pulse Doppler.

14 So it is slightly different, but there is a reason
15 why I'm showing this here, and they have about 28
16 common pregnancies, half with ultrasound and
17 continuous Doppler five times during the pregnancy,
18 18, 24, 28, 34, 38 weeks, and then about 1,500 or
19 1,400 with a single scan at 18 weeks.

20 And what they found was a significantly
21 higher intrauterine growth restriction in the
22 intensive group. There were a lot of problems with

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1 the study, but the point is that their conclusion,
2 that it is plausible that frequent exposure to
3 ultrasound may have influenced fetal growth. Doppler
4 flow, and their conclusion -- and this is really why I
5 show this -- Doppler flow examination should be
6 restricted to those women to whom the information is
7 likely to be of clinical benefit. Again, this is
8 pulse Doppler.

9 Now, there are several unknowns when we
10 speak about ultrasound, the length of exposure,
11 cumulative effect, and the repeat injury. Now, there
12 is no literature showing that there is repeat injury
13 when using repeat Doppler or repeat ultrasound, for
14 that matter. There's no mention of accumulative
15 effect, and length of exposure when one looks at a lot
16 of the literature dealing with the acoustic output,
17 length of exposure is very rarely dealt with.

18 Now, it is true that millions and millions
19 and millions of women have been exposed to continuous
20 Doppler with the hand-held Doppler, but in general --
21 I've been a practicing OB for the last 25 years -- the
22 exposure to pulse Doppler in the office when one

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1 listens to the fetal heart is probably in the vicinity
2 of ten seconds or 20 seconds. It's certainly not more
3 than that, and if we think that there's a risk at 30
4 seconds, this is certainly less than that.

5 So there are also some questions on
6 whether it's safe to use ultrasound in the first
7 trimester, and relative to this conclusion which is
8 important, there's no epidemiological or other
9 evidence then -- that's in the early '90s -- or now --
10 that's in 1999 -- to support the assertion of safety
11 at these high exposures.

12 Now, the fact that we have not found
13 anything doesn't mean that there isn't something that
14 we haven't been able to find, and of course,
15 ultrasound, whether it's Doppler or regular
16 ultrasound, does not kill babies, does not cause
17 babies to be born without arms or legs like with the
18 thalidomide tragedy, but we cannot be sure that there
19 are not subtle things that we may not have been
20 looking for.

21 And in fact, there was an editorial in
22 2000 asking whether it was at all ethical to look at

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1 the fetus with Doppler ultrasound.

2 Now, do we know what is the actual output
3 power of Doppler devices? And we need to ask, well,
4 how reliable are the manufacturers reporting risk
5 data, and there's not a lot of information on that.
6 There's a study from 1995 concluding reported data
7 have almost invariably been underestimated.

8 Now, there are many hand-held Doppler
9 companies. I found these. By the way, Doppler Fetal
10 Angel Sounds sells for 699, Doptone, et cetera, et
11 cetera, et cetera, many, many companies, and a few,
12 actually two that I could find on the Internet gave an
13 output that's less than five milliwatts per centimeter
14 squared.

15 Now, here's just an example of the
16 company. This is the user's manual, and here are the
17 specifications. It's hard to read so I will point to
18 you that they speak about -- sorry -- uncertainties.
19 That doesn't show. But the issue was that there is a
20 plus-minus of 29 percent, 49 percent in the power
21 intensity, 18 to 29 percent. So quite a wide range,
22 which is acceptable for devices.

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1 And there may be major differences between
2 once a month with the health care provider office and
3 the mother using every day, twice a day, five times a
4 day, for a minute, two hours, five hours, who knows
5 how long? And the major issue being the risk-benefit
6 ratio.

7 So there may not be clear proof of risk,
8 but there's a French proverb that says *dans le doute,*
9 *abstiens-toi*, which comes from the Latin, of course,
10 which means when in doubt, abstain, and therefore, if
11 I'm even in doubt I would really abstain from
12 approving it.

13 Thank you.

14 MR. BARNETT: Thank you.

15 We have a third speaker, do we, of the
16 AIUM?

17 (Pause in proceedings.)

18 DR. COPEL: I apologize. I'm a Mac
19 person.

20 (Laughter.)

21 DR. COPEL: And the fonts don't translate
22 well. I got this thing loaded beforehand, and I'll

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1 ask you to bear with me and hope that the one graphic
2 does show up well.

3 I'm Dr. Joshua Copel. I'm a professor of
4 obstetrics, gynecology and reproductive sciences, and
5 of pediatrics at Yale University School of Medicine.
6 My specialty is high risk obstetrics, particularly
7 prenatal diagnosis and therapy, and I'm a Board
8 certified specialist in maternal fetal medicine. I'm
9 here today as president-elect of the AIUM.

10 In terms of disclosures, I have been a
11 consultant to a number of ultrasound companies. As
12 far as I know, none of them are seeking approval for
13 OTC Doppler. I have also advised Oxford about a hand-
14 held Doppler device that was intended only for
15 professional use. In exchange for that consultation,
16 I did receive a free hand-held device that I donated
17 to a clinic for indigent patients in Kingston,
18 Jamaica.

19 I also have to reveal that I'm told I'm an
20 SGE for the FDA OB-GYN Devices Panel. However, I have
21 not performed any reviews or rated in any way in this
22 particular application.

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1 My particular area of expertise is
2 prenatal diagnosis of fetal cardiac abnormalities, an
3 area I focused on for the last 23 years. One of the
4 things we've been known for at Yale has been the
5 management of fetal arrhythmias. My comments today
6 will be limited to that aspect of the petition.

7 In its petition on 29 July 2002, Dr.
8 Russel Thomsen stated, "There are at least anecdotal
9 reports of lifesaving interventions being instituted
10 for the home use of Doppler fetoscopes."

11 Further, on 8 September 2003, there was a
12 petition that said that anecdotal cases reported by
13 consumers back to Doppler fetoscope sellers, renters,
14 or manufacturers, instances exist where pregnancy
15 intervention has occurred for purpose of its home use
16 leading to live or healthy babies.

17 That petition goes on to say to the
18 contrary, there are at least anecdotal reports of
19 lifesaving interventions being instituted because of
20 the home use of Doppler fetoscopes.

21 Furthermore, this would potentially put in
22 their hands an item which might save the life of their

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1 unborn babies.

2 The implication of these statements is
3 that there are abnormalities of fetal cardiac rhythm
4 that occur with some frequency and are easily
5 recognizable to the lay person.

6 Furthermore, it implies that some
7 intervention might be available that would reduce
8 morbidity or mortality once this dysrhythmia is
9 recognized. It has long been known that a sizable
10 number of neonates have benign rhythm abnormalities,
11 almost always extra systems with no health
12 implications.

13 In 2000, we published what was then and
14 what remains the largest series of cases of common
15 fetal arrhythmias, and the reference is provided on
16 the slide and in the text that you have. In that
17 study, we reviewed over 600 fetuses referred to us for
18 irregular heart rates and found that 55 percent of
19 them had no rhythm abnormality when they came for
20 formal ultrasound study and that there was an
21 exceedingly low frequency of significant rhythm
22 disturbances.

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1 From our considerable experiments, I
2 conclude that little benefit would accrue to fetuses
3 from OTC availability of hand-held DOPPLER devices in
4 terms of the detection of dangerous arrhythmias.

5 I also have concerns that false alarms
6 created by detection of internal heart rate, which is
7 typically 60 to 90 in comparison to normal fetal heart
8 rates of 120 to 160 beats per minute, would generate
9 frequent mistaken emergencies as worried women and
10 their partners frantically call their physicians or
11 midwives to report that their babies' heart rates are
12 dangerously low.

13 The slide I'm showing now is taken from an
14 external fetal monitor machine this past month of
15 March on the labor and delivery floor at Yale. It
16 looks like a fetal heart rate tracing and a rate of
17 about 120 beats per minute. In fact, the 24 week
18 fetus being monitored was actually dead.

19 This is a tracing of the tachycardiac
20 maternal heart rate. If the experienced nursing staff
21 at Yale New Haven Hospital can be fooled, I expect
22 that nonprofessionals will be even more prone to such

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1 errors.

2 Also know that when I was evaluating the
3 hand-held device noted in my disclosures, a low cost
4 instrument made outside the United States, my
5 recommendation to the vendor was not to distribute the
6 device. I came to that conclusion after auscultating
7 her fetal heart rate from a woman's arm. Whatever
8 gets sold over the counter is likely to be equally or
9 less reliable.

10 Dr. Thomsen may alternatively be referring
11 to periodic changes in the fetal heart rate, so-called
12 rate decelerations that may occur in labor. These are
13 often subtle alterations from the baseline rate and
14 may be difficult to distinguish even by experienced
15 observers looking at fetal heart rate printouts from
16 electronic fetal heart rate monitoring devices.

17 I do not believe that untrained laypersons
18 would detect those types of decelerations by
19 auscultation alone.

20 There are other forms of periodic
21 decelerations. Most are uncommon outside of labor.
22 Some, such as so-called variable decelerations, maybe

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1 normal variance of a fetal heart rate in the second
2 trimester, and an incidental detection by consumers
3 will certainly lead to more harm than good and would
4 result in unnecessary testing without any discernable
5 benefit to the fetuses or their families.

6 In sum, I see no clear benefit to the
7 consumer from OTC availability of hand-held Doppler
8 devices. While there is certainly the potential for
9 harm from spurious results of laypersons frequently
10 listening to fetal heart rates. I must, therefore,
11 oppose the current petition.

12 Thank you.

13 MR. BARNETT: Thank you.

14 Let me ask the panelists if they have any
15 questions or clarifications they want from many of the
16 three speakers from AIUM that we just heard.

17 DR. STRATMAYER: I think you pointed out
18 an awful lot of issues that I think are important, and
19 one of them is just the issues of the layperson trying
20 to interpret some very difficult patterns in Part B.

21 And I know this has always been a problem
22 for me because I think most of you know when I go to

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1 the AIUM meetings and I take a look at what's going on
2 and all the booths and they're showing off everything,
3 I can't tell what's going on, and I've been around
4 ultrasound for a lot of years.

5 But, again, one of the things that we keep
6 trying to get at is how much information is -- and you
7 pointed this out -- how much is verified, how much do
8 we have statistics on, and I hope that we see this
9 come from some of the other presenters because that's
10 something that to me is very -- I can't believe
11 somebody wanted to hear me -- is very important.

12 And I also have some issues that are
13 biological, as you know, and that's the whole issue of
14 should we have any concern since these devices are not
15 a lot different in output than some of the bone
16 healing devices, and when you start doing something in
17 utero during development, is that an issue that one
18 should consider?

19 DR. COPEL: I think that question is more
20 for Dr. Abramowicz in the safety areas, I think.

21 DR. ABRAMOWICZ: I'm not sure whether this
22 was a question or a comment.

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1 DR. STRATMAYER: It was more of a comment.

2 DR. ABRAMOWICZ: Do you want to rephrase
3 it as a question and I can try it?

4 (Laughter.)

5 DR. ABRAMOWICZ: Or not.

6 DR. STRATMAYER: Am I alone in wondering
7 if there might possibly be an effect? I know there's
8 no good evidence that there's an effect, but is this a
9 possible concern?

10 DR. ABRAMOWICZ: Well, the fact that
11 epidemiological studies have not shown a clear effect
12 of ultrasound (a) does not necessarily mean that
13 there's no clear effect; (b) it depends on what effect
14 we look for.

15 And undoubtedly, the major effects that
16 are being looked at, whether it's low birth weight or
17 problems with hearing or speech or others, these are
18 not proven to be statistically true. However, there
19 may be some subtle effects that have not been looked
20 at, and for instance, there's some reports in the last
21 few years of no right-handedness in fetuses,
22 particularly male fetuses, not so much in female

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1 fetuses, of patients who were exposed to ultrasound
2 during pregnancy. They are newborns. And this was
3 verified by checking these infants who are age 20 or
4 21.

5 Now, it's only one group, but they've
6 reproduced their studies, and there are a lot of other
7 issues. So it's not necessarily true that this is a
8 real thing, but at least there may be some things to
9 look at, and my major point is there's a major
10 difference between ten, 20, 30 seconds once a month
11 and the potential of being used for a prolonged
12 period.

13 MR. BARNETT: Go ahead.

14 DR. MARINAC-DUBIC: Well, I was going to
15 just mention that if we talk about the epidemiologic
16 studies, just to keep this into perspective, that all
17 of those studies are done on the babies who were
18 exposed in early '80s, and we essentially have no
19 published epidemiologic data on the studies after the
20 FDA released or actually allowed higher outputs to be
21 used in fetal exposures.

22 So I strongly voice the same concerns as

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1 Dr. Stratmayer, and I think more studies are needed in
2 this area.

3 DR. STRATMAYER: Let me also ask if you
4 think there's any possibility or not any possibility,
5 but how difficult would it be to do an epi study
6 today, considering how almost every fetus is exposed
7 to various types of ultrasound.

8 DR. ABRAMOWICZ: Well, the reality is that
9 it probably would be impossible to do such a study.
10 One would have to say, well, half of the study
11 population is not going to be exposed to ultrasound of
12 any type and half is going to be exposed under certain
13 controlled methods, and although ultrasound has never
14 been approved as a routine procedure in the United
15 States by the American College of OB-GYN and anyone in
16 reality, I dare say that in clinical practice 90 or 95
17 percent, if not 100 percent, of women who come to
18 prenatal care -- this is an important point -- the
19 vast majority, maybe everybody who comes to prenatal
20 care will have at least one ultrasound.

21 So now you say, well, you're not going to
22 have ultrasound would be (a) impossible from an

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1 ethical standpoint, and to create such a study where
2 you would need 100,000 women and their infants to be
3 followed over several years would be quite expensive.

4 MR. BARNETT: Anyone else on the panel?

5 DR. MARINAC-DUBIC: Well, I was just going
6 to say, yes, it is very difficult. However, there is
7 still some possibilities to control for some of these
8 factors and also to compare the groups that were
9 exposed in different trimesters of pregnancy and also
10 compare the groups with less frequent ultrasound
11 versus those that predicted more.

12 MR. BARNETT: Anyone else on the panel?
13 Yes.

14 DR. HARRIS: I just wanted to follow up
15 briefly on what Mel said. He mentioned the fact that
16 the ultrasound bone healing devices, which have been
17 approved for use in humans have shown to be effective
18 in healing fractures. Similar devices have been shown
19 in animals to cause no regeneration and angiogenesis.

20 The acoustic outputs from these devices
21 are not as low as for the fetal Doppler heart rate
22 monitors, but they're not all that much higher either.

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1 So there is the question of if levels in this range
2 can produce some effect, then what bearing is that
3 going to have in a decision to take a device and
4 basically make it from a controlled prescription
5 device to over the counter.

6 So that's a concern that we are looking
7 at. I just want to amplify what Mel said on those
8 bone healing devices.

9 MR. BARNETT: Anyone from AIUM want to
10 respond to that?

11 (No response.)

12 MR. BARNETT: Okay. Anything else from
13 the panel about clarification?

14 Let me open it to the audience and ask
15 anyone out here to ask the AIUM folks questions or
16 clarification. Yes.

17 Come up to the mic, come up to the mic.
18 Thanks, and identify yourself.

19 MS. HOGAN: My name is Sharon Hogan.

20 It's obvious that you guys are --

21 MR. BARNETT: Just tell us who you
22 represent, if any.

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1 MS. HOGAN: I don't represent anybody. I
2 was an expectant mother with twins who had
3 complications early in my pregnancy. I went out and
4 purchased one of the fetal heart listeners that are
5 made available, and they're basically just microphones
6 that you can use supposedly to hear your heartbeat.
7 They're not regulated by the FDA.

8 And they're crap basically. I had two
9 heartbeats in --

10 MR. BARNETT: Can you spell that?

11 MS. HOGAN: They don't work.

12 (Laughter.)

13 MS. HOGAN: And so I had two heartbeats in
14 there and could not hear anything. I had bleeding
15 early on in pregnancy, was panicked, and was calling
16 my doctor very often asking, "Can I please come in
17 just to hear the heartbeats? I just need to hear them
18 and I'll feel fine."

19 And so I went to the Doppler. The
20 instructions were very clear, told me exactly what my
21 heart rate would be, what the baby's heart rate would
22 be, and in time I could feel them moving. I got the

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1 reassurance that I needed by being able to hear their
2 heartbeat.

3 Now, it's clear that these gentlemen are
4 professional and understand their occupation, but it's
5 also clear that they've never been pregnant and don't
6 understand the benefits to the expectant mother of
7 being able to hear those heartbeats in there.

8 And making Dopplers over-the-counter to
9 these women would just be a tremendous benefit to
10 expectant mothers everywhere. I mean, they have those
11 fetal listening devices that you can buy at Toys R Us.

12 I panicked more by using those \$40 or \$20 items that
13 don't work than by renting a Doppler for \$50 a month,
14 and to me it's more of a crime to have those products
15 on the store shelves than by making a device that
16 actually works over the counter and made available.

17 And so I think that it's doing a
18 disservice to expectant mothers by not having Dopplers
19 available to any expectant Mom, and I guess the
20 question to the FDA is what other countries require
21 prescriptions for fetal Dopplers. Is the United
22 States the only country that requires prescriptions?

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1 And if so, why?

2 MR. BARNETT: Okay. Thank you.

3 MS. HOGAN: Thanks.

4 MR. BARNETT: Is there anyone else in the
5 audience that wants to? Yes, Linda.

6 MS. KAHAN: I'm Linda Kahan, the Deputy
7 Director for the Center for Devices and Radiological
8 Health.

9 And my question really goes to Dr. Copel's
10 presentation, and I think it's also a follow-up to Ms.
11 Hogan's presentation here, and that is if we think
12 that the irregularities are so relatively rare, and
13 you think it's so difficult for the average person to
14 be able to understand some of those --

15 MR. BARNETT: Linda, I'm sorry. It's hard
16 to hear.

17 MS. KAHAN: And my question is if the
18 dangerous irregularities are so rare and the
19 difficulty of interpreting the subtle differences in
20 the heartbeats is, in fact, it is so difficult for the
21 layperson, what's the benefit-risk ratio in your
22 opinion about the prescription home use situation?

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1 It seems to me as though Ms. Hogan's
2 experience was that it was a high risk and there was
3 some reason for her to have that kind of thing at home
4 and some benefit from it. So I was wondering if you
5 could speak to that.

6 DR. COPEL: Okay. I will readily admit
7 that I have not been pregnant, but I spend about ten
8 hours every day with pregnant women, many of whom are
9 quite anxious because my practice is entirely high
10 risk obstetrics and printed ultrasound.

11 The likelihood of a dangerous arrhythmia is
12 hard to estimate, for sure. The pediatric data
13 suggest that maybe two percent of newborns in
14 epidemiologic studies will have extrasystoles. In our
15 study of 600 fetuses, I believe it was 1.5 percent
16 that were referred because of an irregular heartbeat
17 had a dangerous arrhythmia. So we had about one
18 percent of two percent would be the frequency across
19 the entire pregnancy.

20 And many of those arrhythmias are
21 intermittent. So we would also have to further assume
22 that the woman happens to listen at the time that the

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1 arrhythmia is occurring.

2 The issue of the high risk pregnancy, I
3 think, is a little bit different because what we just
4 heard described, the situation of concern about fetal
5 well-being prior to fetal movement, so that was before
6 probably 20 weeks, give or take a week or two, and the
7 reassurance that was gained by understanding that the
8 babies were not dead, but that they were alive.

9 And that's a select group. The
10 obstetrician one hopes will be sensitive enough to
11 recognize the concern that the mother has, and if the
12 devices are available through prescription, the
13 physician should be able to come to some plan with the
14 patient to allow her to get that device easily enough
15 if they're available by prescription.

16 MR. BARNETT: Thank you.

17 Anyone else in the audience have a
18 question? Yes, sir. Please step up.

19 MR. NEWMAN: I'm Dennis Newman again.

20 I guess I think, Dr. Copel, that that's an
21 excellent point, that really so many of these uses
22 that we're talking about here today are truly aimed at

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1 high risk patients, and the important thing is that
2 the patients have some access, whether it's through
3 over-the-counter or prescription to get the Doppler
4 and be able to use at home.

5 I had a couple of questions or comments
6 for Dr. Abramowicz. Some of the slides that you
7 showed there showed on some of these past studies
8 Doppler intensities of 800 plus milliwatts per square
9 centimeter, and if it's true, isn't it that all of
10 these devices that we're talking about here today,
11 continuous wave fetal heart monitors, the current FDA
12 measurement is not increased, but in fact is 20
13 milliwatts per square centimeter?

14 DR. ABRAMOWICZ: Correct.

15 MR. NEWMAN: Dr. Harris, I'm sorry to show
16 my ignorance because I know this paper had been
17 available, but what are the power outputs of these
18 devices in the bone healing experiment?

19 DR. HARRIS: The spatial average, temporal
20 average intensity is 30 milliwatts per square
21 centimeter, but they are pulsed with a duty factor of
22 20 percent.

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1 But if you look at the peak pressures and
2 the potential for a temperature rise, which I think
3 are the main things we're concerned about, the bone
4 fracture healing devices are roughly two to three
5 times greater than the fetal Doppler heart rate
6 monitor.

7 So, again, that is definitely higher, but
8 is it higher by an amount that you can just then
9 critically ignore? And that's the question.

10 MR. NEWMAN: I was just curious. This
11 would be a question for anyone. I'm sure that someone
12 has calculated the potential thermal effects on the
13 fetus of this 20 milliwatts per square centimeter.
14 What kind of temperature are we looking at from the
15 use of these continuously, Dopplers?

16 DR. HARRIS: If you use the thermal
17 indices that are in the AIUM and NEMA output display
18 standard as a guide for calculating the temperature
19 rise, in soft tissue it's much less than one. Bone,
20 it could be as I recall one to two degrees.

21 MR. BARNETT: I'm going to call time out
22 here and recall the purpose of this meeting, which is

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1 for the FDA to hear evidence one way or the other
2 about benefits and risks. So I think we're getting
3 away from that and getting into a kind of general
4 discussion, which is interesting, but possibly not
5 right on target.

6 So is there anyone else that has a
7 question of clarification for the AIUM speakers?

8 (No response.)

9 MR. BARNETT: Okay. If that's the case, I
10 will ask once again if Mr. Martin is here. Is he not
11 here?

12 Okay. Then let's take a break now. We're
13 supposed to have a 15-minute break according to the
14 schedule. I have half past. So why aren't we back
15 here at quarter of?

16 Thank you.

17 (Whereupon, the foregoing matter went off the record
18 at 10:27 a.m. and went back on the record
19 at 10:45 a.m.)

20 MR. BARNETT: If everyone will have a
21 seat, we can get started again.

22 Our next speaker is Dr. Carol Rumack of

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1 the American College of Radiology. Is she here?
2 Okay.

3 DR. RUMACK: Thank you.

4 I'm Dr. Carol Rumack. I'm a practicing
5 radiologist at the University of Colorado School of
6 Medicine in Denver, Colorado. I'm Professor of
7 Radiology in pediatrics at the university, and I
8 specialize in diagnostic ultrasound. I'm the author
9 of a textbook the title of which is Diagnostic
10 Ultrasound, now in its third edition.

11 I'm also chair of the American College of
12 Radiology Commission on Ultrasound. So it's my job in
13 this role to look at all of the issues with regard to
14 ultrasound that we face in terms of radiology. I'm
15 participating in this workshop representing the ACR.

16 And the college is covering the expenses
17 of my attendance here. I was told to mention that. I
18 don't have any relationships with companies. So I am
19 disclosing that I have no other reason to be
20 supporting or not supporting any of these devices.

21 ACR represents more than 28,000
22 radiologists. We have a lot of reasons, a lot of

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1 parts of what we do that have to do with assuring the
2 quality of what we do. We have accreditation
3 programs, just as the AIUM does. We have
4 accreditation programs, and we have 2,200 accredited
5 ultrasound practices.

6 Should we go into practices, we require
7 images. We look at devices, and so we're very
8 interested that there be a high standard and that
9 people practice at that standard.

10 We are all about the quality of radiology
11 and ultrasound. We're also about education. We have
12 education courses. We have courses on the Web. We
13 feel it's very important, and I would say in terms of
14 what I've heard this morning that maybe patient
15 education ought to rise in that regard because I have
16 some concerns that the kinds of information you get
17 from these complex machines is important for people to
18 know, but knowing is not enough. You need to ask for
19 advice, and you need to get advice from medical
20 specialists.

21 In moving on with my statement, the
22 college concurs with both the analysis and the

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1 conclusions set forth in the FDA's denial of Dr.
2 Thomsen's petition to grant over-the-counter status of
3 fetal listening devices as referenced in the Federal
4 Register announcing this workshop.

5 On a fundamental level, the ACR believes
6 that the public health mission of the FDA compels a
7 policy that fetal ultrasound, including fetal
8 listening devices should only be used for medical
9 purposes with a prescription from an appropriately
10 licensed provider under the medical guidance and
11 oversight and help of that provider. That's the
12 point. You don't want to know about an abnormality
13 just to know it. You want to know it so that you can
14 do something with it.

15 Unlike passive listening devices which
16 don't require a medical prescription, Doppler
17 ultrasound imparts energy into the body, and that's
18 the difference between the stethoscope where you're
19 simply listening to sound and ultrasound in which
20 you're inputting sound.

21 And I think those slides shown by AIUM
22 were terrific in demonstrating the difference.

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1 Potential adverse effects related to
2 uncontrolled use of these devices in early pregnancy
3 is my concern, and I think one of the panelists
4 mentioned that as well. You have the cells that are
5 dividing and changing and organizing.

6 It worries me more in the first trimester,
7 not that we have huge amounts of proof, but I think if
8 there's any time you should be careful, it is, indeed,
9 when you don't have fetal movement. It's when you
10 have a fetus that is developing and you don't want to
11 be adding energy that might in some way damage the
12 fetus.

13 The biological effects. The acoustic
14 energy that we're talking about are, indeed, only
15 slightly higher doses than have been demonstrated to
16 cause some effects. These biological effects -- and I
17 have the articles you were talking about, the sound
18 levels. I have those with me if you want to look at
19 them, but I know you have them yourselves.

20 These biological effects include nerve
21 regeneration and bone healing properties, and there
22 are a number of efforts. And when you were talking

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1 about looking at epidemiological studies, it occurred
2 to me you might use some of the efforts from Dr.
3 Holland at the University of Cincinnati who has looked
4 exclusively at biologic effects of ultrasound and
5 looking at exactly these devices used for bone healing
6 and for nerve regeneration, and how can ultrasound be
7 used to encourage healing? You know, that would be a
8 good thing.

9 Moreover, some studies have suggested a
10 link between diagnostic ultrasound and human
11 development.

12 Petitioners have argued that the lack of
13 clear causation between the use of fetal listening
14 devices and recordable adverse events warrants that
15 these devices be granted over-the-counter status. ACR
16 strongly disagrees.

17 Our knowledge of the biological effects of
18 these devices, along with the possibility that
19 confirmed adverse events might be identified in the
20 future, compels us to exercise discretion in their
21 use. These devices should be used only when there's a
22 medical benefit to the patient, and they should be

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1 used in a manner that minimizes potential risk to the
2 patient, both patients, the mother and the fetus, but
3 the fetus is the one of concern in this regard.

4 The current regulatory structure governing
5 fetal listening devices provides for a reasonable
6 balance between the potential benefits and risks of
7 their use in the hands of a lay person. Physicians
8 can evaluate whether home use is needed, whether it's
9 warranted on a case-by-case basis, when home use is
10 deemed to be warranted and the physician can insure
11 the patient is appropriately instructed in how to use
12 the device and understands the risks involved in
13 misusing or misreading the information from the
14 device.

15 On behalf of the American College of
16 Radiology, I want to thank the FDA for holding this
17 workshop, for allowing us the opportunity to present
18 our views. I'm happy to answer any questions in
19 regard to this topic.

20 MR. BARNETT: Thank you, Dr. Rumack.

21 Any member of the panel want clarification
22 or have a question?

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1 (No response.)

2 MR. BARNETT: Okay. How about members of
3 the audience? Anyone want to ask Dr. Rumack anything,
4 ask for clarification?

5 (No response.)

6 MR. BARNETT: Okay. That being the case,
7 thank you very much, Dr. Rumack, and the ACR.

8 And our next presenters are Tom and Stacie
9 Hansen of BabyBeat, Incorporated.

10 MS. HANSEN: Hi. I'm Stacie Hansen, and
11 with my husband Tom Hansen I own BabyBeat.

12 BabyBeat is a distributor of Dopplers. We
13 distribute them to OBs, to hospitals, and to mothers
14 to use at home.

15 For my disclosure up here, I am the
16 daughter of Dennis Newman, and I also worked at Imex-
17 Nicolet in the marketing department when I graduated
18 from college. Obviously I've grown up around the
19 ultrasound business.

20 I know a lot of people today. You know, I
21 can't say I don't have any financial interest in what
22 happens with this decision, but I can honestly say

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1 that, you know, I can't tell you if it would benefit
2 our company for this to go over the counter because
3 that opens the door to huge companies that can make a
4 lot more money and a lot more units than we can make,
5 and maybe that closes our doors.

6 And if it doesn't go over the counter, you
7 know, I mean, I can't say that one way or the other
8 benefits us. So that is not why I'm here today. I'm
9 not here to promote our business.

10 I'm here to, you know, when I read the
11 information that the FDA was requesting information
12 regarding the benefits and the risks of using these
13 Dopplers at home, I knew that I could provide
14 information on real benefits that mothers get from
15 using these units at home.

16 And I have a handout that you can all take
17 with you of a survey that we've done of mothers that
18 have used the units, and also comments that they have
19 given. You know, I have my notes here, and I've read
20 these and reread them, and you know, I am going to
21 stick to what the benefits are and what our survey
22 says. You know, I didn't write down personal

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1 information in here, but you know, being a mother,
2 being a woman that has used a Doppler after suffering
3 the loss of a baby during pregnancy, I have to also
4 speak from my heart, you know.

5 I can stand here and I can say how I feel,
6 and if I had 100 women in this room that used a
7 Doppler, I can say how they would feel, and if I had
8 100,000 I can tell you how they would feel because I
9 think our survey shows that. It backs what the
10 benefits are to these women.

11 We sent out a survey, you know, and it was
12 a small survey on a scale of mothers that had used
13 these at home. We sent a survey to 4,700 users of
14 Dopplers. We received 1,050 responses with a
15 resounding 388 mothers adding additional comments on
16 their experience, and I have provided the entire
17 survey for you there.

18 But I would like to note some of the
19 results because I think it answers a lot of questions
20 that physicians ask, that the FDA asks, that AIUM asks
21 regarding how the mothers use these units.

22 The mothers did not use the Dopplers

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1 excessively. You know, 24 percent of the mothers used
2 it estimating one time per week and another 39 percent
3 used it only once per day. Eighty-five percent of the
4 mothers said that they used the unit for only one to
5 five minutes, but that was the lowest we asked for.
6 We didn't ask if they used it ten seconds or 20
7 seconds. So they couldn't pick anything lower. Maybe
8 that was an error in the survey.

9 And the mothers did not find the unit
10 difficult to use. Ninety-seven percent surveyed said
11 they found it either very easy to use or easy to use
12 after some practice. You know, it's not a difficult
13 unit.

14 And using a Doppler at home greatly
15 influenced or did not greatly influence their
16 interaction with their doctor or midwife. Seventy-
17 four percent said it did not change at all. Thirteen
18 percent said they called less often than they would
19 have otherwise.

20 And I know someone had mentioned that, you
21 know, this can cause a layperson to call their OB more
22 often, to wrongly call them, but even looking at this

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1 number, that 13 percent called them less often, I
2 can't even say that that is definitely a positive.

3 I think that a mother has a right to call
4 her physician. When I was pregnant, if I didn't feel
5 the baby move, I called the physician and I said, "The
6 baby is not moving," and then I went in. I had an ST
7 done, and they said, "The baby is fine. The baby is
8 moving."

9 You know, it's moving but you didn't feel
10 it, you know. So when a mother uses a Doppler and
11 calls the doctor and says, you know, "I feel like
12 something is wrong," that's the doctor's job to say,
13 "Yes, there is something wrong," or, "no, there is not
14 something wrong." And if that takes an extra
15 appointment, you know, that's what it takes.

16 And, you know, along those lines, you
17 know, I can say that a lot of people have said today
18 that they highly discourage the non-medical use of a
19 Doppler, and I do as well. I mean, I am not here to
20 tell the FDA that this should be over the counter or
21 if it should not because you're the experts and the
22 FDA makes that decision, and I do not want to use

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1 something that I feel is harmful, and I don't want my
2 doctor using something on me that is harmful.

3 I think that if I go into the doctor's
4 office and they say, "This is the risk of using this
5 while you're in my office, and make your choice,"
6 because there are women that don't use Dopplers in the
7 doctors office. There's women that do not have
8 ultrasounds during their pregnancy, and I think that's
9 their decision.

10 But I also think if they use it at home,
11 it's still a medical reason. Pregnancy is, you know,
12 medical, and if the woman chooses to use that at home,
13 that doesn't mean that it's for fun or that it's a
14 non-medical reason.

15 In our survey, certain experiences came up
16 again and again, as noted. Like I said, there was 388
17 additional comments, and I was amazed at how many of
18 these women had had a previous miscarriage, had had a
19 high risk pregnancy, had had complications.

20 You can say that some women may use a
21 Doppler for fun, but the majority of women use it for
22 a strong purpose, and I have friends that, you know, I

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1 never have encouraged a friend to use a Doppler, and
2 most people that have not had a complication in a
3 pregnancy probably won't. You know, I mean, they
4 said, "Why would women use this at home?" You know,
5 even pregnant women say, "Why would women use this at
6 home?"

7 But when women have had a miscarriage or a
8 complication during pregnancy, they know the reason to
9 use it at home, and these are just some of the
10 experiences that multiple people have mentioned.
11 After previous miscarriages, I was nervous and
12 stressed during the pregnancy. Using the Doppler gave
13 me peace of mind. It put my mind at ease. It was
14 very reassuring and made me feel better about the
15 pregnancy. It saved me undue stress during the
16 pregnancy.

17 And then I'll read just a few samples of
18 the comments that we had received. "I was very
19 grateful for the Doppler. I had several miscarriages
20 prior to this pregnancy and had went through fertility
21 treatment. I was very anxious about the pregnancy,
22 and the Doppler put my mind at ease. Any time I felt

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1 anxious, I listened to our baby's heartbeat and my
2 mind was put at ease."

3 "After multiple pregnancy losses, I have
4 found that having the Doppler readily available has
5 helped me to relax during my successful pregnancies."

6 "Renting the Doppler was the best thing I
7 could have done. After two miscarriages I was a
8 nervous wreck. It brought peace of mind that I
9 wouldn't have had without it."

10 "I have noticed a lot of doctors recommend
11 not using a Doppler in case you can't find the
12 heartbeat and you start to panic. Having had a
13 stillborn baby, a Doppler definitely gave me the peace
14 of mind in my subsequent pregnancies. I told my
15 doctor how helpful it was, and he began recommending
16 them to his other patients."

17 "Having a previous miscarriage, using the
18 Doppler helps me to keep my sanity, especially when I
19 could not feel him moving. It was a great device to
20 have use of. It helped me to sleep better at night
21 knowing that my baby was fine."

22 "My last pregnancy was a high risk and my

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1 stepsister rented the Doppler for me so that I would
2 know the baby was okay. As it turned out, she was
3 not. On March 30th, she died, and if it would not
4 have been for that Doppler, I would have had to go two
5 weeks with a dead baby, and the thought of that just
6 kills me."

7 "Many doctors have no sensitivity to our
8 emotional needs. After seven failed IVF cycles and a
9 miscarriage, it is very important to us to hear the
10 heartbeat more regularly than a biweekly appointment.
11 Doctors who claim that there is no medical necessity
12 for a Doppler must not recognize the clear connection
13 between emotional and physical health."

14 "For someone who had had pregnancy losses
15 and is experiencing pregnancy complications, the
16 ability to hear a quick heartbeat is incredibly
17 reassuring. It keeps my stress and my nervousness to
18 a minimum."

19 I could go on all day reading these
20 comments, but you have them in the attachment, and you
21 can see for yourself what these mothers feel. It is
22 overwhelming, and it is always sad that you hear more

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1 from the dissatisfied customers than the satisfied
2 one. The squeaky wheel gets the grease, and I think
3 that this is a pretty powerful statement that of these
4 388 comments, I can find only a few, not even a
5 handful, that have anything negative to say about
6 using a Doppler.

7 They are so overwhelmingly positive,
8 they're emotional, and they're given from the mother's
9 heart.

10 Like I said, I can list many benefits that
11 these mothers noted, bonding with the baby before
12 birth, getting fathers, family and friends more
13 involved in the pregnancy, but also greatly reducing
14 the stress in pregnancy, giving the mother peace of
15 mind and even saving the lives of unborn babies.

16 BabyBeat has received a handful of letters
17 and E-mails from parents stating that Dopplers did
18 actually save the life of their unborn baby, and of
19 course, it is not the majority of the users, but I
20 know that these parents would never want to be denied
21 using the Doppler at home.

22 And other parents have used the Doppler to

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1 find out that they have lost the baby, and as heart
2 breaking as that is, they never said that they wished
3 they didn't have the Doppler. They never said that
4 they wished they would have gone into the doctor
5 unknowingly to hear that their baby had died days
6 earlier or weeks earlier.

7 My own cousin had used a Doppler during
8 her second pregnancy. She even recorded the heartbeat
9 into the unit. At the time she did not know that this
10 was the only sound she would ever hear from her baby.
11 He was born not breathing. Even after being
12 resuscitated, he never cried, never made a noise. He
13 died the next day at the hospital, and she still has
14 that heartbeat to cherish.

15 And although maybe not as big as saving a
16 baby's life, I feel the reduction of stress by using a
17 Doppler during pregnancy is unquestionable, and I know
18 this affects a much greater number of women who use
19 the units than actually saving a baby.

20 In researching the effects of stress on
21 pregnancy, I found a lot of interesting information
22 which I'm not here to support or discredit. The

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1 research varies, and you know, I didn't look at the
2 background of these different studies, but nowhere did
3 I ever find information that stress does not have an
4 influence on pregnancy or the outcome of the
5 pregnancy. Stress during pregnancy is definitely a
6 negative.

7 Some of the study information I found was
8 stress during pregnancy may result in a greater risk
9 of miscarriage late in the first trimester and more
10 birth defects if there has been severe stress during
11 the pregnancy. More premature and small for date
12 babies are born to mothers who experience severe
13 stress, particularly during the first trimester. Low
14 birth weight and effects on the brain development in
15 the unborn child, which may lead to mood disorders in
16 adulthood; changes to babies developing nervous system
17 leaving them more vulnerable to psychological and
18 perhaps medical illness later in life; increases in
19 the mother's own levels of cortisol which processes to
20 the fetus and influences the baby's brain development,
21 notably its stress response system, making children
22 more susceptible to a range of psychological and

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1 medical problems.

2 As I read the comments of the survey, it
3 is truly amazing the number of women who said it
4 reduced their stress, gave them peace of mind and made
5 them less anxious and able to relax. And I can tell
6 you first hand how much a Doppler can ease your fears
7 in pregnancy.

8 I can't begin to even imagine the stress
9 and how terrifying the first successful pregnancy
10 could be for a mother that has had previous
11 miscarriages because I myself lost my third baby in
12 pregnancy. I had had two easy, successful
13 pregnancies. I knew that I could do it. I knew my
14 body could do it, but when I got pregnant again after
15 that miscarriage, I was a nervous wreck. I could not
16 bear the thought of losing another baby. I couldn't
17 bear to go to the doctor and have them be the one to
18 tell me that the baby had died. I wanted to know for
19 myself, and I listened with the Doppler before every
20 single doctor appointment so I would know before I
21 stepped into the office.

22 And sometimes I would just listen to know

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1 that everything is okay, to ease my fears, to reduce
2 my stress, and to give me the needed peace of mind.

3 Like I said, I'm not here to debate
4 whether the unit should be over the counter or not. I
5 think that there are people that can make a better
6 decision than myself, but I hope that you can take a
7 look at the very important, positive effects of using
8 a Doppler at home.

9 I think that however mothers obtain the
10 unit, I agree that if the doctors that deal with the
11 high risk patients every day embrace that and say, "I
12 understand how you're feeling and I'm going to write
13 you a prescription for that," but I do hope that
14 mothers would not be denied the right to use this
15 product because so many of them depend on it.

16 MR. BARNETT: Okay. Thank you, Ms.
17 Hansen.

18 MS. HANSEN: Thank you.

19 MR. BARNETT: Do any of the panelists want
20 clarification or have a question?

21 DR. HARRIS: Yes, thanks very much.

22 I think in our handout materials prior to

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1 the meeting we were sent the copy of the survey form,
2 but I don't believe we have the results, and that's
3 what you are presenting today.

4 MS. HANSEN: Right.

5 MR. BARNETT: Thank you. We'll pass these
6 out. Thanks.

7 Anyone else have a clarification they want
8 or question.

9 DR. MARINAC-DUBIC: Can you just clarify
10 one more time what was the response rate to the
11 survey?

12 MS. HANSEN: We sent out 4,700 surveys.
13 One thousand fifty mothers responded.

14 MR. BARNETT: Okay. Anyone else here?

15 Let me pass these out to the panelists
16 right now. This is the result of the surveys.

17 Thank you.

18 Is there anyone in the audience who has a
19 question or a comment or wants a clarification? Yes,
20 if you would just come up to the mic, and reidentify
21 yourself.

22 DR. ABRAMOWICZ: Yes. I'm Jacque

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1 Abramowicz. I'm an obstetrician.

2 A quick question. If I understand
3 correctly, you said that 24 percent of the patients,
4 of the women used it once a week and 39 percent once a
5 day. Is that correct?

6 MS. HANSEN: Yes, that's correct.

7 MR. BARNETT: You have to use the mic.

8 MS. HANSEN: Yes, that's correct.

9 DR. ABRAMOWICZ: So together this is 63
10 percent. Does that mean that 37 percent of them used
11 it much more than that?

12 MS. HANSEN: The breakdown on how often
13 the mothers use the Doppler, the choices given were
14 multiple times per day, as 12 percent; once per day,
15 39 percent; once a week, 24 percent; just a few times,
16 seven percent; and other was 18 percent.

17 MR. BARNETT: Okay. Anyone else? Yes,
18 sir.

19 MR. NEWMAN: Dennis Newman again.

20 I wanted to clarify. What appeared from
21 your responses to the survey that most of the mothers
22 who are looking at this for reassurance and stress

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1 reduction, if you want to call it that, are not really
2 trying to analyze fetal heart rate patterns or
3 abnormalities, but are basically just trying to
4 determine is there a live fetus there, is the baby
5 alive. Is that kind of your understanding from the
6 survey?

7 MS. HANSEN: That would be my
8 understanding from the survey, as well as from women
9 that we have talked to who used the unit. You know,
10 they do have a manual that gives them the heart rate
11 range, and you know, I have mentioned that there have
12 been reported instances that they say the Doppler did
13 actually save the life of the baby.

14 One of those mothers did say when she was
15 listening she just thought it sounded too fast. She
16 thought it sounded wrong, and called her doctor. The
17 nurse listened over the phone and said, "Go
18 immediately to the hospital," and they did an
19 emergency C section.

20 I didn't write those comments down, but
21 they did a C section on the baby, you know. She was
22 30-some weeks along. The baby was going into cardiac

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1 arrest, I believe she had said, and they delivered the
2 baby and everything was okay.

3 But I don't think that that's what they're
4 looking for, no. I think when a mother is using it at
5 home, they are basically just wanting to know if there
6 is a heartbeat.

7 MR. BARNETT: Okay, yes. Come up to the
8 mic and reidentify yourself.

9 DR. GREENBAUM: Lennard Greenbaum, AIUM.

10 Of the people who responded to your
11 survey, do you have any data as to what percentage of
12 them had a previous problem pregnancy, death, problem
13 with the fetus, something like that?

14 MS. HANSEN: No, we didn't ask that
15 specifically. We did say, you know, kind of just
16 which of the following were true for your experience,
17 and one of those is "mine is or was a high risk
18 pregnancy," and that was 39 percent. You know, so I
19 think that gives you somewhat of an answer, but you
20 know, I think sometimes, I mean, I think women think
21 their pregnancy is high risk, but maybe it is not high
22 risk in terms of what an OB would say.

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1 I know, you know, with my pregnancy after
2 the miscarriage I wasn't a high risk pregnancy. You
3 know, one miscarriage does not put you into that
4 category. So I don't know if those women think that
5 they're high risk, but that also doesn't mean that
6 they had previous complications.

7 DR. GREENBAUM: No, I was talking more in
8 terms of, let's say, a sensitized previous pregnancy,
9 but whatever the numbers are, I just, you know, want
10 to make it clear that I don't think any of us are
11 opposed to the use of home Doppler devices under
12 appropriate circumstances, and the emotional needs of
13 the mother certainly are an appropriate circumstance,
14 and sensitized Moms from previous pregnancies are
15 certainly appropriate circumstances.

16 And I think that there is a difference
17 between having a prescription device available for
18 women who fall into these categories and just making
19 it something that is available to go into, you know, a
20 Best Buy or a place like that and buy an over-the-
21 counter device.

22 MR. BARNETT: Thank you.

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1 Anyone else in the audience have a
2 question or want a clarification? Now that the
3 panelists have seen the survey results, do you have
4 any questions?

5 DR. STRATMAYER: Is there any indication
6 of what the percent of these were over the counter
7 versus prescribed one way or another? I didn't notice
8 that.

9 MS. HANSEN: No, this survey is just on
10 mothers that have used them at home.

11 MR. BARNETT: Okay. Anyone else? Yes,
12 please come up.

13 DR. STABINSKY: I'm Dr. Seth Stabinsky, S-
14 e-t-h, last name S-t-a-b-i-n-s-k-y. I'm a formerly
15 practicing OB-GYN. I'm Board certified in obstetrics
16 and gynecology.

17 I have no conflicts related at all to
18 what's being presented today.

19 I left practice about ten years ago to go
20 into the medical device industry, but before that time
21 I practiced general OB-GYN for two years and then
22 subspecialized in laproscopic and histroscopic

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1 surgery.

2 I have a couple of quick comments and then
3 a question for you, and I'm hoping that the Summit
4 Doppler person will address that question as well when
5 their time comes. I think Ms. Hansen and Ms. Hogan
6 both give very good statements on why someone who's
7 concerned about their pregnancy might want to check
8 their fetal heart, but I think we also heard from the
9 AIUM and others that we really don't know the impact
10 of that on the fetus, and I think if these emotionally
11 concerned mothers were to understand that this may
12 have some risk associated with it that we don't know,
13 they might not be so anxious to be listening.

14 And so we currently have a situation where
15 the devices are available by prescription of a
16 physician, and so as was well pointed out by Dr.
17 Abramowicz, that opportunity is available to the
18 woman.

19 Obstetricians have two patients to take
20 care of. They have both the mother and the fetus.
21 Most of us feel pretty strongly that that's a pretty
22 difficult role, and I'll give you an example of a more

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1 severe emotional distress with depression or something
2 like that. We would love to give those patients
3 SSRIs, selected serotonin re-uptake inhibitors, Paxil,
4 Lexapro, a whole bunch of different ones, and some
5 women have been prescribed those medications, and we
6 have now found out that those medicines can, in fact,
7 have some adverse effects on the fetuses when they are
8 born.

9 Now, again, we have to weigh the risk and
10 benefits of that, and that's what happens in the hands
11 of someone who writes a prescription for it. If
12 someone is really seriously in need of their
13 medication, they are going to get it in their
14 pregnancy, but if they think they can hold off without
15 it, if they think they can hold off without it, if
16 they're not that depressed, then you're going to
17 balance that because it's going to have some effects
18 on the fetus later on.

19 So I think the other thing that is
20 important to point out is that in early pregnancy,
21 before 20 weeks, you know, actually before about 23
22 weeks or so, there's nothing we can really do for the

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1 fetus itself if something is discovered by a mother
2 listening to the Doptone. The fetus isn't going to
3 survive at that young gestation. That's already past
4 the time when the mother would feel fetal movement,
5 and one of my concerns is that fetal kick counting and
6 fetal movement counting is a very advantageous thing
7 for women to do, especially women later in the
8 pregnancy when they can feel fetal movement and there
9 is the opportunity to potentially save that fetus.

10 I would be very concerned that someone
11 would use a Doppler because they feel decreased fetal
12 movement and then not call their doctor, and that
13 woman might wind up with a fetal demise that she
14 wouldn't have had.

15 So while you've stated that your company
16 doesn't really know what the effects on having this go
17 over the counter would be on you, there are a lot of
18 Doppler companies, and there's a pretty saturated
19 market now for Dopplers.

20 And so the question becomes if this goes
21 out to this broad community of women to be able to
22 use, as somebody suggested, at Best Buy, et cetera,

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1 I'm concerned about what sort of advertising will be
2 done to women to say, "Hey, listen to your baby's
3 heart to make sure your baby is okay."

4 We already saw something put up about eBay
5 about saying that this is safe, and in fact, we don't
6 know whether it is safe or not. So my question to you
7 and also to Summit would be one of the obligations and
8 responsibilities of FDA is to know how broadly this is
9 going to be brought out and how much widespread use
10 there will be of this, and I'm wondering about what
11 sort of advertising you'll see coming about with the
12 use of these devices in order to penetrate that whole
13 market since the doctor's market is sort of saturated.

14 MR. BARNETT: Thank you.

15 MS. HANSEN: You know, I would say that I
16 agree with everything you said. You know, like I
17 said, being a mother and having gone through
18 pregnancies, I just wanted to present the benefits of
19 using the Doppler, and I think there's other people
20 out there that can better evaluate the risks versus
21 the benefits.

22 You know, I don't want to use something at

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1 home that isn't safe, and I wouldn't want my doctor
2 using something in the office that isn't safe either.

3 As far as, you know, the marketing of
4 these units, you know, like I said, the reason that I
5 can't tell you one way or the other who benefits from
6 the unit going over the counter and who does not is
7 for that very reason. I mean, I cannot tell you what
8 company would enter into that market. I cannot tell
9 you what kind of advertising would be done to present
10 that to the mothers.

11 MR. BARNETT: Okay. Anyone else in the
12 audience or on the panel that wants clarification or
13 questions?

14 (No response.)

15 MR. BARNETT: If that's the case, thank
16 you, Ms. Hansen.

17 Our next presenter is David Jones of
18 Summit Doppler.

19 Mr. Jones, thank you.

20 MR. JONES: Good morning. Dave Jones, and
21 I'm representing Summit Doppler Systems of Golden,
22 Colorado.

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1 First of all, does the panel have a copy
2 of the materials that I provided in advance?

3 Okay. First I'll talk a little bit about
4 who Summit Doppler is and why we have an interest in
5 this issue, and I'll also present some information
6 that's germane to the discussion.

7 Although I recognize that the panel is
8 looking for science based input, what information we'd
9 like to provide is not science based, but I think that
10 you'll see it's very relevant.

11 Summit Doppler is the manufacturer of
12 hand-held ultrasound Dopplers, and we were formed in
13 2002 by former employees of Imex Medical Systems,
14 including myself and, as mentioned previously, Dennis
15 Newman is shareholder in our company. I currently
16 serve as Vice President of Engineering for Summit.

17 We introduced our LifeDop hand-held
18 Doppler in the spring of 2003. The LifeDop can be
19 configured for obstetric or vascular use by selection
20 of interchangeable probes ranging from two to eight
21 megahertz.

22 We are currently the fastest growing hand-

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1 held Doppler manufacturer in North America and
2 possibly the world, although that's not due to a
3 growing market. That's due essentially to taking
4 market share away from other companies.

5 A small fraction of our units are sold
6 directly to clinicians, but the vast majority are sold
7 through a network of distributors that numbers in the
8 hundreds. We are currently aware of one distributor
9 and two other entities that advertise our products for
10 home use. Our distributors are made aware that our
11 devices are for prescription use and our labeling
12 makes that clear as well.

13 Now, it should be obvious as a
14 manufacturer that we do have a significant stake in
15 the outcome of an OTC decision. On one hand, over-
16 the-counter would open a large, new market, and that's
17 something we're well situated to take advantage of
18 from a technical standpoint.

19 On the other hand, OTC status would open
20 up such a large market that we would expect new
21 manufacturers to enter the market. We would expect
22 prices to fall, and it is doubtful that we can

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1 continue operating our company under the existing
2 structure if we were to enter the OTC market.

3 For example, we would probably not
4 continue to manufacture products in the United States,
5 but would move them overseas. Overall we are somewhat
6 uncertain as to what the effect would be on us if
7 over-the-counter status was granted, and in general,
8 our manufacturers dislike uncertainty.

9 Now, the petitioner has acknowledged that
10 fetal Doppler has been in use for over three decades
11 and that the associated risk has been deemed
12 acceptable by clinicians in the United States and by
13 the FDA. Summit recognizes this has been accomplished
14 through cooperation between industry, clinicians, the
15 FDA, and professional societies, all of whom encourage
16 that exposure be kept as low as reasonably achievable.

17 This includes careful regulation of
18 acoustic output levels, recommendations for prudent
19 use, manufacture compliance with GMPs, and FDA review
20 of new products.

21 So the question from our standpoint as far
22 as being a manufacturer is how would OTC status affect

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1 safety and acceptance of ultrasound as an accepted
2 type of exam.

3 Consider first the expectant mother's
4 exposure to ultrasound. In an OTC market,
5 manufacturers might be reluctant to provide proper
6 labeling since, absent of any compelling medical
7 reasons to use the device, suitable warnings and
8 contraindications would likely lead to lost sales.

9 Poor information could easily lead to
10 longer home use exposure durations than are
11 experienced in exams performed with professional
12 guidance.

13 Furthermore, distributors and
14 manufacturers might seek to increase sales by
15 promoting use purely for entertainment purposes.

16 Another concern is that less reputable
17 manufacturers might be tempted to increase acoustic
18 output in a misguided effort to bolster claims of
19 improved sensitivity. These same manufacturers might
20 sacrifice compliance with GMPs and might even forego
21 product clearance via the 510(k) process in order to
22 reduce cost.

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1 None of these things can be expected to
2 reduce or improve control of exposure to ultrasound,
3 and these factors need to be considered as part of
4 FDA's OTC decision making process.

5 Now, the issue is: are these concerns
6 merely hypothetical or are they substantiated? And in
7 fact, we're aware that there are devices being sold
8 over the counter in the United States now, and we have
9 observed problems with these products.

10 I have provided the panel with product
11 literature from a fetal Doppler. We'll call it
12 Product X, and copies of this literature is available
13 for attendees if they would like from the FDA.

14 This product that we call Product X is
15 currently being sold in the United States by
16 distributors over the Internet and possibly at some
17 retail baby stores. The literature is essentially a
18 user manual that we downloaded from the Internet in
19 February of this year, and it's very similar to a user
20 manual that we obtained from a unit that was purchased
21 in October of 2004.

22 In our position to establish safety

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1 principles, the manufacturer instructs, "Repeat the
2 procedure as often as you like making sure to add gel
3 as needed." The brochure also includes the photo of a
4 young child using a Doppler.

5 Neither the user manual or the brochure
6 include the information normally supplied with medical
7 products, such as safety warnings, indications for use
8 and contraindications. Neither of the pieces of
9 literature that we obtained include basic information
10 like manufacturer contact information.

11 Another issue is the increasing use of
12 fetal Doppler for entertainment use. The literature
13 for Product X says that it should "not be used by you
14 in any way for diagnostic or other medical purposes."

15 There's another example that we have
16 provided, a Doppler "especially designed for home
17 use," which is for sale over the Internet by Keepsake
18 Imaging Company located in Oklahoma. This device does
19 not have a 510(k) as far as we can determine.

20 A third issue is what I call the eBay
21 problem. Regardless of the FDA's efforts to the
22 contrary, eBay has become a largely unregulated

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1 marketplace for many types of medical devices,
2 including fetal Doppler units.

3 On one of the examples that we got from
4 eBay in February, the seller says the unit should not
5 be used for medical or diagnostic purposes, but at the
6 same time, the product has an alarm in case the fetal
7 heartbeat is outside the so-called normal range.

8 A second unit that we downloaded from eBay
9 says FDA approved, and it claims that it can give you
10 the peace of mind that your baby is safe and well at
11 all times throughout your pregnancy, and in
12 particular, we'd draw attention to that phrase to say
13 that your baby is safe and well at all times
14 throughout the pregnancy, and as noted by people
15 presenting earlier, we don't feel that the Doppler can
16 provide that level of assurance.

17 Perhaps a proponent of over-the-counter
18 Doppler use would argue, and, in fact, the petitioner
19 has, that the existence of ongoing sales to parents is
20 solid evidence that no harm is associated with the
21 practice.

22 We counter that by asking how would anyone

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1 know if there is a problem. A common thread that
2 we're seeing with the home use products like these on
3 eBay is that the purchaser is not giving the
4 manufacturer contact information that they would need
5 to report a problem. It appears that the complaint
6 handling systems are either insufficient or
7 nonexistent.

8 Summit Doppler and other medical
9 manufacturers have huge investments in our quality
10 systems and in regulatory compliance, and so it's
11 surprising to see these products sold with such
12 disregard for good practices.

13 Besides the obvious implications for
14 patients, from a business standpoint, companies and
15 regulated industries deserve a level playing field.
16 We recognize that the FDA faces significant and
17 problematic shortages of resources, but we'd like to
18 see improved compliance in this area.

19 And I have been working in the medical
20 industry for over 20 years, and I never thought I
21 would be in front of the FDA asking for increased
22 enforcement, but here we are.

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1 (Laughter.)

2 MR. JONES: Patients rely on clinicians,
3 device manufacturers, and the FDA for delivery of
4 safe, effective medical products. Existing and
5 potential problems we have identified point to the
6 likelihood of a poor outcome should OTC status be
7 granted.

8 We fear a situation where patients may be
9 subjected to substantially unsafe products.
10 Clinicians may use access to high quality professional
11 products, and the FDA may be forced with a new and
12 rather difficult enforcement issue.

13 Summit Doppler requests that fetal Doppler
14 devices remain subject to prescription use only.

15 Thank you very much.

16 MR. BARNETT: Thank you.

17 Is there anyone on the panel now who would
18 like to get clarification or have a question?

19 DR. HARRIS: Yes, thank you.

20 In your Item C, OTC and possible safety
21 effects, you mentioned the possibility that OTC use
22 could result in some cases in increased acoustic

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1 output and a potential race to the bottom. Do you
2 have any evidence of that or is it just something that
3 you think is likely to occur?

4 MR. JONES: It's not something I can say
5 we have evidence of, but I think when you think about
6 -- and the physician raised the question how would
7 people advertise these devices. How would they gain
8 market share? And one of the ways they would do that
9 is, I think, by claiming increased performance.

10 And ultrasound in this area is pretty well
11 developed to its potential, I think, in terms of
12 sensitivity, and one of the ways people would try to
13 get around that, I think, is by increasing acoustic
14 output power.

15 DR. HARRIS: thank you.

16 MR. BARNETT: Anyone else on the panel?

17 (No response.)

18 MR. BARNETT: How about folks in the
19 audience? Anyone in the audience want to get some
20 clarification or have a question?

21 (No response.)

22 MR. BARNETT: Okay. That being the case,

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1 thank you again, Mr. Jones.

2 MR. JONES: Thank you.

3 MR. BARNETT: And that's the last of our
4 speakers, and so I think before I close the meeting,
5 I'm going to ask whether Linda Kahan would like to
6 make some closing comments.

7 Linda.

8 MS. KAHAN: I just wanted to really thank
9 people for coming out today and thank the panelists
10 for listening and the group for very, very interesting
11 presentations.

12 I think that the issues have become more
13 clear, and the information that you provided will
14 certainly be looked at very carefully by people in the
15 FDA. And I think it's worth mentioning that the
16 information that was not available before the meeting
17 will be available on the docket. So you'll have
18 access to that information as well.

19 And I think we have to look at what we
20 have heard today and think about it, and we really do
21 appreciate all of you coming out.

22 PARTICIPANT: She asked "How long before

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1 FDA makes a decision?"

2 MS. KAHAN: I don't have a time frame, but
3 obviously this was a very important step for us to see
4 what we could find out about what scientific
5 information was out there about benefits and risks of
6 an OTC switch. So we really do appreciate this as the
7 next step.

8 THE REPORTER: Could you repeat that
9 question for the record?

10 MS. KAHAN: The question was do we know
11 what the next step would be.

12 Thank you all very much. Thank you, Mark.

13 MR. BARNETT: Thanks for coming, and the
14 meeting is now adjourned.

15 (Whereupon, at 11:34 a.m., the meeting was
16 concluded.)

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