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Moderator

MS: ...Women's Health Initiative sponsored by the National Institutes of Health. Now at this point all of your phone lines are muted or in a listen only mode; however, later during the conference there will be opportunities for questions. And those instructions will be given at that time. Now just as a note, if you should require any assistance during the press conference, you can reach an AT&T operator by pressing star and then zero on your phone keypad.

And as a reminder, today's call is being recorded. Well, with that being said let's get right to today's agenda. Here with our opening remarks is Ms. Terry Long, Communications Director for the National Health-Heart, Lung and Blood Institute. Please go ahead.

TERRY LONG

FS: Good morning and thank you for participating in this briefing on the results of the estrogen alone trial of the Women's Health Initiative. As you know, these results are being published in the April 14th issue of the Journal of

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the American Medical Association. As stipulated by JAMA, the contents of the paper and actually any comments made during this briefing are embargoed until 4:00 p.m. eastern time today. So we have three spokespersons on the call this morning. We have Dr. Barbara Alving and she's the Director of the Women's Health Initiative and the Acting Director of the National Heart, Lung, and Blood, Institute at NIH.

So we also have Dr. Jacques Roussow. He's the Project Officer for the Women's Health Initiative and he's been involved with the Women's Health Initiative since its inception and he was a key participant in the team of the NIH scientists who designed this study. As staff of the National Heart, Lung, and Blood Institute Drs. Alving and Roussow are responsible for the federal oversight of the study. And we are also fortunate to have Dr. Marian Limacher joining us today.

Dr. Limacher is a Professor of Medicine at the University of Florida, and she's been involved with the WHI since 1993 and she's served as a principle investigator for both the estrogen alone and the estrogen plus progestin parts of the trial. And she is a cardiologist and an active clinician

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working with women who have heart disease. So we'll start with a brief statement from Dr. Alving and then we'll take your questions. Dr. Alving.

DR. ALVING

FS: Thank you and good morning. The publication of the initial results from the estrogen alone study of the Women's Health Initiative provide a detailed look at the health effects of estrogen alone therapy for healthy, post-menopausal women. As you know, general findings were released March 2nd after NIH stopped the study in the interest of safety. The study was stopped because the hormone increased the risk of stroke and did not reduce the risk of coronary heart disease, which was a key question of the trial.

The paper to be published in tomorrow's issue of JAMA confirms the stroke and heart disease findings announced last month. In addition, the study found that estrogen alone therapy significantly increased the risk of blood clots, had no significant effect on the risk of breast or colorectal cancer, and reduced the risk of hip and other fractures. These findings reinforced the recommendation

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that estrogen alone therapy should not be used for the prevention of clotting chronic disease.

NIH continues to advise women to follow current FDA guidance which says that hormone therapy should be used to treat menopausal symptoms and that it should be used the smallest effective dose for the shortest period of time. As always, women who are considering using estrogen or estrogen plus progestin should discuss the risks and benefits of hormone therapy with their physicians. And now we're pleased to take your questions.

Moderator

MS: Very good and thank you, Doctor. And ladies and gentlemen as you just heard, if you have any questions or comments, we invite you to queue up at this point. Simply press star, then one on your phone keypad. Now you will hear a tone indicating that you have been placed in queue and just as a note, should you wish to remove yourself from the queue, you may do so by pressing the pound key. So once again, to ask a question simply press star, one on your touchtone phone.

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And once again, ladies and gentlemen, we are asking for any of your questions or comments at this time. Please feel free to queue up simply by pressing star, one on your phone keypad. And representing the Baltimore Sun our first question comes from the line of David Cohen. Please go ahead.

QUESTIONS

MS: I was wondering, if this represents the death knell for estrogen and estrogen plus progestin and any kind of preventative medications?

FS: I think that what we have learned is that this goes with estrogen which was being used as a form of estrogen, as well as estrogen and progestin in the doses used in our trial really did not show overall benefits for the prevention of chronic diseases. For example, we saw benefit with respect to prevention of fractures, but we have other medications for that. I think that what this does do is open the way, perhaps, for additional studies or future studies of different doses of estrogen used in different ways.

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Will they be used for chronic disease? As you know now for heart disease we have very, very effective drugs. We have statins. So there would be quite a competition I think to see hormones used in the prevention of chronic disease.

There'd be a lot of competition with other drugs.

MS: And did you have any follow ups, Mr. Cohen?

MS: Yeah, I just... I'm curious about the—you know, what should doctors tell their patients who have been taking estrogen and estrogen progestin for symptoms—for menopausal symptoms for, you know, a long period of time, say 6-7-8 years.

FS: Dr. Limacher, you consultations. What are you gonna be telling your patients?

FS: Well as I see women who primarily have a diagnosis of heart disease. I think I have a very comfortable position that hormone at least these forms of estrogen and estrogen plus progestin does not prevent heart disease. Therefore, my recommendation is to try (inaud.). And I think that it is important to consider this (inaud.) to go away on their own (inaud.) different every women, but she needs to consult her primary provider to decide how to reduce her dose or (inaud.). As Dr. Alving has said, if—we have very effective treatments to reduce the risk of heart disease and stroke.

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These are the things I think that women should be focusing on, not the complex hormones that have many different effects but clearly don't prevent cardiovascular disease.

FS: And I would—I would like to add to that that hormones are very effective in preventing hip fractures and in maintaining bone density. So I think that women need to work with their physicians as they come off hormones to be sure that they are maintaining their bone health as being evaluated for bone density. And this really is, I think, a lifelong issue with many women.

MS: I can add to that specifically for the menopausal symptoms, the menopause. We need to keep in mind that the risks of these diseases are very low overall in our study. And they are much lower in the younger women—who are much younger on average. When they go through the menopause, they might be in their early 50s. And (they realize now that the current study suggesting that heart disease and some of the other cardiovascular diseases are not as increased—they are not as increased in ages 50 -59. Now that is not significant, but it does support the overall thesis that the risk—the risk in the youngest women are likely to be very low.

And the total recommendation of the FDA is consistent with that. They say that these hormones can be used in younger

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women with symptoms and NIH concurs with that. Our data do not contradict that.

MS: And thank you very much, Mr. Cohen. Representing the Heart.org, our next question comes from Susan Jeffrey. Please go ahead.

FS: Hi. I just wondered what you think some of the differences you saw between the 2 trials on the endpoints, the breastcancer?

FS: Dr. Roussow, would you like to answer that question?

MS: Right. There are real similarities in the two trial results. Particularly for cardiovascular disease the similarities are evident in that neither of these formulations include coronary heart disease. They both increase risk of stroke and they both increase the risk of (venous thromboembolism. So cardiovascular disease there are a lot of similarities. There are also similarities for fractures. Both reduce the risks of fractures. They are dissimilar for colorectal cancer in that the estrogen plus progestin suggested a reduction but the estrogen plus progestin did not.

And as you point out in breast cancer, the most striking dissimilarity where estrogen plus progestin is a significant increase in risk significantly (inaud.) is an

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uncertain effect, is neither significant... It's not significant, so we're not sure that the apparent risk reduction is real or not. And for that reason we want to continue following this to see what happens to the breast cancer. In fact, we're following the women in both parts to see what happens over time. In terms of mechanisms, the result is broadly similar to that of other studies—observational studies which have indicated a higher risk for hormone preparation containing progestin than estrogen only.

So there's some broad consistency. There is no question about... Mechanism is (inaud.). There is biologic data suggesting that there's a role for progestin (inaud.) which (add to the effect of estrogen.

FS: Just one question. You talked about potentially that need for future trial or whether avenues should be pursued. Any plans for NIH studies?

FS: We have no definite plans at this time. As you know, NIH always welcomes applications for new trials and also, of course, they're subject to peer review and to available funds. I think also that our results will probably provide a stimulus to pharmaceutical companies that will look at the benefits and with—and consider other preparations as

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well. And, in fact, this has been done. I think since the estrogen plus progestin results were released, Wyeth has been able to receive approval for a-- lower forms doses formulation of Prempro (ph.), and there are now two lower dose formulations for Premrin (ph.) on the market.

And so there are other options available. We don't have the data on those materials that we do certainly on the doses used in WHI. But I think this will stimulate new research.

MS: Okay, Ms. Jeffrey, did you have any follow-up questions?

FS: Well, I think (inaud.).

MS: Very good. Thank you. Next in queue we go to WebMD, Celine Boyle (inaud.).

FS: Hi. I have a couple of questions if I may. With regard to the memory study, when are the findings expected and is there anything you can say right now about what you may find?

FS: The results of the memory study--the WHI memory study will be published in about two months we think. And I think at this time we do not really want to provide any results because they're still undergoing analysis. And the final findings will be in the paper, which hopefully will be available in about two months.

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FS: And I wanted to ask as far as the fracture findings are concerned, do you see—is there any case where it might be a—where estrogen might be an appropriate treatment to prevent bone loss? I'm thinking of women possibly with a low stroke risk may need a cheaper alternative to available osteoporosis drugs.

FS: The FDA has said that certainly hormone therapy is appropriate for reduction of fractures if other alternatives have not been found to be, for example, well tolerated by women or there may be certain contraindications for certain women. Though, I think there probably would be situations in which women would continue on hormone therapy, again, after going over all the other options from their physician.

MS: I might add to that what Dr. Alving is correct (inaud.) and it's consistent with the FDA labeling, there are intriguing findings starting to emerge that possibly (things like transdermal use is much lower than is currently being given for osteoporosis prevention. So an example of, you know, these kinds of findings that we have which although they say that one shouldn't use hormones in the long term because of cardiovascular and other (inaud.), it stimulates research into looking at better ways of preventing these diseases.

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So, yeah, the answer still is that they're in consultation with their physician and with their own risk profile taking care of risk factors that you can take care of, for instance blood pressure particularly as in the case of stroke there would be a place for estrogen for osteoporosis for instance.

MS: And Ms. Boyle, your line is still open. Did you have a follow-up?

FS: No, I didn't. Thank you.

MS: You're very welcome. Next we go to (Inaud.). Lizette Hilton, please go ahead.

FS: Hello. Dr. Roussow, could you please follow up on a quote that you made in the press release, that the baseline, the women in the estrogen only study had a higher risk of cardiovascular disease than those in the estrogen plus progestin st-trial. Why was that?

MS: Well, what we do know is that they had higher rates of coronary heart disease and stroke and, in fact, total death. If you look at the placebo group in the estrogen plus progestin trial versus the estrogen only trial, the rates are much higher than the estrogen only trial. So there's something about women who have had hysterectomies... All the women on the estrogen trial have had hysterectomy.

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That gives them a higher risk. And so far what has been identified is that they have higher levels of risk factors, for instance blood pressure and they increase the high cholesterol and being overweight and having diabetes.

These are all powerful risk factors. So that may be part of the explanation. However, the investigators are analyzing the data in much more detail to see how the characteristics of the women at baseline and a higher risk for cardiovascular disease plays into the results of the trial. We've had a very short time to analyze all the data, and so they'll be many more details and other information coming out in the future which will help them see what's going on.

FS: And then the women who have been taking estrogen for many years, should they be more diligent in their care, you know, even if they go off the estrogen at this point for stroke and...

FS: That's a very good question. And we will continue, as we said, to follow these women on an annual basis through 2007 and even beyond. And so what you're really saying is the stroke risk going to go down? And we're going to be evaluating that.

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MS: (Inaud.). You know, if women previously were using hormones under the impression that it might prevent cardiovascular disease, now that is what the contribution of these studies has made is that these hormones do not prevent cardiovascular disease. So the answer part of the answer. It must be that you can't rely on protection, a women. You have to look at the other ways of preventing disease such as control of the risk factors.

FS: Thank you.

MS: And thank you, Ms. Hilton Representing CNN, our next question comes from the line of Miriam Falco. Please go ahead.

FS: Thank you very much for having this press conference. And I apologize if what I ask is redundant. I was unable to catch the very top of the press conference. With this arm of the WHI closed now and the overall information that's been put out, it's still extremely confusing when we report this to the viewers what does this mean to them, especially when a lot of the estrogen drugs that have been used in these trials are at higher doses than the newer ones that are available now.

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What is the—what's the overall message that women should be taking away from this now that the estrogen arm is closed too?

FS: I think that the overall message should be that hormones are certainly very appropriate for treatment of menopausal symptoms. They should be used as the shortest dose for the lowest possible time. The use... One of the useful messages from these two studies are that if you've been on hormones for years and years and years because you just felt good, didn't bother to go off them and thought perhaps you're getting better cardiovascular protection, you really need to think about is it time to go off the hormones and discuss this with your physician and gradually taper off.

So the take-home message is that for the prevention of diseases such as cardiovascular disease, hormone therapy is not the answer. And so I think what you have to realize, what you have to tell your viewers is that the hormones in these studies were really used in trials to see if they could prevent chronic diseases. And we have found that really they're not the answer. But this does not really affect women who are using them for short-term for relief of menopausal symptoms.

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And most women use hormone therapy for about two years evidently. And that the risks that we report in these studies are really very small risks for the individual women. Dr. Limacher, would you like to add anything to that?

FS: I think that summarizes the intent of our report pretty well. We now know that hormone therapy for women after menopause is not the panacea that was predicted. In fact, it increases the risks particularly stroke, but also (blood clots. The other message, though, is that there are many other effective treatments. Cardiovascular risk is a very serious concern, the leading killer of women. And that needs to be addressed. But it should not be addressed by hormone therapy.

FS: What are the those alternatives if I may follow up?

FS: Certainly. I think high on the list is monitoring the risk factors that have been alluded to earlier, and those risk factors include elevating cholesterol levels. Every adult in America should know their cholesterol fractions and address the LDL numbers as high, HDL numbers as low by either diet, exercise or pharmaceutical therapy. In addition, blood pressure is the major risk factor for stroke, blood pressure. Targets have been lowered recently and we now believe that an ideal blood pressure should be

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less than 120 over 80, not as high as 140 over 90 as had been promoted in previous years.

Diabetes should be controlled tightly and other risk factors in a diabetic patient should be very aggressively maintained. All women should really increase their physical activity levels. As a nation, we are in terrible shape. As a nation, we are also becoming more and more obese. Weight management, diet control and exercise are high on the list. Finally, smoking should never be part of anybody's habits. Fortunately, if (inaud.) women (inaud.) men (inaud.), but these women should also (inaud.).

FS: Thank you.

MS: Ladies and gentlemen, once again if there are any additional questions or comments, feel free to queue up simply by pressing star, then one on your touchtone phone. And our host panel, our next question comes from a freelance writer, Ms. Tabitha Powledge (ph) Please go ahead.

FS: Hi. I was interested in the brief discussion of the dropout rate in this study. Could you talk a little bit about how significant it is? How, for example, the dropout rate compares with the dropout rate in other big clinical studies?

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FS: Dr. Roussow, would you like to answer that question?

MS: Yes. The dropout rate... Keep in mind that this study went on for an unusual length of time. We studied... You know, we stopped it a year early, but it did go on for almost seven years, which is a long period of time. Most trials are three to four years. If you look—if you look at the dropout period in the—dropout rate in the initial period, it's fairly similar to what we found in the HERS trial which lasted almost five years. Almost very similar to that. It's a little lower than we find in a typical statin trial, but we looked into the design of the trial and estimates of the dropout rate and we estimated it pretty high because there was no (inaud.) in practice.

Drop out from hormone therapy is extremely common. Almost half of women who start hormones are no longer on it by the end of the first year. So we will see some estimates. And our experience has been that our actual dropout has been a little higher than anticipated. If you can... But not in the area of the (inaud.). The trial was not stopped because of the dropout rate. That was not the reason for stopping. The reason for stopping was the increased risk of stroke against the background of no benefit for coronary heart disease.

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FS: Dr. Roussow, if I might add, there are a couple other points to bring out. First of all, although these women were off study medication, they are not out of the study. They are (inaud.) follow up. They are still asked to participate (inaud.) very (inaud.). Also, the—even though there is a fairly high percent of women off medication, there is also a recently significant number of women who come back onto study medication, which is apparently unusual

We don't know of—a great deal why the women stop, but the (inaud.) categories of reasons were because—largely because their providers recommended that they either off of active treatment or to be actually on active treatment. And if they were on after treatment, (inaud.). So those were physicians who decided (inaud.). So there are many considerations to this. And finally, if the—the—the high rate of women off study medication would actually make it more difficult to find significant differences between the fact that we did find significant difference and when we analyzed women who didn't stop taking their study medications.

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So I think they—these factors contribute to the validity of our finding.

FS: Can I do my follow up?

MS: Yes, please.

FS: Was there a spike in dropout after the announcement of the combination of hormone study?

FS: Actually, there was not. So women continued to remain active in the estrogen alone trial and they also received letters from the WHI informing of the results and keeping them very up to date. So I think that this reflects the fact that they felt fully informed and that if there were any changes that they needed to know about, that they would be told.

MS: And did you have any follow ups, Ms. (Inaud.)?

FS: No. That'll do it. Thanks.

MS: You're very welcome. Thank you. Next we go to the line of Deborah Hughes, also a freelance writer. Please go ahead.

FS: Thank you. After WHI estrogen plus progestin results the FDA change product label and I think at that time it was said that they would review the results of this study which (inaud.) to see if any additional labeling changes might be required. At that timethe estrogen or the progestin or the combination of the two contributing to the increase stroke of CVD whether this study (inaud.) well, we have to

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(inaud.) all estrogen, all estrogen plus progestin will have to be painted with the same brush. Do you believe that this study will either (inaud.) can't tell at this point (inaud.)? So I guess the question is do you believe it will lead to FDA label changes?

FS: Well, I would—I don't wanna speak for the FDA. Suffice it to say they have all of the information. They have the latest, up-to-date information from the WHI and they are reviewing this information carefully. It could or could not lead to labeling changes. I think for the public right now, the important information is that both the FDA and NIH concur that the fin—the bottom-line message is hormone therapy should be used as the lowest dose for the shortest period of time.

And this is safe, you know, as we've said on the increased stroke risk that we noted, also increased risk for venous thrombosis and no evidence of protection against heart disease. So the—this estrogen alone study is not really changing the bottom-line recommendations, but I'm sure that they will be reviewing the data with respect to whether or not they should change specific information on the package information

FS: Thank you.

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MS: We have a follow-up question from David Cohen once again with the Baltimore Sun. Please go ahead.

MS: Hey, Dr. Limacher, I wonder if you could just spell your name, but the question I have is just (inaud.) years ago people thought this was gonna be a panacea and that seems not to have panned out. How did that happen? I mean, what-what-what were (inaud.) scientists thinking (inaud.)?

FS: The type of studies that were conducted (inaud.)...

MS: Yeah.

FS: ...were observational studies.

MS: Okay, what's that?

FS: And that means that they evaluated with women who were already on or already off medication and study follow (inaud.) What that does is (inaud.) women to have the ability to take medication and to tolerate this so that they stay on it. So that's a very different set up than taking all women who are eligible and assigning them by random mechanism to treatment or placebo, which is what a clinical trial is.

MS: I...

FS: And that's what women (inaud.). So there is the opportunity for bias in the observational study and to eliminate in the clinical trial. We know that women in the observational studies are taking estrogen tended to be

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healthier. They were more educated, more physically active, had lower risk factors. So there are other features other than the medications, per se, that have contributed to the results—to the results that were promoted as being the benefits of the medication.

MS: Okay, so it may have been for other reasons besides estrogen?

FS: Yes. And then finally who had already been on them, we would not have seen an early effect of risk because those people would not have been still on medication to participate in observational studies. So there are a number of factors that contribute to the differences in the findings.

MS: (Inaud.). Thank you.

MS: And thank you, Mr. Cohen. Ladies and gentlemen, I'll offer once again if you have any additional questions or comments, please take this opportunity to queue up by pressing star, one on your touchtone phone. We also have a follow-up question from Lizette Hilton once again with Nursing Spectrum. Please go ahead.

FS: Yes, I think that last question was a really good one. What have we learned then for future research because I know as a woman I was always under the impression that taking hormone therapy was kind of the way to stay young

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and healthy? How do we keep that from happening again now that we have such a great use of let's say the cholesterol lowering drugs (inaud.)? That message is coming across with those. How do we learn from this experience before we promote the use of medication the way we did with the hormone therapy?

FS: I think that one of the ways in which we do this is to still work through randomized controlled clinical trials. They so far seem to be the golden standard, although they aren't the only way to obtain scientific information. Observational tri-studies are extremely valuable. For example, the Framingham Heart Study is an observational study and has provided much information. But I think that we have to learn the boundaries and the limits of what we can learn from observational studies, as well as the boundaries and limits of what we can learn in clinical trials. Dr. Limacher, would you like to add any of your thoughts to this?

FS: Sure. I certainly agree that (inaud.) yet. (Inaud.) proving basically the overall risks and benefits of any medication. I would say that most of the statins have been studied by these randomized controlled clinical trials, and they are not being promoted or recommended based on observational studies alone. Also, though, observational

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studies do have a considerable value. And what I think their major role is is to envelope the kind of findings that leads to further testing.

If you can't even in an observational study demonstrate that one behavior or one characteristic actually seems to prevents or (inaud.) reduce the risk of some outcome, then it might not be worth testing in a clinical trial. Then they have a lot of value in giving us a whole picture, but not in promoting specific medication, particularly for long periods of time. I believe that WHI has made a tremendously valuable contribution to the argument to use appropriate, long enough duration randomized, controlled clinical trial about what should we be recommending for long-term (inaud.) treatment.

FS: And I might add that, you know, the NIH, or I should say our federal government, perhaps, cannot always afford to do the same kinds of long-term trials that have been done in WHI and that are being done. However, the FDA, I think, has very useful mechanisms for follow up of drugs. And when a new drug or a new device or therapy comes on the market, they can ask the manufacturers to do continued surveillance. And, in fact, NIH has worked with FDA in

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developing surveillance with particular procedures or devices.

So that once a drug or therapy or device is licensed, we can still continue to see what it looks like in the general population.

FS: Who funded this study?

FS: Who funded this study?

FS: Uh huh.

FS: This study was really funded by the American tax payers. And this was an NIH study. NHLBI has oversight of the study but works mostly with the other NIH institutes, the National Cancer Institute, National Institutes of Arthritis, (Unint.) Muscular Skeleton Diseases, the National Institute of Aging and the Office of Research in Women's Health. In addition, Wyeth did donate—did provide the Premrin and the Prempro that were used for these studies.

FS: Okay. And my last question is what about... I'm assuming, and tell me if you know that I'm wrong, that a lot of women take hormone therapy to manage symptoms—post-menopausal symptoms. Is that where the gap might be, that we don't have great therapy to manage those symptoms?

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FS: Actually, hormone therapy is the most effective therapy for managing menopausal symptoms. But there are many women who can't take hormone therapy for various reasons. For example, those women who are at high risk for breast cancer or who have had breast cancer certainly are not interested in taking hormone therapy for relief of hot flashes. And much research still needs to be done I think on the basic biology of hot flashes. And, in fact, NIH is very interested in looking into basic research in this area.

And this, again, could provide an emphasis for the pharmaceutical companies to come up with alternative therapies for relief of hot flashes for those who cannot take hormone therapy.

FS: Thank you.

MS: And thank you, Ms. Hilton, and for Mr. Cohen with the Baltimore Sun and all of our participants. Dr. Marian Limacher (unint.) is Marian, M-A-R-I-A-N, Limacher, L-I-M-A-C-H-E-R. And with that, Drs. Limacher and Alving and our host panel, we have no further questions. Please continue with your closing remarks.

FS: Well, thank you for calling in today. We all look forward to further (inaud.) knowledge for the Women's Health Initiative and we expect findings from the WHI memory study

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to be published soon. And additional findings from the estrogen alone study will be reported in coming months. The WHI diet and vitamin studies continue as planned and should end in 2005. If you have additional questions, please contact the NHLBI Communications Office at (301) 496-4236. Thank you.

MS: And ladies and gentlemen, that does conclude our Women's Health Initiative Press Conference for today. Thank you very much for your participation as well as for using AT&T Executive Teleconference Service. You may now disconnect.

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