

NIH/WOMEN'S HEALTH INITIATIVES

TELEBRIEFING

FEBRUARY 15, 2006

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OPERATOR: Thank you for standing by. Your conference will begin in a few minutes. Please do continue to hold.

MODERATOR: Thank you very much for standing by. We do appreciate your patience today while the conference assembles.

Good morning and welcome to the WHI telebriefing. Now, at this point we have all of your phone lines muted or in a listen only mode. However, after our guest speaker's presentation today, there will be opportunities for your questions. If you would like to cue up, simply press star then one on your phone key pad.

As a note, ladies and gentlemen, if you should require any assistance during the press conference, you may reach an AT&T operator by pressing star, then zero. And as a reminder, today's call is being recorded.

So with that being said, let's get right to today's agenda.

Here, with our opening remarks, is Communications Director for the National Heart, Lung, and Blood Institute, Ms. Terry Long.

Please go ahead.

MS. LONG: Good morning, everyone. I want to welcome you to today's briefing on the Women's Health Initiative Calcium and Vitamin D trial results. These results are published in tomorrow's issue of the New England Journal of Medicine. And I just want to remind everyone that all stories are embargoed until 5:00 p.m. Eastern time today.

We'll begin the briefing with a statement and introduction from Dr. Elizabeth Nabel, the Director of the National Heart, Lung, and Blood Institute. Dr. Nabel is also the Director of the Women's Health Initiative.

Dr. Nabel's remarks will then be followed by a question and answer session with our assembled experts. Dr. Nabel?

DR. NABEL: Thank you, and good morning everyone.

The WHI Calcium with Vitamin D trial studied the effect of Calcium and Vitamin D supplements on preventing hip fracture in healthy post menopausal women. The study also tested the effects of supplements on spine and other types of fracture, as well as on colorectal cancer.

Of the 36,000 participants in the trial, half received a daily dose of 1,000 milligrams of elemental Calcium in the form of Calcium Carbonate, combined with 400 units of Vitamin D. The other half of the participants received placebo pills. Study participants were followed for an average of seven years. And three fourths of them were still taking their pills by the end of the study.

Now, as you've seen, the results show that Calcium and Vitamin D supplements offer a modest benefit in preserving bone mass. There was a small, a significant 1 percent higher hip bone density for those taking the supplements compared to those taking placebos.

The results also show that supplements prevent hip fractures in certain groups, including older women.

The 12 percent reduction hip fracture in the supplemental group was not statistically significant across the entire population. However, women who took consistently took the full supplemental dose did have a significant 29 percent decrease in hip fracture. And those older than 60 had a 21 percent reduction.

The study also found that supplements do not prevent other types of fracture, such as spine fracture. And they do not prevent colorectal cancer.

The Calcium Vitamin D supplements generally were well tolerated, although they were associated with increase risk of kidney stones.

The WHI's findings offer guidance for women on the risks and benefits of adding Calcium and Vitamin D supplements to their diet. Based on all of the results, women, particularly those over 60, should consider taking Calcium and Vitamin D for

bone health. However, women should not expect these supplements to prevent colorectal cancer.

Our recommendations are that dietary Calcium remain as the preferred source of Calcium and sunlight for Vitamin D.

Now, to answer any questions that you might have this morning, we've assembled a panel of WHI investigators and experts from the NIH. On the phone with us this morning is Dr. Rebecca Jackson, an endocrinologist at Ohio State University. And the article's lead author is here with us now on the phone, Dr. Gene Witkowski-Wemby [ph.], an epidemiologist with the University at Buffalo, and the lead author of the colorectal cancer paper is also with us. In addition, we have NIH experts including study co-author Dr. Joan McGowan of the National Institute of Arthritis and Musculoskeletal and Skin Diseases and Dr. Donna Grabel at the National Cancer Institute Division of Cancer Prevention. In addition is the National Heart, Lung, and Blood Dr. Jacques Rosseau, who is the WHI project officer.

And we would be very pleased to take your questions at this point.

MODERATOR: Indeed, well, thank you very much, Dr. Nabel, for your time and that presentation today. And ladies and gentlemen, as you just heard, at this point we turn to your questions and comments.

We invite you to cue up simply by pressing star and then one on your phone key pad. You do hear a tone indicating you've been placed in cue. And if you'd like to remove yourself from the cue, simply press the pound key.

So once again, ladies and gentlemen, we have a full panel assembled today for your questions and comments. Please take this opportunity to cue up just by pressing star, one on your touch tone phone.

And representing the New York Times, we go to the line of Gina Kolata. Please go ahead.

QUESTION: Hi! Thank you very much.

I would just like to ask a little bit about the recommendation that women, particularly those

over 60 should consider taking Calcium and Vitamin D for bone health.

I was wondering, well, first of all, when you look at the--if you say women particularly those over 60, that sounds like you're also including those under 60. And were you basing that on the subgroup analysis of the compliance women or were you basing that on the entire study which did not show an effect?

DR. NABEL: Good morning, Gina, how are you?

QUESTION: Hi! Good.

DR. NABEL: We appreciate your question, and I'm going to ask Dr. Rebecca Jackson to address that.

DR. JACKSON: Good morning, Gina. This is Rebecca Jackson.

I think that the recommendation is for the population of postmenopausal women, but particularly those over 60. The subgroup analysis does show that there was a significant 21 percent reduction in hip fractures in women over the 60, an age group of

women where the incident of hip fractures is certainly the greatest.

However, in the adherence analyses, women 50 to 79 in the entry into the trial, when we look at those that were adhering to the full dose of study medication, there was a significant 29 percent decrease in hip fracture, which was four fewer hip fractures per 10,000 women. And in the entire group, there was a modest improvement in hip bone density.

QUESTION: And so the 21 percent reduction was this significant, as well, the--

DR. JACKSON: Yes, it was.

QUESTION: Okay. That was my question.

MODERATOR: All right. And thank you very much.

Next, representing the Los Angeles Times, we'll go to the line of Denise Gellene [ph.]. Please go ahead.

QUESTION: Yes. I was wondering if there was anything else about the women in the subgroup that might have assisted the kind of results that

you saw? In other words, you know, they were complaint taking their pills, were these women also more into exercise, ate better diets, and so forth, compared to the general group that you were looking at?

DR. NABEL: Good morning, Denise. I'm going to ask Dr. Joan McGowan from NIAMS to address your question.

DR. MCGOWAN: Thank you. That's a very insightful question, because we know that women who follow lifestyle recommendations or women who take pills in clinical trials may be different from women who are not adherent.

But in this situation, we are comparing women who were adherent to a placebo pill with women who were adherent to the active Calcium Vitamin D pill. So we think in this situation they're very comparable.

QUESTION: Okay. Thank you.
Can I ask another question?

DR. NABEL: Please.

QUESTION: So there is some statistics in your release four of ten women over 50 have a fracture in their lifetime. But since this study is only telling us something positive about hip fractures, can you, you know, put that in better context for us? I mean, what is the risk of hip fracture over lifetime for women?

DR. NABEL: Dr. McGowan?

DR. MCGOWAN: The background information on the overall lifetime risk of fracture comes from the Rochester Epidemiology Study. That really was the basis for the WHI to project how many fractures we would see. And that study was looking at three main types of fractures, hip, spine, and wrist fractures. And found that there was a 40 percent chance that a women of 50 would have one of those fractures over a lifetime.

Right now I'm forgetting the exact number on hip, but I can provide that. And it is, of course, much less as you can see from the data in this study indicating how many hip fractures there

were compared to the spine fractures or the total number of fractures.

DR. JACKSON: Dr. Nabel, may I--this is Rebecca Jackson. I'd like to make an additional comment.

DR. NABEL: Yes. Please.

DR. JACKSON: I think that one of the important things when looking at the hip fracture is that hip fracture is the most debilitating fracture and certainly that fracture which has the greatest impact on loss of independence and potentially loss of life. And so interventions that can decrease the risk of hip fractures may have a significant benefit in improving the quality as well as the length of life for postmenopausal women.

MODERATOR: Ms. Gellene, we still have your line open. Did you have any follow-up question?

QUESTION: Yes. I wanted to ask on the colon cancer, can we extrapolate that result to men? I mean, obviously you're only looking at women, but-

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DR. NABEL: Yes. I'm going to ask Dr. Witkowski-Wemby to address that question.

DR. WITKOWSKI-WEMBY: Thank you.

Certainly, when we do these studies we would want to only clearly look at the results as they relate to the population under study. And in this group we had a group of postmenopausal women. I don't know that we can directly extrapolate to men. However, these results for postmenopausal women were very consistent that there was no effect on colorectal cancer [technical interruption] polyps in this group who were on this intervention for seven years.

DR. NABEL: Dr. Grabel, would you like to add to that as well?

DR. GRABEL: I completely agree. Technically, when you conduct a trial the conclusions that you draw are limited to the population. But we have no reason, in terms of background studies and information that we have, to believe that there would be any other outcome in men.

QUESTION: Okay.

MODERATOR: Thank you, Ms. Gellene.

Next, we go to the line of Michelle Cortez, representing Bloomberg News. Please go ahead.

QUESTION: Hi! Thanks so much for taking the question. I'm wondering about two parts of the study. Number one, the dosing, do you think that you might have found different results if you had had a higher dose? And also the time line, do you think following these women longer you will see a different result from the study? And if so--and either way, is there more study coming on that will give us more information or is this at this point the definitive information that we have?

DR. NABEL: Thank you.

Good morning, Michelle.

Dr. McGowan, could you address that, please?

DR. MCGOWAN: Thank you.

I think that it's very important to designate that at the beginning of this trial of supplement, we recognized that we were adding a

Calcium supplement to the diet of individuals. So we certainly chose the, what was near the recommendation at the time as the dose of the supplement recognizing that many people would be meeting those guidelines in their own diet. So I wouldn't have suggested, nor do I now, increasing that dose of supplement.

The Vitamin D was also added at the time we planned the study at the current national recommendations for Vitamin D. And it was thought to be adjunctive to Calcium. It was there to optimize the availability of the Calcium supplement. So I wouldn't think that in that case either we would use a different dose.

You had another part to your question?

QUESTION: The other part was on timing.

DR. MCGOWAN: I think that for a dietary supplement, and this is a nutrient, generally when you're giving it like this, it is expected that it will not be taken for a short period of time but would be a lifetime practice. So it certainly may be that over a much longer period of time you would

see greater effect. But we're limited by the time that we could engage women in a clinical trial. So beyond that would just be conjecture.

DR. NABEL: Dr. Rosseau?

DR. ROSSEAU: Just to put this in perspective. As Dr. McGowan says, if you're using a supplement, you don't expect a big result. And the same if you're using a diet, you don't expect a big result in the short term.

When we designed the study, we were projecting an 18 percent reduction in hip fracture for that reason. It's a very modest reduction we were aiming for. And we achieved 12 percent, which was not statistically significant except in some subgroups. So it would be well worthwhile to examine these subgroups in more detail in the next few months and also to follow up the participants to see if the fracture rates diverge more between the placebo and the treatment group.

MODERATOR: Do you still have your line open, Ms. Cortez?

QUESTION: I'm good. Thank you very much.

MODERATOR: You're very welcome, ma'am.

Thank you.

Ladies and gentlemen, I'll just offer once again, if there are any additional questions or comments, please press star, one on your touch tone phone.

We do have Andy Dworkin with the Oregonian in cue. Please go ahead.

QUESTION: Yes. Thank you.

I'm curious about the hip fractures versus the other, the spine and the wrist fractures. Is there any knowledge or theory about why the results differed? Do we know it's just mechanical for the stress on the bones or it's something about the endocrinology or something else?

DR. NABEL: Yes. I'm going to ask Dr. Jackson to address that question.

DR. JACKSON: Good morning, Andy. (ph) Actually, I think that's an excellent question. There are really several factors that make hipbone unique. First of all, it has a larger amount of cortical bone, and it's exposed to weight bearing.

And previous studies have suggested that there are certain factors relating to calcium balance that might play a role in hip fractures in older women.

So the fact that the WHI calcium Vitamin D trial showed that calcium Vitamin D reduced hip fractures but not other types of fractures in older women was certainly consistent with some of these biologically plausible hypothesis or the role of a negative calcium balance contributing to that. And I think, importantly, as I said earlier, because hip fracture's our most debilitating fracture, these results are very important to women's health.

QUESTION: Thanks. And I also wanted to ask a second question if I could, which is--broader--now that the three main intervention arms of this have finished up, I wondered if you could sort of address overall what you're happiest about with the WHI trial--these intervention trials, and also in retrospect if there's anything that maybe you might have changed in terms of the design of the trial or the enrollment or length or anything like that?

DR. NABEL: That's an excellent question. We really view the WHI as a tremendous success story. When you think back to the last 1980s, early 1990s, we had very little clinical trial data on issues that affect women's health. And so this study was really initiated to collect that information so that we could provide evidence-based recommendations for the most important issues that affect women's health in their older years.

Over 161,000 women participated in the study; that in and of itself is a landmark. Women did that with enthusiasm. They have remained bonded to the study in many ways. So I think that that's a tremendous success story. Clearly, we had information from this study that we did not anticipate, but that's why you do rigorous clinical research, and we now are going forward.

We will be funding an additional 5 years of an observational period to follow up on many of the women in the three studies, and in addition, we are soliciting proposals from investigators to continue to do analysis of the very rich data base. We're

very interested, for example, in doing genetic analysis of why some women may be predisposed to certain outcomes. So we see this as a very rich heritage that will continue for a number of years to come.

DR. JACKSON: Dr. [inaudible] could I--this is--

DR. NABEL: Yes, please.

DR. JACKSON: --Rebecca Jackson. I'd like to make an addition. As a clinician as well, I will tell you that information is empowering, and the ability to utilize the information that the--has been generated from the trials of the Women's Health Initiative to make health care decisions and to be able to weigh the risks and benefits has been a major step in improving women's health.

MODERATOR: Great. Thanks. And thank you, Mr. Dorkin. (ph)

Next representing U.S. News and World Reports, we go to the line of Betsy Quirna. (ph) Please go ahead.

QUESTION: Hi. Sorry. Thanks so much for taking my question. Can you guys hear me?

DR. NABEL: Yes.

QUESTION: I guess I'm just wondering why there isn't more emphasis on--or why the main analysis included noncompliant women, because the risk reduction is so much different in the two groups, the main group versus the compliant women. I guess I'm just confused about what women should take from that.

DR. NABEL: Yes, Dr. Rousseau (ph).

ROUSSEAU: Well, the most rigorous statistical test is to take what we--take the entire group--it's the analysis where you analyze women in two groups, and on average, the two groups will be similar; that's the magic of antomization; (?) that's why you do clinical trials. So that so-called intention-to-treat analysis is the most robust analysis, and that's where we focus most of our attention.

Now, as soon as you start looking as subgroups--as an earlier questioner indicated, there

is the possibility of differences between the subgroups. And this study being so large and being placebo controlled, as Dr. McGowan (ph) said, that possibility is less. But, you know, subgroups are not--the numbers are smaller--of events, and so you don't have the same reliability of the data as in the trial overall.

So the subgroups are secondary analysis and exploratory to some extent, and we look to them to find explanations for the overall findings, but they're not the primary analysis, so we'll be doing further examinations of the subgroups to see what explains the apparent differences between the older groups of women and the younger groups, for example.

QUESTION: Okay. Can I just ask a follow-up?

DR. NABEL: Yes, please.

QUESTION: But if the numbers--the older women or the compliant women aren't as reliable, what can women--what can we take--I mean, is there a significant finding we can take from that?

DR. ROUSSEAU: Well, that finding in the older women was conventionally, statistically significant, and it was different from the finding in the younger group. So we have some confidence that these findings are real and should be transmitted to women, and they--women, certainly older women--I think our findings tell you that all older women should--you know, would be Okay with getting adequate calcium and Vitamin D. And if they don't meet it with dietary means and sunlight, then they can take the supplements.

But the benefit appears to be particularly pronounced in women older than 60, and these are the women who get most of the fractures--fractures are very uncommon in younger women. So we have more confidence because of the larger numbers in the subgroups of older women because that's where the fractures were than we have in the analysis of the younger women. And that's why we emphasized the findings in the older women. So although it's a secondary analysis, it is, you know, almost as robust as the overall findings in statistical terms.

QUESTION: Okay. Thank you.

MODERATOR: And thank you, Ms. Quirna. We have three participants left in que. Next, we go to the line of Tara Pope, (ph) representing the Wall Street Journal. Please go ahead.

QUESTION: Hi. And I joined the call late, so I apologize if you've already talked--if you have just tell me, and I'll go back and listen to the call. I had in the [inaudible] there was a discussion of kidney stones. I'm just wondering about the other potential adverse events and how significant that issue is relative to the benefits?

DR. NABEL: That's an important question.

Dr. Jackson, could you address that, please?

DR. JACKSON: The study found that 17 percent of the women developed kidney stones--or there was a 17 percent increase, excuse me, in the risk of kidney stones associated with calcium plus Vitamin D. We're really exploring this finding in more depth right now to be able to understand and be able to determine whether there were some groups or

certain factors that might have predisposed women to developing this.

In terms of other symptoms, the most common symptoms reported were gastrointestinal, and those were equally balanced in women who placebo and women who received calcium plus Vitamin D. So, in general, these medications were well tolerated.

QUESTION: Can I follow up? Now just to clarify: There was a 17 percent increase in the--

DR. JACKSON: In the risk. Correct.

QUESTION: So do you know what percent of women developed kidney stones; do you have that number?

DR. JACKSON: I am double checking for you.

DR. JACKSON: Dr. McGowan

DR. MCGOWAN: Six out of 10,000 per year.

QUESTION: Thank you.

DR. ROUSSEAU: Additional kidney stones.

DR. NABEL: Excess.

QUESTION: Excess.

DR. ROUSSEAU: Compared to the placebo group. Yes.

QUESTION: Do you know what the overall risk, the real risk of--you know in any given year developing a, you know, you talk about this whole issue of absolute risk, and what is a woman's risk of developing a kidney stone?

Dr. ROUSSEAU: It's 45 per 10,000 per year in the treated group with 39 per 10,000 per year in the placebo group.

QUESTION: I'm sorry, versus how many?

Dr. ROUSSOU: Forty-five versus 39 per 10,000 per year on average.

QUESTION: Oh, I'm sorry. Thirty-nine was the placebo group?

Dr. ROUSSOU: Correct. So the difference is six per 10,000.

QUESTION: Six per 10,000 per year?

Dr. ROUSSOU: Right.

QUESTION: Okay. And so there weren't any other adverse events that were different among the placebo group and the--

DR. NABEL: Correct.

QUESTION: Okay. Thank you.

MODERATOR: And thank you very much, Ms. Pope. (ph) And representing the Voice of America, we go to the line now of Art Chimes. Please go ahead.

QUESTION: Hi. Good morning. I think I understood Dr. Nabel, I believe it was, early on, who said that it's best to get the calcium and the Vitamin D from diet and from sun light, respectively. My two-part question is, why is that, and how do you know if you're getting enough?

DR. ABLE: Well, we really recommend that people turn first to diet. We know that if you have three to four dairy servings a day that that should really cover your daily dose with about 300 milligrams per dairy serving in addition with an adequate intake of fruit, grains and vegetables when also takes in about 300 milligrams worth of calcium. Again, Vitamin D does come from the sun. There is some supplements within foods themselves. We think it's important to turn to diet first.

However, if for whatever reason you're not getting it from food, then we would recommend using

a supplement, but using a supplement only if the diet's insufficient.

QUESTION: Thank you.

MODERATOR: And thank you very much, Mr. Chimes. We do have a follow-up question with Denise Gellene, once again with the Los Angeles Times.

QUESTION: Hi! Thank you.

I was wondering if you would just comment on the results that you received in the bone density study. It wasn't what you expected. Can you just comment on the results?

DR. NABEL: [Inaudible.]

DR. MCGOWAN: The results on the bone mineral density were significant at the hip. And this is over a much longer period of time than many other studies are conducted. And there's not a direct relationship between bone mineral density and fractures. They are associated, but there are many other things that determine fracture. There are aspects of bone quality that we don't completely understand what that may be affected by Calcium and Vitamin D and not captured by the bone mineral

density. Also, the bone mineral density was measured on a subset of the entire population.

So we're not surprised, but not seeing any effect on bone mineral density at the other sites was, perhaps, the most surprising part of this. And as Dr. Jackson said, it may be that the hip, and particularly in older women, is much more sensitive to positive effects of Calcium and Vitamin D. There are Calcium balance abnormalities in older women that might suggest a mechanism for this effect.

QUESTION: Were you, were you surprised that you didn't see overall any effect on the fracture rate?

DR. MCGOWAN: On the overall fracture rate?

QUESTION: Yeah.

DR. MCGOWAN: The hip is particularly sensitive. And as Dr. Jackson said, it is the most devastating fracture so that it's not surprising. The different bone sites, although all may be experiencing osteoporosis, they're not all operating in the same way. And as Dr. Jackson said, the hip

has more cortical bone that may be very sensitive to Calcium and Vitamin D.

There have been other studies of very much older women, women who were living in nursing homes who may have been deficient in not only Calcium but Vitamin D that showed a more vigorous response to Calcium and Vitamin D supplements.

What is important about this study is that we targeted quite normal American postmenopausal women who were pretty healthy, who had a substantial weight. They had high intakes of Calcium and Vitamin D. And they had low rates of osteoporosis.

In the overall study, we observed about 50 percent of the rate, the incidents of hip fractures that we had anticipated, indicating that these were normal, healthy, American women. So we're very pleased, in fact, to have shown that the Calcium and Vitamin D that we have been recommending and the national recommendations are for diet to be your first source of Calcium, the levels we've been recommending are the backbone for a healthy life, and indeed, will prevent hip fracture.

MODERATOR: Ms. Gellene, we still have your line open.

QUESTION: Yes. Thank you.

Just to clarify, who was that speaking?

DR. NABEL: Dr. McGowan, Dr. Joan McGowan.

QUESTION: Okay. Thank you.

MODERATOR: Okay. And thank you.

We do have a follow-up from Michelle Cortez, once again with Bloomberg News. Please go ahead.

QUESTION: Thanks so much for taking a question again.

Now, so American women, we spend a lot of money on these supplements for Calcium and Vitamin D. So I just wanted to clarify. You're saying that that is not--that is money well spent, that we should continue to do that? I guess I'm just a little bit, you know, what would be the impact on a woman if she decided that it was just too much. She's already taking enough things and doesn't want to continue spending the money and exerting the

effort to take the supplements? Is there a downside to that?

DR. NABEL: I'm going to ask Dr. McGowan again to emphasize what the U.S. guidelines. And, again, our first recommendation is to obtain the adequate amounts of Calcium and Vitamin D through diet. If diet is not sufficient, then supplements would be in order.

Dr. McGowan?

DR. MCGOWAN: I think it would be a mistake to equate supplements with Calcium. We use supplements as a tool in this study. But I think the study supports overall intake of Calcium at about the recommended levels. In postmenopausal women, that level is 1200 milligrams of Calcium a day. And for all of us, you know, a third of that comes from all the other non dairy things we eat like fruits, vegetables and grains and bread. There's plenty of Calcium in other foods. And in addition, including any of a variety of either dairy products or Calcium-fortified products in food.

Someone else asked earlier, you know, why does the government recommend food over supplements? It's the matrix. Food provides you with so much more in terms of other nutrients that may help balance and even mitigate what might be the adverse event, kidney stones, that we saw in this study. So it seems like a good policy to try to achieve the guideline amounts with food. And if you can't, a small amount of a supplement as really supplementing to bring you up to the level of 1200 milligrams a day.

DR. NABEL: And Dr. McGowan, perhaps you can clarify then the recommendation on Vitamin D intake, because we understand that the recommendations do vary a bit by age?

DR. MCGOWAN: The last intense scrutiny of the data on Vitamin D was done by the Institute of Medicine in 1997. And for women and men over 50, the recommendation is 400 international units of D for day, and for men and women over 70, it's 600 international units a day.

This discounts any amount of Vitamin D that you might get from the sun. So obviously, people who are in the sun a lot might require less Vitamin D than that. But that hasn't been really scrutinized since 1997. And I think as you may all know, there has been a lot of talk about raising, increasing the levels of Vitamin D as a tool to prevent chronic disease. This study actually has nothing to say about that.

MODERATOR: Ms. Cortez, we still have your line open?

QUESTION: No. I'm good. Thank you.

MODERATOR: And we do have Gina Kolata with a follow-up, once again with the New York Times. Please go ahead.

QUESTION: Hi! I had another question for Dr. McGowan.

When you said this study supports the Calcium at the recommended levels. I was wondering, I looked at table three and it didn't look like there was any more of an effect on the women who were getting less than the recommended level as

there were in the women who were getting the recommended levels or more.

So I was wondering if I'm missing something in the story that tells you that women--that this supports the recommended level of Calcium?

DR. MCGOWAN: No. The recommendation is approximate and in the table that Ms. Kolata is looking at, we're really only distinguishing between those above 800 milligrams a day. And that's, you know, in some people it's probably pretty adequate. It is only an approximation so I can only say that in this analysis, we really didn't see variation by the amount of total Calcium in the diet.

But with adding 1,000 milligrams of a supplement, that would be--that is kind of an overwhelming addition to anyone's diet. This is a target area for more exploratory analyses.

QUESTION: Thank you.

MODERATOR: Thank you.

And with that Dr. Nabel, and our host panel, there are no further questions, please continue with your closing remarks.

DR. NABEL: Okay. Actually, Dr. McGowan just would like to clarify one additional factor to Ms. Kolata's last question.

DR. MCGOWAN: Yes. There was one thing that we mentioned in the paper, Gina, that the intervention, the Calcium and Vitamin D was particularly effective in the women who took no personal supplements at all. So that's some indication and some reason why we want to explore this more carefully. That in the women who were taking no supplements, the intervention, the Calcium Vitamin D was more effective.

DR. NABEL: Thank you.

I want to thank all of you for calling in today.

For those of you who may have called in late, just a reminder that all of the studies--or the stories on this study are embargoed until 5:00 p.m. Eastern time today.

As you know, the Calcium Vitamin D trial is the last of the major Women's Health Initiative clinical trials to publish their primary results.

As I said earlier, the ongoing five-year extension study promises to extend our knowledge about the major health conditions effecting women.

Further genetic and blood studies promise to enhance our knowledge even further.

To learn more about the contributions of the Women's Health Initiative and the future direction of this landmark study, I would encourage each of you to attend our upcoming Women's Health Initiative conference. This is entitled, "Women's Health Initiative, A Legacy To Future Generations." It will be held on February 28th and March 1, here, on the NIH campus. And for more information about this conference or anything else related to the Women's Health Initiative, please do call our NHLBI communications office at 301-496-4236.

And with that, I'd like to thank each of you again for joining us.

MODERATOR: And ladies and gentlemen, that does conclude our telebriefing for today.

Thank you very much for your participation
as well as using AT&T's executive teleconference
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[END OF TAPED TELECONFERENCE.]

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