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BALANCING ACT: THE HEALTH ADVANTAGES OF NATURALLY-OCCURRING HORMONES IN HORMONE REPLACEMENT THERAPY

HEARING

BEFORE THE

SUBCOMMITTEE ON HUMAN RIGHTS AND WELLNESS

OF THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED EIGHTH CONGRESS

SECOND SESSION

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BALANCING ACT: THE HEALTH ADVANTAGES OF NATURALLY-OCCURRING HORMONES IN HORMONE REPLACEMENT THERAPY

THURSDAY, JULY 22, 2004

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HUMAN RIGHTS AND WELLNESS,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The subcommittee met, pursuant to notice, at 2:30 p.m., in room 2154, Rayburn House Office Building, Hon. Dan Burton (chairman of the subcommittee) presiding.

Present: Representatives Burton and Watson.

Staff present: Mark Walker, chief of staff; Mindi Walker, Brian Fauls, and Dan Getz, professional staff members; Nick Mutton, press secretary; Danielle Perraut, clerk; Sarah Despres, minority counsel; Richard Butcher, minority professional staff member; and Cecelia Morton, minority office manager.

Mr. BURTON. First of all, I want to apologize for my tardiness. We were supposed to start at 2:30, but we've had a very involved, contentious hearing down in the committee room. And I've learned something after 22 years, and that is that the last week of the session before we go out on the August break, you shouldn't have a hearing. Because it's absolutely a madhouse around here. We've got a lot of votes and a lot of things going on.

Good afternoon. A quorum being present, the Subcommittee on Human Rights and Wellness will come to order.

I ask unanimous consent that all Members and witnesses' written and opening statements be included in the record. Without objection, so ordered.

I ask unanimous consent that all articles, exhibits and extraneous or tabular materials referred to be included in the record, and without objection, so ordered.

And in the event that other Members attend the hearing that are not on the committee, I ask unanimous consent that they be permitted to serve as a member of the subcommittee for today's hearing. And without objection, so ordered.

We're convening today to examine the health benefits of using natural hormones in hormone replacement therapy.

As you might know, millions of American women are prescribed synthetic hormones by their doctors to assist with the decreasing levels of estrogen and progesterone in their bodies experienced during menopause as well as other hormonal fluctuations that might occur. It might be surprising to note that many men in the United

States are administered testosterone for similar decreases in hormonal levels during the aging process, which progresses at a similar rate as menopause, called andropause.

While the declining concentrations of hormones in the body is entirely normal, hormone replacement therapy should not be undervalued as a highly effective medical treatment. It not only balances the hormone level within a patient, but it also serves as a preventative measure to ward off potential health risks associated with imbalanced hormones such as osteoporosis and the No. 1 cause of death in the United States, heart disease.

Because naturally occurring substances cannot be patented in the United States, pharmaceutical companies must somehow manipulate hormones with additional chemicals in order to be able to hold the manufacturing rights of these formulas.

Since pharmaceutical companies must mass produce these synthetic hormones according to the formulations covered by a patent, they are only offered in certain doses as a "one size fits all" solution to hormonal imbalances. This results in many American women and men being administered either too much or too little of the hormones they need to properly address their wellness needs, thus creating the potential for further health complications.

Even more concerning is the nature of the synthetic hormones. Because natural hormones must be manipulated by chemicals in order to be patented, the body does not recognize some of the components of the synthetic hormones, which causes some serious and potentially life-threatening side effects.

In 1991, the National Institutes of Health [NIH], launched the "Women's Health Initiative," one of the largest studies on hormone replacement therapy ever initiated in the United States. This clinical trial observed 16,608 postmenopausal women who received estrogen and progestin therapy or a placebo, as well as 10,739 women who had a hysterectomy and were given estrogen alone or a placebo. This study was supposed to continue until 2005; however, it was ceased in July 2002 because the NIH's Data and Safety Monitoring Board found an increased risk of breast cancer, heart attacks, strokes and total blood clots.

This information is especially sobering to me, as it has devastated my family forever. Barbara, my wife, was taking synthetic hormones when she contracted breast cancer that eventually, at least in part, took her life. And I firmly believe that her overall health and quality of life deteriorated because she was taking those doctor-prescribed hormones. Of course, at the time, we didn't know that.

There is an alternative to the mass produced and chemically altered hormones, and these are called biologically identical or natural hormones. Essentially, there are entities known as compounding pharmacies that are smaller scale operations to pharmaceutical companies that produce medicines more specialized to accommodate a wide variety of patients, rather than the one size fits all approach to manufacturing hormones.

These compounding pharmacies are located around the country and have the capacity to concoct natural, plant-based hormone medications for use in hormone replacement therapy. Because these biologically identical hormones are the same chemical struc-

ture as the hormones created in the body, the body does not have the same harmful reactions as it does when the synthetic hormones are administered.

To better explain the health benefits of naturally occurring hormones, as well as the operation of compounding pharmacies, the subcommittee will have the pleasure of hearing from Dr. Steven Hotze, a physician and founder of the Hotze Health and Wellness Center located in Houston, TX. Dr. Hotze's practice specializes in using biologically identical hormones to assist both men and women correct hormonal imbalances. To gain a better perspective into the benefits of natural hormones in hormone replacement therapy, Ms. Vicki Reynolds, a patient of Dr. Hotze's, is here with us today to share her personal experience.

In addition, the subcommittee will hear testimony from Ms. Carol Petersen with the Women's International Pharmacy, to discuss the operations of compounding pharmacies in the United States.

Dr. David Brownstein is with us as well to discuss the further benefits of using natural hormonal therapy to combat hypothyroidism. Dr. Brownstein has written a number of books on this subject and is considered one of the foremost experts in the field of holistic medicine. The doctor also serves as the medical director at the Center for Holistic Medicine.

While many physicians believe that administering their patients hormones, whether synthetic or natural, is a beneficial tool to assist with hormonal transitions, there are some doctors who contend that scientific literature shows that these tactics are not necessarily the healthiest option for patients. In order to explain this viewpoint, the subcommittee will hear testimony from Dr. Adriane Fugh-Berman, an associate professor with the Department of Physiology and Biophysics at Georgetown University. Dr. Fugh-Berman is internationally known as an expert in the scientific evaluation of alternative medicine, as well as nationally recognized expert on the topic of women's health.

The U.S. Federal Government has produced many studies and has approved various drugs to assist in hormone replacement therapy. The subcommittee has the distinct pleasure of hearing from Dr. Barbara Alving, who is married to a Hoosier, is that what you told me?

Dr. ALVING. No, I'm the Hoosier.

Mr. BURTON. You're the Hoosier? Where are you from?

Dr. ALVING. Fort Wayne, IN.

Mr. BURTON. That's right on the edge of my district, so God bless you, my child. [Laughter.]

Dr. ALVING. My brother lives in Indianapolis.

Mr. BURTON. What part?

Dr. ALVING. The south part.

Mr. BURTON. Oh, well, he may not be able to vote for me, so I'll have to pass on him. [Laughter.]

She's the Acting Director of the National Heart, Lung and Blood Institute at the Department of HHS, and she will give an overview of the Department's activities in regard to this issue.

I look forward to hearing from all of you today. And once again, since we started late, we'll get started right away with you, Dr. Alving. We appreciate your being here.

[The prepared statement of Hon. Dan Burton follows:]

Opening Statement
Chairman Dan Burton
Government Reform Committee
Subcommittee on Human Rights & Wellness
"Balancing Act: The Health Advantages of Naturally-Occurring Hormone in Hormone Replacement Therapy"
July 22, 2004

The Subcommittee is convening today to examine the health benefits of using natural hormones in hormone replacement therapy.

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While the declining concentrations of hormones in the body is entirely normal, hormone replacement therapy should not be undervalued as a highly effective medical treatment. It not only balances the hormone level within a patient, but it also serves as a preventative measure to ward off potential health risks associated with imbalanced hormone levels such as: osteoporosis, and the #1 cause of death in the United States – heart disease.

Because naturally occurring substances cannot be patented in the United States, pharmaceutical companies must somehow manipulate hormones with additional chemicals in order to be able to hold the manufacturing rights of these formulas.

Since pharmaceutical companies must mass-produce these synthetic hormones according to the formulations covered by a patent, they are only offered in certain doses as a "one size fits all" solution to hormonal imbalances. This results in many American women and men being administered either too much or too little of the hormones they need to properly address their wellness needs, thus creating the potential for further health complications.

Even more concerning is the nature of synthetic hormones. Because natural hormones must be manipulated by chemicals in order to be patented, the body does not recognize some of the components of the synthetic hormones, which causes some serious and potentially life-threatening side effects.

In 1991, the National Institutes of Health (NIH) launched the "Women's Health Initiative," one of the largest studies on hormone replacement therapy ever initiated in the U.S. This clinical trial observed 16, 608 postmenopausal women who received estrogen and progestin therapy or a placebo, as well as 10, 739 women who had a hysterectomy and were given estrogen alone or a placebo. This study was supposed to continue until 2005; however, it was ceased in July of 2002 because the NIH's Data and Safety

Monitoring Board found an increased risk of breast cancer, heart attacks, strokes, and total blood clots.

This information is especially sobering to me, as it has devastated my family forever. My wife, Barbara, was taking synthetic hormones when she contracted the breast cancer that eventually took her life, and I firmly believe that her overall health and quality of life deteriorated because she was taking those doctor-prescribed hormones.

There is an alternative to the mass-produced and chemically altered hormones, and these are called biologically identical, or natural, hormones. Essentially, there are entities known as compounding pharmacies that are smaller-scale operations to pharmaceutical companies that produce medicines more specialized to accommodate a wide variety of patients, rather than the one-size fits all approach to manufacturing hormones.

These compounding pharmacies are located around the country, and have the capacity to concoct natural, plant-based hormone medications for use in hormone replacement therapy. Because these biologically identical hormones are the same chemical structure as the hormones created in the body, the body does not have the same harmful reactions as it does when the synthetic hormones are administered.

To better explain the health benefits of naturally occurring hormone, as well as the operation of compounding pharmacies, the Subcommittee will have the pleasure of

hearing from Dr. Stephen Hotze (Haute-zee), a physician and founder of the Hotze (Haute-Zee) Health & Wellness Center located in Houston, Texas. Dr. Hotze's (Haute-zees) practice specializes in using biologically identical hormones to assist both men and women correct hormonal imbalances. To gain a better perspective into the benefits of natural hormones in hormone replacement therapy, Ms. Vicki Reynolds, a patient of Dr. Hotze's (Haute-zees), is here with us today to share her personal experiences.

In addition, the Subcommittee will hear testimony from Ms. Carol Peterson with the Women's International Pharmacy to discuss the operations of compounding pharmacies in the U.S.

Dr. David Brownstein is with us today to discuss the further benefits of using natural hormonal therapy to combat hypothyroidism. Dr. Brownstein has written a number of books on this subject, and is considered one of the foremost experts in the field of holistic medicine. The doctor also serves as the Medical Director at the Center for Holistic Medicine.

While many physicians believe that administering their patients hormones, whether synthetic or natural, is a beneficial tool to assist with hormonal transitions, there are some doctors who contend that scientific literature shows that these tactics are not necessarily the healthiest option for patients. In order to explain this viewpoint, the Subcommittee will hear testimony from Dr. Adriane Fugh-Berman (Few - Bur-man), an Associate Professor with the Department of Physiology and Biophysics at Georgetown

University. Dr. Fugh-Berman (Few - Ber-man) is internationally known as an expert in the scientific evaluation of alternative medicine, as well as a nationally recognized expert on the topic of women's health.

The U.S. Federal Government has produced many studies and has approved various drugs to assist in hormone replacement therapy. The Subcommittee has the distinct pleasure of hearing from Dr. Barbara Alving, the Acting Director of the National Heart, Lung, and Blood Institute at the Department of Health and Human Services, who will give an overview of the Department's activities in regard to this issue.

I look forward to hearing testimony from all our esteemed witnesses today, and I hope that the evidence presented in this hearing will empower both physicians and patients to weigh all possible options when selecting a course of treatment to correct hormonal imbalances.

STATEMENT OF BARBARA ALVING, M.D., ACTING DIRECTOR, NATIONAL HEART, LUNG, AND BLOOD INSTITUTE, NATIONAL INSTITUTES OF HEALTH, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. ALVING. Thank you, Mr. Chairman. I'm pleased to appear before this committee in my capacity not only as the Acting Director of the National Heart, Lung and Blood Institute, but also Director of the NIH's Women's Health Initiative. I have been the Director of this since 2002. This was after the first paper was released on the role of Prempro in protection against heart disease. The Women's Health Initiative, however, has been administered by my institute since 1997.

So I'm first here to tell you what we've learned from the WHI, with regard to hormone therapy, using conjugated equine estrogen, and second, to comment on alternative therapies that are now receiving attention. The WHI began in 1991 and the purpose was to really investigate approaches that might be helpful to older women in preventing common chronic diseases, particularly coronary heart disease and also to determine if this would increase the risk for breast cancer, alter the risk for colorectal cancers and have an effect on osteoporosis.

Estrogen replacement was just one such approach. For much of the 20th century, popular thinking was that restoring the levels of estrogen which ebb during middle age would enable women to remain forever young. And we're still trying on that end. Although estrogen was initially prescribed to alleviate troublesome menopausal symptoms, a number of observational or epidemiologic studies really suggested that women who took estrogen experienced a lower incidence of chronic diseases, particularly heart disease, and enjoyed better health overall than women who did not take prolonged hormone therapy. And data from many basic science investigations really provided explanations for how this might occur.

But we really didn't have actual proof that this was the case. So in 1991, a very bold woman, Dr. Bernadine Healy, said it's time to really initiate a very large scale study. So the Women's Health Initiative hormone trial was designed to answer these questions. And remember, this was before the era of statins and other therapies that have been widely accepted in this current era.

So as you've said, the Women's Health Initiative recruited about 27,000 healthy postmenopausal women of 50 to 79 years of age. This age group was recruited because this is the age at which one would begin to see cardiovascular events and other adverse effects. And these women were divided into one of two groups, depending on whether or not they had undergone a hysterectomy. Those who still had a uterus were assigned to take a pill containing estrogen and progestin. This was 0.625 milligrams of conjugated equine estrogen, plus 2.5 milligrams of medroxyprogesterone acetate, also known as Prempro, or a placebo. And those who had undergone a hysterectomy took Premarin, 0.625 milligrams of conjugated equine estrogen or a placebo.

And you may say, well, why those drugs? Why those doses? These drugs were the most widely used at this time in the United States. So it was decided that not all doses and not all different

combinations could be studied. So this was the one that was accepted for study.

It's worth noting that there was a lot of controversy at the beginning of this trial. Many interested parties said the trial should not be done, it's obvious that hormone therapy is beneficial, it's a foregone conclusion. Some even said it was not ethical to do, because it would take half of the participating women to take placebos and thereby deny them the positive effect of hormones.

Nonetheless, the arguments in favor of a randomized placebo controlled clinical trial prevailed, so now as we know, we've seen results. The WHI trial of estrogen plus progestin was halted in 2002, as you have said, Mr. Chairman, after an average followup of 5.2 years. Compared with women who took a placebo, women taking the hormones of Prempro or estrogen plus progestin experienced an increased risk of breast cancer and more episodes of heart attacks, strokes and blood clots. However, they also had lower rates of colo-rectal cancer and fractures. But it was felt that overall, this did not merit using this drug as protection against chronic disease.

And furthermore, an ancillary study, that is a study that really hadn't been included in the beginning but was sort of added on, well, which actually was funded by the manufacturer, Wyeth funded this study initially in women 65 years and older who were in this study were tested for cognitive effects of Prempro. Surprisingly enough, it was found that in these older women, there was an increased risk of dementia and no really improvement of cognitive impairment with the taking of Prempro. This too was a very big surprise because there had been papers suggesting that Prempro could actually be protective against cognitive impairment.

Subsequently, in the spring of 2004, the estrogen alone trial, which the DSMB, or Data Safety Modern Board have said should be continued was halted, because the NIH, on looking over all of the data and in listening to the DSMB, felt that there was really no effect on coronary heart disease, that is, there was no benefit or risk but there was a continued increased risk for stroke. What was also interesting with the estrogen alone study was that there did not appear to be any increased risk for breast cancer during the time of this study. There was, however, an increased risk of deep venous thrombosis, and there was a reduced risk of hip and other fractures.

And again, finding from the cognitive study in women taking estrogen alone revealed that really, estrogen did not reduce the incidence of dementia and really did not have any improvement, in fact had an adverse effect on cognitive function.

So in light of the WHI findings and the findings from the dementia studies, the Food and Drug Administration provided the following update in April 2004. Estrogens and progestins should not be used to prevent chronic diseases, such as memory loss, heart disease, heart attacks or stroke. Estrogens provide valuable therapy for many women for menopausal hot flashes. But they do carry risks. And therefore, menopausal women who are considering using estrogen or estrogen with progestin should discuss with their physicians the benefits versus risks and for hot flashes and significant symptoms of vulvar and vaginal atrophy, the products are approved and effective therapies.

There are also approved for women whose significant risk of osteoporosis outweighs the potential adverse effects and if they cannot other drugs that are approved for postmenopausal osteoporosis. And then the FDA said, estrogens and progestins should be used, when they're used, at the lowest doses for the shortest duration to reach treatment goals. Although we do not know at what dose there may be a less risk of serious side effects and that women indeed are encouraged to talk to their health care provider regularly about their ongoing treatment.

There's also in women who take hormone therapy a higher incidence of abnormal mammograms which require medical attention and really need to be evaluated in greater detail when those abnormalities do occur. Therefore, each woman's individual medical situation needs to be carefully discussed with her health care provider to make the best decisions.

Now, for prescription hormone formulations other than those studied in the WHI, the FDA advises, although other estrogens and progestins were not studied, it's important to tell postmenopausal women who take hormone therapy about the potential risks which are assumed to be the same for other products, and they have put these labels on those products.

In the aftermath of the Women's Health Initiative finding, increased attention has been focused on the use of complementary and alternative medicine to manage symptoms associated with the menopausal transition. This includes dietary supplements, botanicals, which are probably the most commonly used. The National Center for Complementary and Alternative Medicine supports both basic and clinical research on the safety and efficacy of botanicals such as soy, black cohosh and red clover in alleviating hot flashes, osteoporosis and cognitive and affective problems.

Other studies are generating laboratory data that are vital to the understanding of the mechanism of action and characterizing these botanicals to identify the active ingredients in the botanicals so that standardized supplements can be prepared. For example, two ongoing basic studies are looking at the effect of black cohosh extract on human breast tissue and its role as a serotonin modulator and other research is looking at the effect of soy on breast and endometrial tissue, as well as on bone. In addition to individual research project grants, the National Center for Complementary and Alternative Medicine supports several research centers on women's health.

The National Institute of Aging is supporting a 4-year randomized control trial to evaluate the efficacy and safety of phytoestrogen based approaches, such as black cohosh and multibotanical preparations given with and without soy diet counseling for treating vasomotor symptoms in premenopausal and in postmenopausal women. The toxicity of black cohosh and other herbals and phytoestrogens is being evaluated by the National Institute of Environmental Health Sciences as a part of an overall effect to establish the safety of herbal medicines.

The scientific literature on complementary and alternative medicines is equivocal, due to problems of very small trials, short duration of treatment, very large placebo effects and very imprecise measures for measuring hot flashes. Investigations of the efficacy

of soy to treat cognitive changes has produced conflicting results. Now, the NCCAM, National Center for Complementary and Alternative Medicine, has contracted with the Agency for Health Care Research and Quality to conduct and review and to assess the literature to provide a clearer idea of what is known about soy.

Clearly, additional research will be needed to provide the safety and efficacy of the information on the range of these alternative modalities. And the NIH is working with other institutes all together in this area, as well as with the FDA and the women's health component of the Department of Health and Human Services. Also, there are studies on assessing hot flashes, what is the biology behind the hot flashes and in March 2005, the NCCAM, National Institute of Aging and other institutes will co-sponsor a state of the science meeting on the management of menopausal related symptoms.

So women are eagerly awaiting the outcome of Federal efforts to uncover new approaches to address the menopausal symptoms. And in discussions with gynecologists, we know that women also are seeking natural or biologically identical hormone therapies via entities such as the Women's Health International Pharmacy. In addition, the FDA has been very proactive in the approval of additional hormone therapy since the ending of the Women's Health Initiative. For example, lower doses of Premarin are now available as well as Prempro. And most recently, a drug known as Menotestam has just been approved by the FDA. This is an estrogen patch.

So some of what the FDA has approved is biologically identical and other components are not. I thought that all of this was very well laid out on the Web site of the Women's International Pharmacy.

So I thank you for the opportunity to address you, and I'd be pleased to answer any questions.

[The prepared statement of Dr. Alving follows:]

Testimony
Before the Subcommittee on Human Rights and Wellness
Committee on Government Reform
United States House of Representatives

Balancing Act: The Health Advantages of Naturally Occurring Hormones in Hormone Replacement Therapy

Statement of
Barbara Alving, M.D., MACP
Acting Director
National Heart, Lung, and Blood Institute
National Institutes of Health
U.S. Department of Health and Human Services

For Release on Delivery
Expected at 2:00 p.m.
on Thursday, July 22, 2004

I am pleased to appear before this Committee in my capacity as Acting Director of the National Heart, Lung, and Blood Institute (NHLBI) and director of the NIH Women's Health Initiative (WHI), which has been administered by the NHLBI since 1997. I am here, first, to tell you what we learned from the WHI with regard to hormone therapy using conjugated equine estrogen and, second, to comment on alternative therapies that are now receiving attention.

The WHI began in 1991 to investigate approaches that might be helpful to older women in preventing common chronic diseases – coronary heart disease, breast and colorectal cancers, and osteoporosis. Estrogen "replacement" therapy is one such approach. For much of the 20th century, popular thinking was that restoring levels of estrogen, which ebb during middle age, would enable women to remain "forever young." Although estrogen was initially prescribed to alleviate troublesome menopausal symptoms, a number of epidemiological studies provided evidence that women who took estrogen experienced a lower incidence of disease, particularly cardiovascular disease (CVD), and enjoyed better health overall than women who did not. Data from many basic science investigations provided plausible explanations for the observed CVD benefit, and an NHLBI-supported clinical trial documented improvements in CVD risk factors (e.g., cholesterol levels) that might account for such a benefit.

But, the observation that women who took estrogen tended to enjoy better health did not prove causality, and important questions remained. Does estrogen make women healthy? Or … does being healthy (or, at least, health-conscious) make women take estrogen? The WHI hormone trial was designed to address these questions. It recruited about 27,000 healthy postmenopausal women, 50-79 years of age, and divided them into

one of two groups according to whether they had still had a uterus. Those who had a uterus were assigned to take either a pill containing estrogen and progestin (0.625 mg of conjugated equine estrogen plus 2.5 mg medroxyprogesterone acetate – Prempro) or a placebo; those who had undergone a hysterectomy took an estrogen pill (0.625 mg of conjugated equine estrogen – Premarin) or a placebo.

It is worth noting that at the outset of the WHI trial, many interested parties believed that an outcome favoring estrogen was a foregone conclusion. Indeed, some doctors and researchers argued that such a trial was unethical because it would require half of the participating women to take placebos and thereby deny them the presumed benefits of hormones. Nonetheless, arguments in favor of randomized, placebo-controlled, clinical trials prevailed – and, as we now know, they were justified.

The WHI trial of estrogen plus progestin was halted in 2002 after an average follow-up of 5.2 years. Compared with women who took a placebo pill, women taking the hormones experienced an excess risk of breast cancer and more episodes of heart attack, stroke, and blood clots. Although the hormone-treated women had lower rates of colorectal cancer and fractures, and overall death rates were equal, it was concluded that the hormone combination should not be recommended as a health-promoting regimen. Moreover, the WHI Memory Study (WHIMS), which focused on women aged 65 years and older, found an increased risk of dementia and no effect on cognitive impairment among recipients of estrogen plus progestin.

Subsequently, in the spring of 2004, the WHI estrogen-alone trial also was halted upon determination that the hormone therapy had no effect on coronary heart disease risk but increased the risk of stroke. The study also found that estrogen-alone therapy

significantly increased the risk of deep vein thrombosis, had no significant effect on the risk of breast or colorectal cancer, and reduced the risk of hip and other fractures. Findings from the WHIMS, published just last month, indicated that estrogen therapy did not reduce incidence of dementia and had an adverse effect on cognitive function.

In light of the WHI and WHIMS findings, the Food and Drug Administration (FDA) offers the following recommendations (updated April 19, 2004):

- Estrogens and progestins should not be used to prevent memory loss, heart disease, heart attacks, or strokes.
- Estrogens provide valuable therapy for many women, but carry serious risks, and therefore postmenopausal women who use or are considering using estrogen or estrogen with progestin treatments should discuss with their physicians whether the benefits outweigh the risks.
- For hot flashes and significant symptoms of vulvar and vaginal atrophy, these products are the most effective approved therapies. These products are also options for women whose significant risk of osteoporosis outweighs the risks of treatment; other treatments for prevention of postmenopausal osteoporosis are available.
- Estrogens and progestins should be used at the lowest doses for the shortest duration to reach treatment goals, although it is not known at what dose there may be less risk of serious side effects. Women are encouraged to talk to their health care provider regularly about whether treatment is still needed.
- There is a higher incidence of abnormal mammograms which require medical attention.

- Each woman's individual medical situation needs to be carefully discussed with her health care provider to make the best decision for her.

For prescription hormone formulations other than those studied in the WHI, the FDA advises the following: "Although … other estrogens and progestins were not studied, it is important to warn postmenopausal women who take estrogens and progestins about the potential risks, which must be presumed to be the same."

In the aftermath of the WHI findings, increased attention has been focused on the use of complementary and alternative medicine (CAM) to manage symptoms associated with the menopausal transition. Dietary supplements, including botanicals, are the most commonly used CAM modality for menopausal symptoms.

The National Center for Complementary and Alternative Medicine (NCCAM) supports basic and clinical research on the safety and efficacy of botanicals such as soy, black cohosh, and red clover in alleviating hot flashes, osteoporosis, and cognitive and affective problems. Other studies are generating laboratory data that are vital to understanding mechanism of action, characterizing the botanicals, identifying active constituents, and preparing standardized supplements. For example, two ongoing basic studies are looking at the effect of black cohosh extract on human breast tissue and its role as a serotonin modulator, and other research is looking at the effect of soy on breast and endometrial tissue as well as bone. In addition to individual research project grants, the NCCAM supports several research centers on women's health.

The National Institute on Aging (NIA) is supporting a 4-year, randomized, controlled trial to evaluate the efficacy and safety of phytoestrogen-based approaches

(black cohosh, and a multibotanical preparation given with and without soy diet counseling) for treating vasomotor symptoms in perimenopausal and postmenopausal women.

Toxicity of black cohosh and other herbals and phytoestrogens is being evaluated by the National Institute of Environmental Health Sciences as part of an overall effort to establish the safety of herbal medicines.

The scientific literature on CAM therapies for menopause is equivocal, due to problems with small trials, short duration of treatment, large placebo effects, and imprecise measures for critical outcomes such as hot flashes. Investigations of the efficacy of soy to prevent cognitive changes, for example, have produced conflicting results, with the latest study (published in the July 7, 2004, issue of the Journal of the American Medical Association) finding no effect. The NCCAM has contracted with the Agency for Healthcare Research and Quality to conduct a review and assessment of the literature to provide a clearer picture of what is known about soy.

Clearly, additional research will be needed to provide safety and efficacy information on the range of CAM modalities being used by women to manage menopausal symptoms. The NIH is working to improve the rigor of future studies in this area. In collaboration with eight other NIH components, the NCCAM convened a working group of scientists to assess the quality of hot flash measurements currently in use and to make recommendations for research needed to improve these measurements. In addition the NCCAM, the NIA, and others at the NIH will co-sponsor a state-of-the-science meeting in March 2005 on the management of menopause-related symptoms.

Women are eagerly awaiting the outcome of federal efforts to uncover new approaches to address menopausal symptoms. Moreover, in discussions with gynecologists in the community, we have learned that women are seeking natural (biologically identical) hormone therapies via entities such as the Women's International Pharmacy (http://www.womensinternational.com/about.html).

Thank you for the opportunity to address these issues of great importance to women. I would be pleased to answer any questions the committee may have.

Mr. BURTON. Thank you very much.

I heard you mention there were studies on dementia.

Dr. ALVING. Yes.

Mr. BURTON. Who conducted those studies? Was that the FDA?

Dr. ALVING. No. The investigators in the Women's Health Initiative conducted those studies.

Mr. BURTON. What company sponsored those studies?

Dr. ALVING. Actually, one of the principal investigators received funding from Wyeth to do——

Mr. BURTON. OK, that's all I wanted to know. A pharmaceutical company. That's all I wanted to know.

Dr. ALVING. However, they switched the funding after that.

Mr. BURTON. I know. Did you know, Doctor, that they've been putting mercury in vaccines, which is another subject——

Dr. ALVING. Yes.

Mr. BURTON [continuing]. Since 1929. Do you know the FDA has never tested it, ever? And yet our kids are getting up to 26 vaccinations before they start to school? And they've been containing mercury, and we've gone from 1 in 10,000 children that were autistic to 1 in 166? An absolutely epidemic. And the FDA never really tested it.

What I'd like to know about estrogen is, why did it take so long to do these tests? They've been giving synthetic estrogen for how many years?

Dr. ALVING. I think they were probably developed, maybe in the last, about 40, 45 years old.

Mr. BURTON. Did the FDA test those?

Dr. ALVING. In terms of tests such as the Women's Health Initiative?

Mr. BURTON. Yes.

Dr. ALVING. They did not. And I think really the only——

Mr. BURTON. You don't need to go into detail. They didn't do it?

Dr. ALVING. As far as I know, they did not.

Mr. BURTON. And they just conducted a test in 1991?

Dr. ALVING. They started it in 1991.

Mr. BURTON. And the tests showed that the people who had the estrogen had higher rates of heart disease and what else was it?

Dr. ALVING. Well, if you look at Prempro or estrogen plus progestin, it was a higher rate of heart disease and breast cancer and stroke, blood count.

Mr. BURTON. This they found after 40 years?

Dr. ALVING. Five years.

Mr. BURTON. But they've been using it for 35 or 40 years?

Dr. ALVING. Yes.

Mr. BURTON. What do we pay those people for over there? I'm not being facetious. I mean, because they're getting billions and billions and billions of dollars and they are still putting mercury in almost every vaccination for adults and we have a tremendous increase in Alzheimer's. My grandson got autism after getting nine shots in 1 day, seven of which contained mercury. We've got an epidemic in that. And now we're finding out that the synthetic estrogen caused problems probably more than it helped.

Now, you said they've gone to lower doses of some of these estrogen products, right? Those are still the synthetics, aren't they?

Dr. ALVING. Yes, lower doses have been approved by the FDA.

Mr. BURTON. OK, they've been approved. Have they tested those lower doses?

Dr. ALVING. No.

Mr. BURTON. Oh, my God. Do you mean to tell me they had a test, then went 5 years, and it showed that people were getting sicker by using the stuff, and so they went to lower doses? Why? If it's causing more problems than it's solving, why not take it off the market until they do all the testing? Until they test lower doses, higher doses, middle doses? It makes no sense.

Do you know why they didn't? I want to tell you why they didn't. I know why. Because the pharmaceutical companies would lose a lot of money. Just like they would lose a lot of money if they took mercury out of all the vaccines.

Do you know, and I want you to hear all this, because I want you to take it back to FDA and HHS. The NIH, I think it was, just completed a study saying that the mercury in children's vaccines and adult vaccines really didn't cause any problems. One of the principal studies that they cited was from Denmark. And the company in Denmark that did the study manufactures thimerosal, which is 50 percent mercury, and they sell it into the United States.

Would you say they have a conflict of interest? Hell, I would think so.

Anyhow, the NIH and HHS and the other agencies over there are too tied to the pharmaceutical industry and it's going to come up and bite them in the butt one of these days. It really is. Because the American people are finding this out.

Now, why in the world they're going with lower doses of a product that caused women's problems like high blood pressure, heart attacks, whatever else you mentioned there, I don't have it all in front of me right now, why in the world they would even continue to do that instead of taking it off the market until it's properly tested boggles my mind. And the only conclusion you can come to is the pharmaceutical companies would take a hit. And they don't want to do that. They just don't want to do that.

Can you give me another answer?

Dr. ALVING. Yes.

Mr. BURTON. What's the other answer? I'd like to hear it.

Dr. ALVING. I think you make some very good points. I think what women want hormone therapy for most, if you ask any woman of a certain age in this room, is for hot flashes, for the symptoms of menopause.

Mr. BURTON. Well, I date some women about your age, and I want to tell you, they take them for other reasons, too. [Laughter.]

Dr. ALVING. And so, I think that what the, we are unable to really, we'd have to wait another 5, 10 years go get the answer on these hormones. So what has been asked in the meantime is to take the lowest dose for the shortest period of time, and the FDA has put this type of branding and warning on every product, whether it's bioidentical or not.

Mr. BURTON. But these are still the synthetic hormones, are they not?

Dr. ALVING. No, they put the branding also on the bioidenticals.

Mr. BURTON. Oh. Well, you said that the FDA was evaluating the safety of herbal medicines now, didn't you?

Dr. ALVING. I said the NIH, because the FDA has not approved any herbal medicines. It is not under FDA approval. They do not regulate them.

Mr. BURTON. Does the FDA have to approve herbals?

Dr. ALVING. No, they don't.

Mr. BURTON. But they do have to approve the synthetics?

Dr. ALVING. Well, anything that is made by a drug company, yes.

Mr. BURTON. So the synthetics that have been causing all these health side effects, they have to approve but they never tested until just recently. And the herbals, I noticed the way you phrased that, you said that HHS is looking at the safety of the herbal medicines.

Why didn't they look at the safety of the biologically altered medicines that they've been prescribing for years, doctors have? I wonder why they didn't do that earlier?

Dr. ALVING. That would be in the province of the NIH to conduct the clinical trials. And I think that this was then started in 1991, and as I've told you even then it was considered to be a very brave undertaking.

Mr. BURTON. In 1991?

Dr. ALVING. Yes.

Mr. BURTON. But the women who didn't take the hormones, synthetic hormones, did better over all the ones that didn't?

Dr. ALVING. That's correct.

Mr. BURTON. Oh, man.

Dr. ALVING. Well, it all depends on what you're talking about.

Mr. BURTON. Let's just look at overall health.

Dr. ALVING. Overall, I would say yes, that's why the trial was stopped.

Mr. BURTON. Yes, they did a lot better if they didn't take the synthetics.

Dr. ALVING. Absolutely. And that's why the trial was stopped.

Mr. BURTON. And synthetics have been used for 40 some years, approximately.

Dr. ALVING. Yes.

Mr. BURTON. And they started testing them 10 years ago?

Dr. ALVING. Yes.

Mr. BURTON. And HHS and FDA let that happen. What are we paying them for over there? I just don't understand it.

I still can't understand why they went to lower doses of a product that was causing all of these health side effects. I just can't understand it. Do they know? Does HHS and FDA and our health agencies, do they know that the smaller doses won't produce the same side effects?

Dr. ALVING. They do not know that.

Mr. BURTON. Then why do they do it?

Dr. ALVING. Because what they've also done, what they have seen is that these side effects occur over a period of time. And that's why they have said, in the absence of knowing, we are going to tell all women about these risks at whatever dose, even though we don't know if it's safer or better, but we're going to let them know the risks and we're going to say, use it the shortest period of time at the lowest possible dose.

Mr. BURTON. You know, in a perfect world, every doctor in the country, in the world, would know what the HHS and FDA are saying should be done. But they don't. They don't read all the circulars and they don't see all this stuff. When my wife was dying of cancer, I talked to doctors about the things that were talked about in medical journals and they didn't know anything about it. We changed doctors, but it was too late, she died anyhow.

But it just boggles my mind that you would go on with lower doses of a substance that's caused all these problems when you know that they cause severe side effects and you knew that women that didn't even take the stuff did better health-wise, so you go to lower doses. Then the doctors back at my hometown and elsewhere are supposed to understand all this when they've been out of medical school for 10, 15 years. I just don't get it.

And I don't understand why they haven't done studies on the herbals right now. Why hasn't HHS conducted a study on biological hormones, bioidentical hormones? If they did a study on the synthetics, why didn't they do it on those?

Dr. ALVING. I think the reason that they chose, as I said, that dose and that particular drug at that particular time in 1991 was that is what the majority of American women who were taking hormone therapy were taking.

Mr. BURTON. Well, this is 2004.

Dr. ALVING. Yes, and times have changed.

Mr. BURTON. That was 13 years ago.

Dr. ALVING. I know. Times have changed.

Mr. BURTON. Why haven't they started testing on these bioidentical hormones that aren't from pigs and cows and all this other stuff?

Dr. ALVING. I think if the funding were available——

Mr. BURTON. If the funding—do you know how much money we give you guys over there? Do you have any idea? We give you billions and billions and billions and every year you want more. And we've got women who are getting sicker than a dog and some probably dying from something that was never tested. And then what you say after you find out that the stuff that you were putting in their bodies was causing more problems than if they didn't take it at all, you say, oh, we're going to go back and we're going to just cut the doses, instead of saying, why not just get off of it or go on these bioidentical hormones, or at least study them? And you haven't even started to study on them, have you, the bioidentical hormones?

Dr. ALVING. They have not started any long terms studies in terms of women's health as an issue.

Mr. BURTON. Have you started any short term studies?

Dr. ALVING. The bioidenticals that have received FDA approval have undergone short term studies.

Mr. BURTON. What do they show?

Dr. ALVING. They are looking for efficacy against hot flashes and any adverse effects that could be picked up on a short term study.

Mr. BURTON. I see. Are they showing any side effects at all like the long term study that we showed with the synthetics?

Dr. ALVING. Not that I am aware of. And that would be for the labeling of the FDA.

Mr. BURTON. If they did a short term study, why didn't they decide to go on with a long term study? If the short term study was beneficial, why not go with a long term study to find out their side effects?

Dr. ALVING. I think one of the issues is that of cost and duration. One would have to continue such a study for about 10 years——

Mr. BURTON. Well, if you did it with synthetics and you knew it didn't work and it cost a lot of money to do that study, why wouldn't you say, OK, we're going to spend a like amount on the bioidentical hormones? Why?

Dr. ALVING. May I say why?

Mr. BURTON. Yes, I'd like to know. I think I know why. It's because the pharmaceutical companies won't make any money off of it.

Dr. ALVING. What I would say is that what it appears is that the reason one would take hormones long term is to prevent chronic diseases. Most women take hormone therapy for about 5 years or less. And they take it for menopausal symptoms. Since this study was started in 1991, newer drugs have come out. For example, we have other drugs that will protect against osteoporosis.

Mr. BURTON. Are they synthetics?

Dr. ALVING. I'm talking about other drugs against osteoporosis, the bisphosphonates, for example. We have other drugs for heart disease, statins.

Mr. BURTON. Have those been tested, the ones that you're talking about that just came out?

Dr. ALVING. Well, yes. In terms of risks and benefits, and all of them have——

Mr. BURTON. No, no, no. Have they had any long term tests with placebos and all that?

Dr. ALVING. As long term as the FDA requires.

Mr. BURTON. And how long is that?

Dr. ALVING. I think, I am going to say at least 3 to 4 to up to 10 years. I would have to go back and look at that literature to get the specific literature.

So what I'm trying to say is that there has been a changing of the landscape in terms of the drug therapies. Some women don't even want to take hormone therapy at all——

Mr. BURTON. I wouldn't either.

Dr. ALVING [continuing]. And don't have hot flashes.

Mr. BURTON. You say they've got these for men. There ain't no way, Jose, I'm going to take that stuff. You guys over there are using human beings as guinea pigs without testing them. You're a lovely lady, but this, it really isn't right. It isn't right to run a study after 40 years or 30 years and then find out that the people who are taking the medicine that the pharmaceutical companies are producing are doing worse than the ones that aren't taking it. Then what you say instead of stopping it is, OK, we're going to go to lower doses.

That's like saying, OK, one bullet won't kill you, so we'll cut it in two and just use half a bullet.

Dr. ALVING. It will half kill you.

Mr. BURTON. Yes, it will half kill you. Let me ask you this. Is the National Center for Complementary and Alternative Medicine

looking at bioidentical hormones as a possible recommendation for FDA to suggest to women? Are they looking at that right now?

Dr. ALVING. They are not looking at that to my knowledge.

Mr. BURTON. Why? Why?

Dr. ALVING. Because they are centered on the other alternatives that are undergoing study that I mentioned.

Mr. BURTON. And the other alternatives are?

Dr. ALVING. As I mentioned, black cohosh and the flavonoids, phytoestrogens, other things such as that.

Mr. BURTON. Are those natural hormones?

Dr. ALVING. They're natural agents, in that you can buy black cohosh, it's extracted. Now, you don't know what else is in there, because it's not regulated by the FDA.

Mr. BURTON. Well, you know what, I really would want the one that's approved by the FDA because it would only kill me. [Laughter.]

And I don't mean to be facetious, but since my grandson became autistic, I started checking into the things that FDA is putting on the market and the conflicts of interest that have taken place by some of the advisory committees over there who have an interest in pharmaceutical stocks that are making the decisions on this stuff. There's too much money and too much complicity between the pharmaceutical companies and our health agencies.

And if you've got a study that shows that women are getting more heart disease, for instance, from taking these synthetic hormones than a woman who doesn't take any, that would lead you to believe they're better off not taking it. Wouldn't that lead you to believe you're better off not taking it?

Dr. ALVING. But I would make another——

Mr. BURTON. You can answer in just a second. And if that conclusion is accurate, why would you say, OK, we're going to cut the dose in half and you just take half the poison? Why?

Dr. ALVING. In the Women's Health Initiative, the women who were enrolled in the studies were between 50 and 79 years. The mean age was 63 years. In fact, it's been very highly criticized for that. When you do a study, as you can see, you get criticism from all sides.

So one of the critics, a big criticism of this, you started this in women whose mean age is 63 years old. That's not who has hot flashes. Well, this was not a hot flash study. Currently, the FDA guidelines, and I don't work for the FDA, I work for NIH, are that these drugs are to be used for treatment of menopausal symptoms. And about the average age of women having menopausal symptoms is around 45 to 50. So you're getting a different age range.

Mr. BURTON. I hear you. I'm going to yield to Ms. Watson, but let me just say one more thing in conclusion. That is when my wife got breast cancer, and she took those damned hormones for years, those synthetics, we found, when we went to buy furniture, went to buy groceries, an absolute plethora of women who were having breast cancer problems. It is an epidemic. Women don't talk about it to people like me, but they'll talk about it to another woman who's experiencing breast cancer.

And I want you to know, it's an epidemic. It's absolutely a sin. It's a sin. It's an absolute sin for our Government to approve things

that we're putting into human bodies, especially women, of age 30, 50, 100 that hasn't been properly tested. And you say they don't have enough money over there. They have enough money. It's just where they set their priorities. And if they find out that the synthetic estrogen is causing women to have severe heart trouble and other problems, and the women who don't take it are doing much, much better, then why in the world would they not take it off the market?

And the reason is the same reason that they haven't taken mercury out of vaccines. Mercury is one of the most toxic substances on the face of the Earth. When we had a spill in my district, they brought in people who looked like they were from outer space, in uniforms, to clean up a spill of this much. And they evacuated the neighborhood. And yet we're putting it into our kids' bodies, into your body, if you got a flu shot or a tetanus shot or anything else right now. And it's one of the contributing factors, according to scientists around the world, of autism and other neurological diseases, like Alzheimer's.

Yet the FDA continues to let it be on the market. And at the same time, they're doing the same thing with estrogen, only in lower doses. And it is absolutely criminal. And that's being subsidized by me and you and the taxpayers, and nobody's doing a doggone thing about it. And it really bothers me.

And you're a lovely lady, but we've got a problem.

Go ahead, Ms. Watson.

Ms. WATSON. I want to thank Mr. Chairman for his passion, his interest, his concern. And we work together as a team. We both have an aversion to using these toxic substances in medication that's ingested by humans, and so I've always looked for a biological, natural kind of alternative.

If you don't get anything else out of these hearings, Madam Colonel, just know that there is a directive to ask NIH and WHI to start research that will include the biological identical hormones. We are finding from casual information coming in that they are far more healthful and they have a far more beneficial way of treating. Because they're done on an individual basis.

Dr. ALVING. Yes.

Ms. WATSON. And not everything works for everyone.

Dr. ALVING. I understand that.

Ms. WATSON. So I wish that you would go back as an emissary of this approach. The women of the world will thank you, particularly the women here. And I as a woman definitely am going to push this with my partner here, who, and I don't have to explain to you how deeply he feels about this, I think you've been hearing it for quite a few minutes. And we're going to work as a team to be sure that we take the toxic substances out of the environment.

My big thing right now is mercury. We're trying to get mercury out of dental amalgams and we're being fought by the dental community. And they say, well, it's sealed and so on. But you crack a tooth, vapors come up.

So we have to change the thinking. We have to change the culture. And I hope that now that we're in a new millennium, the FDA can follow behind us a little bit in changing the culture. We

certainly are going to be working toward that. And thank you, Mr. Chair. I'm going to zip to the floor.

Mr. BURTON. Well, Doctor, thank you very much. We didn't mean to abuse you. But the one thing I try to do when we have witnesses from HHS and our health agencies, FDA, is to try to impress upon them the strong feelings that we have in the Congress. And it's not just me. We've had a number of votes on the floor on reimportation and other things where the pharmaceutical companies are concerned. And they've been surprising in that the representatives of the people realize what's going on.

I want to continue to give you guys billions of dollars. I really do. I think we have the highest quality and standard of life and health of any country on the face of the Earth, because we have good health agencies. But they drop the ball too many times. And they're allowing the pharmaceutical industry to have too much influence.

I want the pharmaceutical industry to make a lot of money. But I don't want them to do it at the expense of people because we haven't tested these things properly. And I hope that you'll look at these complementary medical procedures, the hormones, the natural hormones we're talking about, we're going to have witnesses testify at the next panel. And incidentally, if you've got a minute, if you can stick around and listen to what they say, or have you already heard what they have to say?

Dr. ALVING. I'd be happy to stick around.

Mr. BURTON. OK, well, thank you very much for being here.

Well, we have 10 minutes before we conclude our first vote. I think I probably ought to run over and vote and come back. I really apologize for the mess we've got today. What you're saying and doing is going to be recorded and passed onto my colleagues, and it's very important. So I hope you'll bear with me and stick around for a little bit. We'll be right back as soon as the votes are taken.

[Recess.]

Mr. BURTON. First of all, I want to apologize once again. It's been a long day. But we want to get as much information from this hearing as possible. So we're going to be here as long as it takes.

We now have Adriane Fugh-Berman. Would you come to the table, Dr. Fugh-Berman. And David Brownstein, Dr. Brownstein, he's the director of Holistic Medicine. Ms. Carol Petersen, pharmacist with the Women's International Pharmacy.

Ms. Fugh-Berman is the assistant professor of physiology and biophysics at Georgetown Medical Center.

Ms. Vicki Reynolds, hormone replacement therapy patient, Houston, TX. And Steven F. Hotze, Dr. Hotze, founder of the Hotze Health and Wellness Center.

OK, we're going to start with Dr. Fugh-Berman. Since we have a pretty large panel, we'd like to get to questions as quickly as possible. So if you can keep your comments to 5 or 6 minutes, we'd really appreciate it, if it's possible. Thank you.

STATEMENTS OF ADRIANE FUGH-BERMAN, M.D., ASSOCIATE PROFESSOR, DEPARTMENT OF PHYSIOLOGY AND BIOPHYSICS, GEORGETOWN UNIVERSITY SCHOOL OF MEDICINE; DAVID BROWNSTEIN, M.D., CENTER FOR HOLISTIC MEDICINE; CAROL PETERSEN, MANAGING PHARMACIST, WOMEN'S INTERNATIONAL PHARMACY; VICKI REYNOLDS, OWNER, TEXAS RELIANT AIR-CONDITIONING AND HEATING, INC.; AND STEVEN F. HOTZE, M.D., HOTZE HEALTH AND WELLNESS CENTER

Dr. FUGH-BERMAN. Thank you, Mr. Chairman.

I'm here today representing the National Women's Health Network, which is a consumer advocacy group that takes no money from drug companies, medical device companies or dietary supplement companies.

Sex hormones, including estrogen and testosterone, do decline with age. But restoring hormone levels to youthful levels has not restored youth in anyone. But it's quite an old concept. It's actually more than 100 years old. Animal testicle extracts used to be injected into men, and in the 1920's there was a briefly popular operation in which slices of animal testicles were actually inserted into men's scrota.

So the first promotion of hormones for rejuvenation was first directed toward men. But in the last few decades, most of the emphasis of hormones for sort of achieving youthfulness has really been aimed at women. And hormones are very useful therapies for many medical conditions, insulin, for example, for diabetes. Estrogens are actually very, and different kinds of estrogens are very useful for treating hot flashes. Hot flashes and vaginal dryness are actually the only proven benefits of hormone therapy, estrogen therapy at this point.

But unfortunately, hormones don't prevent aging, and unfortunately, there is no such thing as a harmless hormone. All hormones, including the hormones that we make within our own bodies, have side effects. And claims that bioidentical, natural or naturally occurring hormones are safer than conventional hormones are not backed by science. I'm just going to talk about estrogen today, just for time reasons. The three estrogens that humans make are estriol, estradiol and estrone. And these are the hormones that are touted by compounding pharmacies and some alternative physicians as harmless alternatives to conventional therapy.

So people may recommend estriol alone, estriol and estradiol, which is called Bi-Est sometimes, or all three, which are called Tri-Est. Sometimes they're combined with other hormones. Synthesized versions of these hormones, and they are synthesized, are identical to human versions. But just because humans make a hormone doesn't mean that it's good for us. High doses of insulin can kill you. High doses of adrenaline can kill you. High doses of thyroid can kill you, even if they're natural. And cortisol, which is an adrenal hormone that is promoted on Dr. Hotze's site, for example, increases the risk of osteoporosis, increases glucose levels and causes immune suppression. It is, however, a mood elevator, so probably people feel good as they're developing osteoporosis and diabetes. [Laughter.]

I've said that even the hormones that we make within our bodies are not harmless. There are many studies that show that women who have naturally higher levels of estrone, estradiol, and estriol, actually of estradiol and estrone in their bodies, are at higher risk of breast cancer than women who have naturally lower levels of these hormones. A meta-analysis, for example, that was published in the Journal of the National Cancer Institute in 2002 analyzed nine studies on the subject and found that levels of estradiol, estrone, testosterone, DHEA and other sex hormones were strongly associated with breast cancer risk in postmenopausal women. So postmenopausal women who had higher naturally occurring levels of these natural hormones had higher breast cancer risk.

And more recent studies that have been done in 2003, 2004, have also backed this up. Higher levels of testosterone are also associated with higher breast cancer risk in women.

Natural hormone proponents believe that estriol decreases breast cancer risk. And in contrast to other estrogens, does not increase uterine cancer risk. This belief is based on publications, every single one of them more than 30 years old and all of them written by one guy, Henry Lemon. Lemon theorized that estriol could be a useful treatment in preventing and treating breast cancer. There's only one commentary by a guy named Fallingstad that isn't written by Lemon, and it quotes an unpublished study by Lemon that says that Lemon successfully treated some cases of breast cancer with estriol.

Even Henry Lemon never claimed that. Henry Lemon never published a clinical study of estriol. There is some evidence, he did have some evidence from cell cultures, high doses of estriol in breast cancer cells in culture will decrease the growth of cells. But this is true of every estrogen. Low doses stimulate growth, high doses decrease growth. In fact, estrogen used to be used as a treatment, high doses of estrogen. So that's true of any estrogen, it does not evidence.

Henry Lemon never published a clinical study. He did, however, publish a review on estriol in 1980 in which he describes giving estriol to 24 women. Six of them had their metastases grow. That's one quarter of the treated population. So this experiment can hardly be considered a success in breast cancer treatment. Two women also developed endometrial hyperplasia, a precancerous condition to endometrial cancer. We know that estrogen causes endometrial or uterine cancer. And 2 out of 24 subjects in this study did develop the precursor to uterine cancer.

In the review that the author wrote, he still seems to be enthusiastic about estriol. I have no idea why. But I think it's really frightening that there are still people today who think that his theory holds any water.

We actually have information on estriol. Estriol is a perfectly decent treatment for hot flashes. And it's used in Europe, it's a very commonly used hormone therapy in Europe. It's been used for decades in England and Sweden and other countries. It's a conventional treatment, sold by conventional drug companies. And in conventional medicine in Europe, it was thought that you didn't have to use it with a progestin to protect the uterus because it's such as weak estrogen.

So there were many women who received estriol alone because it was thought it was too weak to cause estrogen induced uterine cancer. That turned out that to be wrong. We now know that estriol is associated with endometrial hyperplasia and endometrial cancer. Women who have ever used estriol, this is a Swedish study, had twice the risk of endometrial cancer as women who never used estriol, and 5 years worth of use of oral estriol tripled the risk. The use of vaginal estriol did not seem to be associated with an increased risk.

So this is less of a risk than with stronger estrogens, but it still caused cancer in women. So nowadays, estriol is used with a progestin in the same way that other estrogens are.

In terms of cardiovascular risk——

Mr. BURTON. Excuse me, Doctor, if you could summarize. I want to make sure we get to the questions. We have six people, five people on the panel.

Dr. FUGH-BERMAN. OK. Then I won't cover the data on cardiovascular risk.

There is no reason to think that the estrogens promoted by compounding pharmacies protect against heart disease or stroke because estradiol has actually been tested in trials. There has been a randomized placebo controlled trial of estradiol and natural bioidentical hormone in 664 women after a stroke, and it did not protect against stroke. There is also another trial, the Esprit trial, in more than 1,000 women with a previous heart attack, estradiol did not protect against heart attack or death.

So it's not true that only conjugated estrogens have been tested in randomized controlled trials. So has estradiol.

So compounding pharmacies are uniquely unregulated, at least with commercially available pharmaceuticals of the quality of the preparations is regulated, that's not true of those in compounding pharmacies.

And I'll just conclude by saying that human studies, and they have all the references, show that naturally high levels of estrone and estradiol are associated with breast cancer risks. Estriol pills increase uterine cancer risk and estradiol does not protect against heart disease or stroke.

And I just wanted to add one thing, Mr. Chairman. I'm very sorry about your wife, and I agree with you that pharmaceutical estrogens were really over-promoted inappropriately for really dozens of years for things that they shouldn't have been used for. And that they do contribute to increased breast cancer. But the estrogens that are promoted by compounding pharmacies are also very likely to increase the risk of breast cancer in other women. Thank you.

[The prepared statement of Dr. Fugh-Berman follows:]

Subcommittee on Human Rights and Wellness
House Committee on Government Reform
"Balancing Act: The Health Advantages of Naturally-Occurring Hormones in Hormone Replacement Therapy"

July 22, 2004

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Sex hormones, including estrogen and testosterone, decline with age, but restoring hormone levels to youthful levels will not restore youth. Hormones as an anti-aging treatment have been promoted for more than a century and were initially aimed at men (Kaptchuk 1998). In the 1920s, grafts of animal testicles were surgically implanted into men (Veronoff 1921). In recent decades, however, hormones have been marketed primarily to women as a preventive against age-related disease.

Hormones are very useful therapies for specific medical conditions. For example, insulin is a vital treatment for diabetes, and many estrogens are effective treatments for hot flashes. However, insulin, estrogens and other hormones don't prevent aging, and, unfortunately, there's no such thing as a harmless hormone.

All hormones, including those that humans create within their bodies, have side effects. Claims that so-called bioidentical, natural, or naturally-occurring hormones are safer than conventional hormones are not backed by science.

The three estrogens that humans make are estriol, estradiol, and estrone, and these are the hormones touted by some compounding pharmacies and physicians as harmless alternatives to conventional hormone therapy. Natural hormone proponents may recommend estriol alone, estriol and estradiol (Bi-Est), or estriol, estradiol, and estrone (Tri-Est), sometimes combined with other hormones. Synthesized versions of these hormones are identical to human versions. But just because humans make a hormone doesn't mean it's good for us.

Breast and Uterine Cancer Risk

Many studies show that women who have naturally higher levels of estradiol and estrone in their bodies are at higher risk of breast cancer than women who have lower levels of these estrogens. A meta-analysis published in the Journal of the National Cancer Institute analyzed nine studies on the subject and concluded that levels of estradiol, estrone, testosterone, DHEA, and other sex hormones were strongly associated with breast cancer risk in postmenopausal women (EHBCCG 2002). More recent studies have also found that naturally higher levels of estradiol and estrone (Zeleniuch-Jacotte 2004, Manjer 2003, Key 2003 Onland-Moret 2003), as well as testosterone, are associated with increased breast cancer risk in women (Onland-Moret 2003, Yu 2003).[1]

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[1] An increase in breast cancer risk was one of the reasons that the estrogen-progestin arm of the NIH-funded Women's Health Initiative trial on hormone therapy was stopped early (WGWHI 2002). Another randomized trial of hormones in breast cancer survivors was stopped early because of an unacceptably high number of breast cancer recurrences in the hormone-treated group (Holmberg 2004). And an observational study of more than a million women in the UK found that estrogen-progestin hormone therapies were associated with increased breast cancer risk (Beral 2003).

Natural hormone proponents believe that estriol decreases breast cancer risk, and, in contrast to other estrogens, does not increase uterine cancer risk. The belief that estriol prevents breast cancer is based entirely on publications, all more than three decades old, written by Henry M. Lemon. Lemon theorized that estriol had potential in preventing and treating breast cancer. The only non-Lemon-authored support for this idiosyncratic theory is a single commentary that mentions an unpublished study in which Lemon used estriol as a successful treatment in breast cancer patients (Follingstad 1978).

As big a fan of estriol as Lemon was, even he never claimed that estriol was a successful breast cancer treatment. Lemon did publish a review on estriol in which he describes giving estriol to 24 subjects with breast cancer (Lemon 1980), but as the treatment stimulated the growth of metastases in six women – one quarter of the treated population -- the experiment can hardly be considered a success. Two women also developed endometrial hyperplasia (estrogen-stimulated cell growth that precedes uterine cancer). Frighteningly, the author's enthusiasm for estriol appears to have remained undimmed. It is even more frightening that his theory still attracts followers.

In Europe, estriol is available as a pharmaceutical and is commonly prescribed by conventional physicians for treating menopausal symptoms. It is quite a weak estrogen and it was thought for many years that there was no need to use a progestin with estriol to protect the uterus[2]. However, we now know that estriol is associated with endometrial hyperplasia (Granberg 1997) as well as endometrial cancer. Women who had ever used estriol had twice the risk of developing endometrial cancer as never-users, and five years of oral estriol tripled the risk (Weiderpass 1999).

Cardiovascular Risk

Data from randomized controlled trials have shown no protection of estrogen alone (Anderson 2004) or an estrogen-progestin combination (WGWHI 2002) in preventing heart attack or stroke[3]. Is there reason to believe that the estrogens promoted by compounding pharmacies protect against heart disease or stroke?

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[2] Used alone, estrogen increases the risk of endometrial (uterine) cancer. A progestin (medroxyprogesterone acetate/ Provera, progesterone, etc.) is used with estrogen in women with a uterus to prevent estrogen-induced stimulation of the uterus, which can cause uterine cancer or endometrial hyperplasia (thickening of the uterus, a risk factor for endometrial cancer).

[3] In July 2002, the combined estrogen-progestin arm of the Women's Health Initiative (WHI), a large, NIH-funded randomized controlled trial, was stopped early because the treated group experienced higher rates of breast cancer, cardiovascular disease, and overall harm (WGWHI). In February 2004, the estrogen-only arm of the WHI was halted early because of an increase in stroke among the treated group, and because estrogen failed to show any cardiovascular benefit (Anderson 2004). Neither preparation prevented dementia (Shumaker 2003, Shumaker 2004), and hormones improved quality of life only in women with hot flashes (Hays 2003).

No. In fact, estradiol has been tested in trials. A randomized, placebo-controlled trial tested estradiol in 664 postmenopausal women after a recent stroke or transient ischemic attack ("mini-stroke"). Estradiol did not protect against stroke, cardiovascular events or death (Viscoli 2002). In ESPRIT (the oEstrogen in the Prevention of Reinfarction Trial), 1017 postmenopausal women with a previous heart attack were given estradiol or placebo for two years. There was no difference between groups in frequency of heart attack or death (Cherry 2002).

Uniquely Unregulated

Although promoters of bioidentical hormones claim that their products are unique and have no relationship to synthetic hormones or commercial pharmaceutical preparations, both claims are misleading. Most bioidentical hormones are synthesized. And bioidentical hormones are commonly available as commercial pharmaceuticals in the United States. Estradiol is available in branded preparations as tablets, patches, vaginal cream, vaginal tablets, and a vaginal ring; the pills and patches are also available as low-cost generic forms. Estrone is available in branded tablets. Branded estriol tablets are not commercially available in tablets or capsules in the U.S., but In the U.K., estriol is marketed by Organon under the brand name Ovestin.

No safety or efficacy studies have been published on bi-estrogen or tri-estrogen preparations. We have plenty of information on the adverse health effects of health risks of pharmaceutical estrogens, but we also have information on documented benefits. And the quality of drugs made by pharmaceutical manufacturers is regulated.

To quote Sarah Sellers, PharmD:

> "Hormone creams, gels, troches, capsules, patches, injections, and surgically implanted hormone pellets are compounded with little or no substantiation that the dosage forms can be safely administered and the active ingredients are actually bioavailable...Much concern is currently focused on the importation of drugs from other countries that may not match our gold standard system of regulation for pharmaceuticals, while we have within our own borders a flourishing, unregulated drug industry that manufactures, markets and sells substandard products throughout the United States." (Sellers 2004).

Conclusion

In summary, human studies have shown that

- Naturally high levels of estrone and estradiol are associated with increased breast cancer risk.
- Estriol pills increase uterine cancer risk.
- Estradiol does not protect against heart disease or stroke.

All of these effects are consistent with what is known about commercially marketed pharmaceutical hormones. The quality of commercially available

pharmaceuticals, in contrast to compounded drugs, is regulated. Claims that the hormones in compounded hormone prescriptions are safer than commercial pharmaceuticals can only be made by those unfamiliar with or resistant to scientific data. Compounding pharmacies should be regulated to ensure the quality of compounded preparations and to prevent them from making misleading and dangerous claims. To do otherwise risks the health of consumers.

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Mr. BURTON. Before we go to the next witness, who did you say sponsors your foundation?

Dr. FUGH-BERMAN. I don't have a foundation. I'm an associate professor of physiology at Georgetown University School of Medicine.

Mr. BURTON. Does Georgetown get any grants from NIH?

Dr. FUGH-BERMAN. Does Georgetown get any grants from NIH? I'm sure there are researchers there who do. I do not.

Mr. BURTON. Do you get any benefit from any of the pharmaceutical companies or any of that?

Dr. FUGH-BERMAN. No. And if you're talking about my consumer advocacy, the consumer advocacy group that I represent, the National Women's Health Network, we also do not get any NIH funding.

Mr. BURTON. Where do you get your funding?

Dr. FUGH-BERMAN. Twenty-five dollar a year membership and some foundation support.

Mr. BURTON. What foundations?

Dr. FUGH-BERMAN. Private foundations not associated with any drug companies.

Mr. BURTON. Where do the foundations get their money?

Dr. FUGH-BERMAN. From their investment portfolios, I assume.

Mr. BURTON. Could you for the record give me a list of the people that contribute to the foundation? I'd like to see where the money comes from.

Dr. FUGH-BERMAN. I can give you a list of the foundation funders of the organization.

Mr. BURTON. That would be helpful. Thank you.

Dr. Brownstein.

Dr. BROWNSTEIN. Chairman Burton, I'm honored to be speaking to you, and I bring you greetings from the Wolverine State.

Mr. BURTON. Just north.

Dr. BROWNSTEIN. Many of us involved in holistic medicine have gotten into it because of an ill family member or an illness themselves. And I got involved in it just as your interest seems to have been peaked in it from ill family members because my father was very ill with heart disease.

I had wanted to be a doctor since I was a little child. And I was conventionally trained in medical school, began a conventional practice, was not interested in anything alternative or holistic. I used to tell my patients, don't do the alternative therapies, because I thought they were worthless, even though I didn't know much about that. And I would make derisive comments to them. I remember telling my mother-in-law, don't take your vitamins, because I thought she was wasting her money, which she never fails to remind me of today.

However, all through medical school and post-medical school and residence, my father was very ill with heart disease. He had his first heart attack at 40, his second heart attack a few years later. He had bypass surgeries in the midst of a number of years. He had a couple of angioplasties. He had continual angina for 25 years, cholesterol that was uncontrolled in the 300's or 400's on cholesterol lowering medications. He was seeing the best doctors from the University of Michigan and wasn't getting any better.

And I finished my residency, I'm in a busy conventional practice. And a patient sees me and gives me a book, Healing with Nutrition by Dr. Jonathan Wright. I took that book home, wasn't much interested in it, but I flipped to the section on cardiovascular disease, since my father was dying before my eyes. He did not have long to live at that point. And Dr. Wright talked about how he used natural hormones to treat heart disease.

When I started pulling the literature on natural hormones and heart disease, there was a plethora of literature on testosterone and heart diseases dating back to the early 1900's, most of it out of Europe. And I became very interested in that, and I checked my father and his testosterone level and DHEA level and estrogen levels, and ended up putting my father on three or four natural hormones, natural testosterone, DHEA, natural progesterone and pregnenolone.

Within a matter of a week of putting him on these four hormones, a 25 year history of angina resolved, never to return. His cholesterol, which was stuck in the mid 300's, went below 200, off cholesterol lowering medication. He lost weight, he had a pale, sick looking face that now turned pink. His friends and my mothers friends were asking what's going on with him, he's looking so much better. He was able to walk around without popping nitro pills all day. Once this conventional physician saw the changes in my father with using natural hormones, I decided that's what I wanted to do in medicine.

Since that point about 12 years ago, I have been researching and utilizing natural hormones. And though I agree with Dr. Fugh-Berman that there are a lot of problems with estrogens in the environment, I think most of us men and women are over-estrogenized. The problem isn't so much estrogen deficiency, it's a hormonal imbalance, in part exacerbated by estrogen excess. And the use of conventional hormones exacerbates that and causes problems, like stroke, heart disease, heart attacks, just as was found in the Women's Health Initiative.

What I've found is that an imbalanced hormonal system leads to chronic illness, such as auto-immune disorders, lupus, MS, Hashimoto's, Grave's Diseases, the list can go on and on. It leads to cancer, breast cancer, uterine cancer, ovarian cancer, thyroid cancer, headaches, heart disease, the list goes on and on.

And when somebody can get their hormonal system rebalanced natural hormones, these conditions get markedly better. I see it every day in my practice. Those of us that have used natural hormones see the results in our patients and these items need to be studied and they need to be kept available for patients. As a physician, I want to be able to prescribe natural hormones when they are indicated. We need the help of compounding pharmacists to utilize these items.

My experience has been that most people with chronic disorders have severely deficient levels of hormones when I check them, including DHEA and pregnenolone and thyroid and testosterone, with elevated estrogen levels present.

I'd like to just close by just explaining to you what a normal hormone is. And I've got it in my handout, I wanted to do a Power

Point presentation, but I was told I wasn't able to do it, although I would have my own projector.

Mr. BURTON. If we had the other committee room. But we had a big hearing there on scandal in Iraq. So we had to pass on that.

Dr. BROWNSTEIN. Well, you don't even have to look at that handout. Let me just explain to you in my mind what a natural hormone is. The hormones work in our body in a lock and key model. Just as you go out to your car door to start your car, your key fits in your car door fine. If I put my key in your car door, it's not going to fit quite right.

A natural hormone has the same structure as our own hormones. So it's like the key that goes to find its lock. And there are hormone receptors in our bones, our hearts, our brain, our lungs. So when this key or this hormone goes to find its receptor, it's like a perfect fit. It's like a perfect puzzle fit.

When you use a synthetic hormone that's been altered, this puzzle piece doesn't fit quite right. It's been altered. And that's what I had for the slides to show you, just the difference between the two. But this difference in this puzzle piece not fitting quite right is what leads to the adverse effects of synthetic hormones. And you just, as a practicing physician, you just don't see the adverse effects with the natural hormones that you do with the synthetic hormones. It doesn't make sense to me to use something that doesn't fit quite right in the body, when there is something available that has a perfect fit.

[The prepared statement of Dr. Brownstein follows:]

Testimony on Biologically Identical Hormone Therapy
House Subcommittee on Human Rights and Wellness
Washignton, D.C.
July 22, 2004

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The 21st century presents a challenging time for physicians and patients alike. One day, headlines in the newspapers proclaim the effectiveness of conventional hormones in treating Alzheimer's disease, heart disease, osteoporosis, etc. The next day, different headlines claim that conventional hormones may not help the above conditions and may actually worsen them.

What is the doctor and what is the patient to do?

For the doctor, it is essential to search for an underlying cause(s) of illness and to prescribe treatments that help promote healing and that strengthen the immune system.

For the patient, it is necessary to become knowledgeable about different treatment options available. Patients need to educate themselves about the prescription drugs they use and about the natural items they use. The more involved the patient is in their health care decisions, the better outcome they will receive.

In the 21st century, the scope and complexity of chronic medical conditions plaguing our society is breathtaking-- fibromyalgia, lupus, multiple sclerosis, Crohn's disease, ulcerative colitis, migraine headaches, chronic fatigue syndrome, cancer, osteoporosis, etc. All too often, the treatments proposed by conventional medicine are so toxic that the "cure" is worse than the illness—just ask anyone who has been on long-term steroids to treat some of the above conditions. In order to treat any illness, it is necessary to understand the underlying cause of the illness. If you don't understand the underlying cause of the illness, then how can you develop an effective treatment plan?

As a society, we have settled for sub-par health. People who suffer from chronic fatigue syndrome are often told by their physicians, "There is no treatment, you just have to live with it." Those who suffer from headaches, including migraine headaches, are often given medicines that have side effects worse than the headache itself. If one medication doesn't work, there is always another one to take its place. Many times, these medications only treat the symptoms of disease; they do not address the underlying cause of the illness.

Often times the underlying cause of many chronic illnesses may be a hormonal imbalance. It is impossible to achieve your optimal health without first achieving balance within the hormonal system. All of the systems of the body, including the nervous system, the cardiovascular system, the immune system and the circulatory system depend upon a balanced hormonal system.

A hormone is a chemical messenger produced in the body by a gland. Examples of the different glands of the body include the thyroid gland, adrenals, ovaries, testicles, etc. Hormones have a specific regulatory effect on the activity of the body. For example, the thyroid gland produces thyroid hormones which regulate the metabolism of the body.

Natural, biologically identical hormones are substances generally produced from plant products that mimic the body's own hormone production, both structurally and chemically. Examples of natural, biologically identical hormones include desiccated thyroid, DHEA, natural progesterone, natural estrogens, natural testosterone, melatonin, hydrocortisone, human growth hormone and pregnenolone. Drug companies alter the structure of natural hormones in order to creat e a synthetic version of a hormone that is patentable. Hormones that have been chemically altered are termed synthetic hormones.

I have found that the clinical use of natural, biologically identical hormones restores hormonal balance. Natural, biologically identical hormones can be an effective treatment option not only for promoting optimal health but also for treating many chronic illnesses including; chronic fatigue syndrome, fibromyalgia, PMS, heart disease, menopausal symptoms, autoimmune disorders and many other conditions.

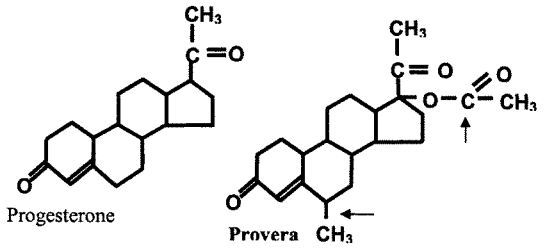
Natural, biologically identical hormones are an important part of my medical practice. These items are made by a compounding pharmacist. It is imperative that the FDA not limit or restrict compounding pharmacies from providing patients with safe and

useful products which are used to treat a variety of illnesses. I could not effectively practice medicine without the use of a compounding pharmacist.

Natural, biologically identical hormones are contrasted with synthetic hormones. Synthetic hormones are not naturally occurring substances in the body. In fact, synthetic hormones are not found in any living forms. Synthetic hormones can be thought of as foreign substances to the body. Because they are foreign substances to the body, is there any wonder that there are so many serious side effects with the use of synthetic hormones? Examples of synthetic hormones include Provera, birth control pills, etc.

Hormones work in our bodies via a "lock and key"' model. When a hormone is released from its gland the hormone (the "key") binds to its receptor (the "lock"). This binding is analogous to a key being put in the ignition of the car. When the binding occurs a chemical reaction takes place. Natural, biologically identical hormones have a perfect fit in these receptors. The "key" fits perfectly in its complimentary "lock". This is contrasted with a synthetic hormone in which the un-natural hormone (i.e., the "key") does not fit well in the body's receptor (i.e., the "lock"). This un-natural fit results in the high rate of adverse effects seen with the use of synthetic hormones. A comparison of the chemical structure of a natural hormone (natural progesterone) and a synthetic hormone (Provera) is shown in the slide (Figure 1). If we are going to use a hormone to treat any condition, then we should use a natural hormone over a synthetic hormone every time.

Figure 1: A Comparison of a Natural Hormone (Natural Progesterone) and a Synthetic Hormone (Provera)



The difference between the natural hormone, progesterone, and the synthetic version, Provera, is illustrated in this diagram. The arrows in the Provera illustration point out the additional side chains added to progesterone. These added chains make Provera a foreign substance in the body, leading to an increased risk of adverse effects.

Natural, biologically identical hormones, when used appropriately, will enhance one's health and will treat or even cure diseases, all without any appreciable side effects. Many physicians erroneously believe there is no difference between a synthetic hormone and a natural hormone. That is usually because these physicians have little or no experience in the use of natural, biologically identical hormones and other natural products. My clinical experience shows that there is no better substitute for the body's own production of hormones than using a natural form of that hormone. This experience has been repeatedly confirmed by my patients' positive responses to natural, biologically identical hormones.

Natural, biologically identical hormones can improve well-being, slow aging and reverse many chronic conditions. After taking natural, biologically identical hormones, my older patients constantly proclaim that they feel like they did when they were in their 20's. I have found natural, biologically identical hormones to be a great benefit and often a cure for many conditions including; chronic fatigue syndrome, PMS, endometriosis, infertility, headaches and migraine headaches, recurrent infections, fibromyalgia, ulcerative colitis, Crohn's, and other autoimmune disorders. It is rare for a patient with any of the above conditions not to show significant improvement in their conditions after taking natural hormones. I am continually amazed at how many chronic diseases can be halted and, many times, cured through the use of natural, biologically identical hormones.

Man has searched for a fountain of youth for thousands of years. Although there is no "cure" for aging, my clinical experience has shown that natural, biologically identical hormones, when used appropriately, can slow down many of the signs of aging including deteriorating mental function, loss of muscle tone, and wrinkled skin. Hormone production peaks when we are young, usually in the age range from 20 to 30. In older people, supplementation with natural, biologically identical hormones can

reverse many of the signs of aging. Synthetic hormones do not provide the same anti-aging benefit as natural hormones.

My patients are familiar with the following question: "If it is found that you are low in a hormone, and you are given a choice of a natural hormone—one that closely mimics your own hormone chemically and structurally, versus a synthetic hormone—a man-made derivative of a hormone that has been structurally altered to become a patentable product, which one would you pick?" A vast scientific knowledge base is not needed to realize a natural hormone will perform better than a synthetic hormone every time. This statement holds true when comparing all natural products to synthetic products, including vitamins, minerals and herbs. It is a common-sense argument to use a natural product to treat disease and promote health, and there are many studies that back up this idea.

Natural, biologically identical hormones work better when used in combinations. When I see books about individual natural hormones such as DHEA, I find the fault of these theories is they only address one hormone at a time. My experience shows that this is not the correct approach. A chronic condition is often a sign of a serious imbalance in the immune system of the body. This imbalance usually cannot be successfully treated with a single agent. In order to bring the immune system into a more balanced state, combinations of therapies are often necessary. I have found using combinations of natural hormones, when indicated, can often reverse this imbalance and even cure many chronic diseases. I have not had nearly as much success in my practice using natural hormones individually to treat disease or to slow down the signs of aging.

The natural hormones described here and in my books are used only in "physiologic doses." A physiologic dose of a natural, biologically identical hormone refers to a small enough dose so as not to cause the body to cease production of the hormone. When hormones are given in "pharmacologic doses," (i.e., doses larger than the normal production in the body), the body senses an overload of that particular hormone and will cease all production of it. Many problems attributed to hormones- for example, body builders getting cancer and other side effects from using too much testosterone- can be attributed to using excessive or large pharmacologic doses. I have observed no serious side effects from any of the natural, biologically identical hormones

used in my practice covered in this book when physiologic doses are used.

All of the natural treatments I have described should be managed with a health care provider—someone knowledgeable in the use of natural, biologically identical hormones. The hormones included in this paper can significantly help chronic conditions, improve health, and slow down the signs of aging. However, they can also harm you if not used appropriately and under the guidance of a knowledgeable health care provider. Improved results are achieved when other natural agents, such as vitamins, minerals, and herbs, are used to support these hormones.

I believe the most effective way to use natural, biologically identical hormones is to use natural hormones compounded from a compounding pharmacist. Many natural hormones sold over the counter are not of good quality. My professional experience has shown that natural, biologically identical hormones made from a compounding pharmacist are a safe and effective treatment for a wide range of medical problems.

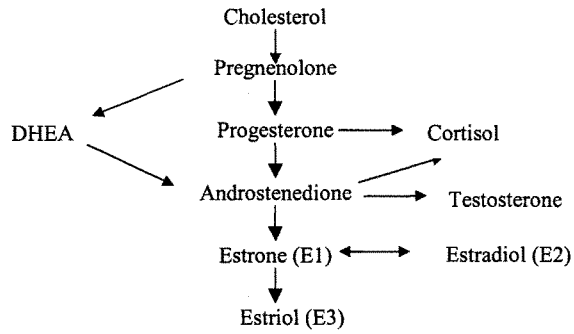


Figure: 2: Biosynthetic Pathway for Adrenal and Gonadal Hormones

I would like to review some of the natural compounded hormones that I use in my practice. All of the adrenal hormones are produced from the fat-like substance cholesterol, as shown in Figure 2.

Pregnenolone

Pregnenolone is a steroid hormone produced in the adrenal glands. Pregnenolone is often referred to as the "mother hormone", since it is the precursor hormone to all of the adrenal hormones (refer to Figure 2 above). It is formed from cholesterol and is necessary to produce other adrenal hormones including progesterone, DHEA, hydrocortisone, testosterone, and the estrogens. Pregnenolone is also produced in the brain. In fact, pregnenolone levels in the brain are much higher than they are in the peripheral tissues.[i] Pregnenolone has been shown to affect many of the neurotransmitters in the brain. Pregnenolone like the other hormones mentioned here, decline with age. At age 75, there is a 65% reduction in pregnenolone production in the body as compared to levels at age 35.[ii] I have found pregnenolone particularly useful in treating memory problems, fatigue and depression.

Progesterone

Progesterone is one of two main hormones produced by the ovaries. The other main ovarian hormone is estrogen. Progesterone is primarily produced in the second half of the woman's menstrual cycle and is the hormone necessary for the survival of the fetus. Men produce very tiny amounts of progesterone from the testicles. In men and women, a small amount of progesterone is also produced in the adrenal glands, where it acts as a precursor for the adrenal estrogens, testosterone, and cortical steroids. There are two types of progesterone currently available: natural progesterone and synthetic progesterone (e.g., Provera). Natural progesterone is made from plant products and has the same chemical structure as the progesterone that is produced in the human body. A compounding pharmacist can make natural progesterone. The difference in the chemical structures of natural progesterone and Provera are illustrated in Figure 1. I have found natural progesterone safer and much more effective for treating illness and promoting health than synthetic progesterone.

Natural Estrogens

A difficult decision women have to make is whether to use estrogen for hormone replacement therapy. This is a very controversial topic. One must weigh the benefits of

estrogen, which include providing relief from hot flashes as well as slowing down the rate of osteoporosis, versus the potential side effects such as an increased risk of endometrial cancer and, most likely, an increased risk of breast cancer. I will explain the risks and benefits of estrogen replacement therapy and offer you a safer, more natural approach.

Estrogen is produced primarily in the ovaries. It is produced in a cyclical fashion in a menstruating woman. In a typical 28-day cycle, estrogen is produced in both the first half of the cycle known as the follicular phase, and in the second half of the cycle known as the luteal phase. There are three different types of estrogens manufactured by the body: estrone, estradiol and estriol. Each of these different types of estrogen has very different properties in the body. Jonathan Wright M.D., a pioneer in natural therapies, measured the serum levels and urinary excretion of the three estrogens and reported that of the three types of estrogen measured, 80% was estriol, 10% was estrone and 10% was estradiol. If we're going to give estrogen replacement therapy to a woman, doesn't it make sense to give it in the same proportions as naturally made in the body? Unfortunately, traditional medicine's approach to estrogen replacement is not even close to these proportions.

Conventional estrogen replacement therapy usually consists of using synthetic derivatives of estrogen. Premarin, which is the most common synthetic estrogen product in use today, is a horse-derived estrogen complex, consisting primarily of estrone. Estrace, another common synthetic estrogen hormone, contains 100% estradiol. Neither contains the three forms of estrogen--estriol, estrone and estradiol--in the percentages that are found naturally in the human body. Common sense would argue that to achieve the greatest benefit from estrogen replacement therapy, we should try to mimic the body's own production of estrogen. In other words, we should use the same proportions of estriol, estrone and estradiol normally produced in the body. A natural estrogen preparation has been formulated by Dr. Wright and is known as Triest. Triest is made from plant products and has the same chemical structure of the three types of estrogen produced in the human body. Triest mimics the body's own production of estrogens by containing 80% estriol, 10% estradiol and 10% estrone. I believe that using Triest as

compared to a synthetic estradiol or estrone compound is a much safer and more effective method to replace estrogens in a woman.

DHEA

The benefits of taking DHEA include preventing and treating: Alzheimer's, asthma and allergies, bacterial and viral infections, cancer, cardiovascular disease, diabetes, hypertension, high cholesterol, obesity, osteoporosis and immune system diseases including AIDS. I have also found DHEA particularly effective for treating autoimmune disorders such as fibromyalgia, rheumatoid arthritis, lupus, Crohn's, and others.

Natural Testosterone

The benefits of replacement doses of testosterone are truly amazing. The benefits include: improving osteoporosis, improving the symptoms of diabetes, increasing a general sense of well being and improving libido and sexual functioning. In addition, testosterone can decrease negative mood parameters including anger, irritability, nervousness, and tiredness. Testosterone has been shown to prevent and treat coronary artery disease and improve and treat autoimmune disorders such as lupus and rheumatoid arthritis. Also, it has been shown that testosterone has the ability to rejuvenate muscle mass.

Final Thoughts

Natural, biologically identical hormones are an integral part of my treatment regimen for combating a variety of illnesses from autoimmune illnesses to cancer. Natural, biologically identical hormones are a safe and effective treatment option and it is imperative that physicians, compounding pharmacists and patients alike are allowed to continue to utilize natural, biologically identical hormones.

[i] Sahelian, Ray. Pregnenolone, Nature's Feel Good Hormone. Avery Publishing. 1997
[ii] Roberts, Eugene. Pregnenolone-From Selye to Alzheimer and a Model of the pregnenolone sulfate binding site on the GABA Receptor. Biochemical Pharmacology, Vol. 49, No. 1. P. 1-16, 1995

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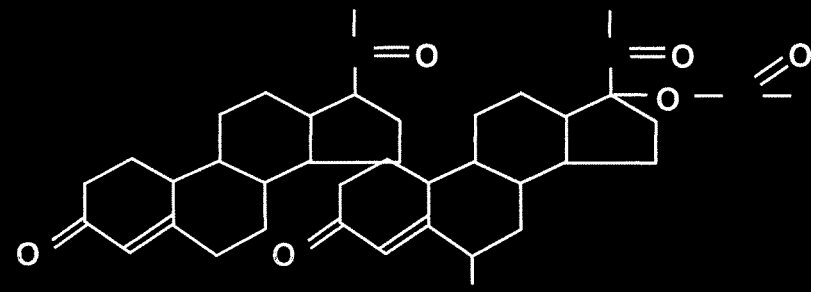
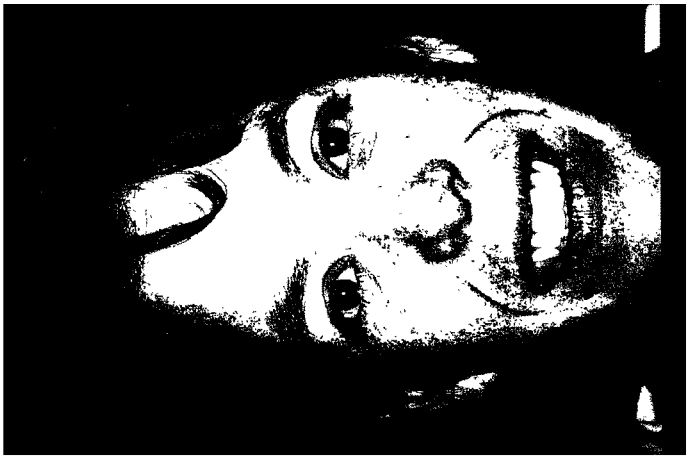
Natural Versus Synthetic



Progesterone

Progesterone



Mr. BURTON. I want to talk to you after the hearing.

Dr. BROWNSTEIN. And I have some books for you that I'd like to give you.

Mr. BURTON. Well, don't give me too much to read. I have in my office 9 million books. And although I read fairly fast, I ain't going to get through them all. But I would like to talk to you about that.

Ms. Petersen.

Ms. PETERSEN. Thank you, Chairman Burton. It's a pleasure to be here.

I am one of the compounding pharmacists. I can speak for thousands and thousands of patients and thousands of practitioners throughout the United States. We have a quiet revolution going on here in health care. People are no longer accepting substandard care, and they're finding alternatives and alternative practitioners such as Dr. Brownstein and Dr. Hotze. It makes a huge difference in their lives.

I've been involved in this business since 1993, and professionally and personally it's been the most rewarding business of my whole life. People often ask us, where do these hormones come from, when we talk about natural or bioidentical hormones. Because they are identical to human, conceivably you could think, well, maybe we squeeze these out of humans, and certainly it could be done. In France for the longest time their source of progesterone was human placenta, and they extracted it from there.

But it's made semi-synthetically. Many plants have a compound in their body made from cholesterol that is very, it's in their body and it's similar to cholesterol in the human body. This is the basis for all the steroidal hormones, like estrogen, progesterone, testosterone, DHEA, cholesterol is. From this plant nucleus that is similar to cholesterol, they can make in the laboratory any of the hormones that you would wish to have. You can make them chemically identical to human, you can alter them and get a patent. For example, birth controls are 100 percent synthetic, but also made from this beginning plant material.

So the big difference is what it does in your body, just as Dr. Brownstein had said. I'd like to say that the FDA has the ability to authorize drugs in this country. And I believe that they should have full power to do so when anybody wishes to introduce into the general population something that is a brand new chemical. Lord knows we have plenty of those. And I think they don't regulate them as well as they should in many cases.

We don't reward manufacturers very well, there are some ways around it, for instance the estrogen patches. The companies have to obtain a patent on the patch, not the hormone. I think if our medical industry took a positive stance and looked for ways to be using these hormones in a positive way, and some of them are, we'd end up much better.

The other really interesting thing about using bioidentical hormones is I think reflected in some papers that were written by a professor at the University of Washington. He wrote several papers on N–1 studies. He believes that our current gold standard of double blind placebo crossover studies are a farce. You and I are not biochemically identical, you and I aren't biochemically identical. If you participate in a study, no matter how large, whatever you

glean from there does not apply to me as an individual. It never can. I am biochemically unique.

So with N–1 studies, a certain protocol is embarked on with a patient for a particular issue and it's done for a while, a washout period maybe, another trial tried, until you find what works best. And I submit that compounded bioidentical hormones made for the individual and done in a clinical practice satisfies this N–1 study. That's probably the only real scientific, true scientific method for each individual.

Bioidentical hormones are very easy to track. You can test, as Dr. Brownstein has mentioned, you can test in saliva, urine, blood. It doesn't take a rocket scientist to figure out if something is lower than normal. I'm not talking about higher than normal, lower than normal. And you have symptoms of those hormones being lower than normal. And you take those hormones and you put it back in that patient, you can recheck clinically, you can recheck blood saliva and urine, it's all available now. And you can make a big difference for that particular person's life. And I have heard it over and over and over again, thank you for giving me back my life, thank you for giving me back my brain, thank you for giving me back my wife. And money can't buy what that kind of practice is.

[The prepared statement of Ms. Petersen follows:]

Committee on Government Reform Hearing entitled "Balancing Act: The Health Advantages of Naturally Occurring Hormones in Hormone Replacement Therapy" July 22, 2004

Testimony by Carol Petersen

Thank you for the opportunity to address you on the subject of bio-identical hormones. I am the Managing Pharmacist for Women's International Pharmacy in Madison, Wisconsin. Women's International Pharmacy is a practice that is devoted to compounding with bio-identical or natural hormones. Compounding involves weighing hormone powders and incorporating them into creams, gels, lozenges or capsules. A new chemical substance is not created. We dispense our compounded products and those manufactured products that qualify as bio-identical. This business was started in 1985. Our business has grown in response to the success in using bio-identical hormone therapies.

I would like to speak from my viewpoint as a pharmacist. I have been working as a pharmacist since 1972. I have been personally involved with compounded bio-identical hormones since 1993. This work has been the most rewarding of my career.

Bio-identical or biologically-identical or natural hormones refer to the fact that these hormones are exact duplicates of the hormones produced in the body. They have not been altered to something similar but not identical and patent protection is not available on bio-identical compounds.

These hormones are produced synthetically or semi-synthetically. In the case of sex hormones or adrenal hormones, a compound from plants similar to cholesterol in the human body is used as a starting material. Alteration of this starting material can yield hormones that are identical to human or those that are foreign to the human body such as those in birth control pills.

Because our health care system rewards manufacturers for producing non-hormone hormones much of the data available via medical journals are from studies done using altered hormones and has nothing to do with the normal functioning of the human body. A lot of money, time and energy are spent in this country trying to establish that altered hormone-like substances can function as well as the actual hormone does in the body. It would make a lot more sense to develop the means to restore the actual hormones and, indeed, some manufacturers have done this. The estrogen patch is an example. Estradiol, a hormone natural to the human body, is delivered by a patch that retards the absorption. The patch technology is patented.

Early in my career, I started graduate school in pharmacy with an intent to study pharmaceutics. This involves studying how a drug distributes itself in the human body. Later, I had an epiphany of sorts, when buying an updated book on the subject. Even though, you can make predictions about where a drug is in the body, it has absolutely no meaning in the context of the normal functioning of a human body.

We gain an understanding of the function of hormones form the vast work in the fields of physiology, biochemistry, endocrinology and even medicine The amount of information generated has risen exponentially in the last two decades. Having gained that knowledge, it is only a small step to consider clinical application.

It doesn't take much medical background to understand that, if you replenish the human body with a hormone that is identical to what the body can produce itself, you can expect that the activity of the hormone can be predicted to behave exactly in the human body as if it were produced there. That is exactly what does happen.

Some have argued that there is not enough scientific study done on the clinical use of bio-identical hormones. The use of bio-identical hormones is THE most scientific therapy, you can contemplate. It is possible to identify hormone depletion by clinical symptoms and by laboratory testing in blood, saliva and urine. It is also possible to replenish a particular hormone and find that the symptoms disappear and the laboratory readings return to normal.

Years ago, a researcher at the University of Washington published some papers on the validity of N-1 studies. This means that the number of people being studied each time is only one. He maintained that the current "gold standard" of double blind cross-over studies is flawed. Trying to gather data on groups of people, who are all bio-chemically different, and extrapolating that data to predict the success or failure of a certain treatment will not necessarily apply to the individual. In reality, N-1 studies are what actually happen in clinical practice. The medical practitioner develops a treatment plan for his or her patient. If the plan does not yield the hoped for results, a different plan will be developed and started.

The process of compounding is ideally suited for the N-1 study paradigm. It is simple to address replenishing the body with hormones that have become deficient. The kind of hormones, the amount of hormone, the best way to deliver the hormones, can all be tailored to the individual.

I would like to give you a specific scenario. It is no secret that hysterectomy surgeries are one of the most performed surgeries in this country. Women submit to these surgeries in an effort to find relief from such things as pain from fibroids, endometriosis or from excessive uterine bleeding. Unless, the surgery is for cancer, all of these are unnecessary. All of these involve aberrations in the normal levels of hormones. These medical problems have solutions with identifying the metabolic problems and treating with the appropriate hormones and other support substances.

According to the HERS Foundation, about 76% of these women also have their ovaries removed. This means that the organ that has normally produced estrogens, progesterone, testosterone, some DHEA is now gone. Current medical dogma insists that these women only "need" estrogen.

The number of medical problems that ensue are limitless. Because the estrogen is not "balanced" with progesterone. These women experience anxiety, sleep disorders and weight gain. Because of this imbalance, high blood pressure develops. The thyroid gland activity is compromised leading to fatigue and pain. Blood sugar disorders lead to diabetes. Diminished testosterone leads to lack of interest in sex and a diminished zest for life as well. The function of proteins in our body is the function of life itself. Testosterone directs the synthesis of all the protein in our bodies.

In our so called "traditional" medical treatment, this woman has now become a customer for 5 to 10 drugs in an effort to treat her symptoms and the side-effects. Her quality of life is terrible. Her family and friends are alienated.

It is enormously satisfying and a thrill to help these women restore their lost hormones. When a client calls to say "You have given me back my life" or "You have given me back my mind" or the client's husband calls to say "Thank you for giving me my wife back", because the information and the help you directed to her has been effective. When your work is as rewarding as that, there is no question that you will do the best you can to make sure that this option is available.

In recent years, we have experienced a threat from a government agency – the FDA. The FDA would compromise the ability of pharmacists to try to meet the challenges of the needs of the individual. Pharmacists have always done this work, long before the FDA was even conceived. We maintain that the Food and Drug Act was never meant to interfere with pharmacists and physicians providing this service.

It is important to note again that compounding does not involve a chemical process that produces a new substance. There is no change to the integrity of the substance that is used. These processes include mixing, blending, heating, dissolving, measuring, weighing and encapsulating. This does not produce new chemicals. The FDA has issued several CPG's on the issue of compounding. They are anxious to define compounding by the number of products compounded or by the sophistication of the equipment used. They speak of some mysterious line that is crossed when suddenly compounding hormones becomes manufacturing. It is confusing to the pharmacy industry and to regulators since no one knows when this "number" has become too large. I would submit that the distinction between compounding and manufacturing is easy and clear. The FDA has a clear responsibility for ensuring that man-made new chemicals that are introduced into medical practice should be thoroughly screened for potential human damage. Remember compounding produces no new chemicals. Additionally, when a practitioner seeks a compounded product for his or her patient that is specific to that patient and writes a prescription order this is a practice that no manufacturer can or is willing to do.

Finally, there are words that we use in the pharmacy industry such as "risk benefit ratios" and "drug misadventures" to address the failure of drug therapies. Using compounded bio-identical hormones makes the portrayal of these concepts unneeded.

Mr. BURTON. I have some questions for you when we get to how you determine what the level should be in each individual.

Ms. Reynolds.

Ms. REYNOLDS. I'm also very honored to be here, and I want to thank you for your time, because I know your time is important now.

Mr. BURTON. That's fine. No more votes for another hour or so.

Ms. REYNOLDS. After 40 years, 40 plus years of frustration, exasperation and desperation, I finally had what I considered at least now a quality of life, because of prescribed all natural hormone replacement therapy. And my saga began at age 13, and I know that I speak for many women in America and many of my friends who have suffered the same symptoms and the same things that I have suffered. As a teenager, it began with excessive pain, excessive bleeding that would last sometimes a solid week, extreme pain and nausea and missing school.

This continued throughout my teen years. This continued on up into my 20's. And after I married, I don't know if some of the symptoms disappeared, or maybe you just get so busy that maybe you put some of those symptoms behind you. But these continued, these same symptoms continued. I went for my year examinations as I thought I was supposed to. I would explain each time, and I would go through these symptoms. And either I got a shake of the head or I got, well, some women are just that way. I thought, well, OK, so some women are just that way.

OK, so you go to another doctor and you explain your symptoms and finally in your 30's, you tell them, you know, I think I'm losing some of my hair. I only have half my eyebrows. Do you think possibly maybe I have a problem? And they prescribe things for you that then cause you to have other things that they then have to prescribe something else on top of that to counteract what they have already prescribed for you, which causes you to have other problems, such as dizziness, nausea and breaking out in rashes.

So then you decide, well, you know, I believe I could live with what I was presently having rather than go into a whole new realm of concerns for which I'm sure there would not be an answer. So I thought, OK, I think I look forward to menopause, because I bet all this will be behind me.

Well, of course, that's not the case. Once you hit menopause, you have those symptoms you've carried over from teenage years and your married life, and you've just about killed everyone in your family. So then you get to move into menopause with a whole new set of symptoms, of fatigue, of dizziness, of nausea, of high fevers and you still are not given answers to your problems, except that, well, you know you are getting older. Well, yes, I know that I'm getting older. But when I was here when I was 30, it was because some women are just that way. Now suddenly it's because I'm just getting older is why I'm having these symptoms.

So after being prescribed about six synthetic medications, which each one gave me a new symptom with which I had to deal, and of course, you don't know what to do except go back to your doctor, who then gives you another prescription drug in order to treat the new problem you've just acquired.

Well, when I went through a series of all of these where I had other symptoms with which they were now going to give me other prescription medications to treat those new symptoms, on the last prescription drug I was given, which was the patch, which caused a whole realm of new things that we could be all day into the next vote on this one, so I'll just tell you that I had several symptoms to deal with at that point. And the last climactic symptom I had was severe migraine headaches that lasted 3 days. And so when I called the doctor, and I noticed that one of the side effects listed other than the fact that I could die of a heart attack was also one of the side effects, and that I could have dizzy spells. But in case I had severe migraine headaches, do notify your physician.

I notified my physician. And my physician called me in a prescription for the severe migraine headache, without saying, oh, by the way, why don't you come in to see me. When I hung up the phone and I realized he was just going to call me in a prescription for something to cover that new symptom, I called him back and I said, you don't want to see me, you don't want to know why I'm having this headache? I believe there must be a reason. He said, no, I don't need to see you, I have called you in a prescription.

I said, and what is this prescription? And when he told me the name of it, he said, it's the newest thing on the market for treating severe migraine headaches. I said, oh, wonderful, could you give me the name of some patients for whom you've given this to that I might talk to them about what now this might do to me? And he said, no, because it's so new I haven't prescribed anyone this medication yet. I said, thank you so much. Since you don't need to see me, I don't need to see you again either.

At that point, I found a magazine article that talked about Dr. Hotze's wellness center that treated with all natural medications. I ended up there, and I ended up getting on all natural hormone therapies, which I have yet to have a symptom that I have to take something else for.

And I am well. I have energy, which we have more than just night sweats when we go into menopause, ladies and gentlemen. We have all kinds of things happen to us. And all of those things are gone. I have energy. I feel good. I lost the 20 pounds that I gained during all this 40 plus years of battling with this. And I am at least alive. My family can tolerate me. I don't feel the need to strangle people at any moment, in some cases. And I have a quality of life.

And I hope that this option is never taken from me.

[The prepared statement of Ms. Reynolds follows:]

Subcommittee on Human Rights and Wellness
House of Representatives

Congress of the United States

"Balancing Act: The Health Advantages of Naturally-Occurring Hormone Replacement Therapy

Testimony of: Vicki Reynolds

Owner: Texas Reliant Air-Conditioning & Heating, Inc.

June 4, 2004

Vicki Reynolds
A mother, teacher, wife, bookkeeper, friend and lover of one tolerant husband
12202 Ella Lee Lane
Houston, Texas 77077-5922

From the time I was a very young girl, I was extremely eager to become a grown-up person. At age thirteen, it happened- fever, bloating, intense pain and many other uncomfortable experiences suddenly consumed my small world. These, however, were not symptoms of childhood diseases which would have eventually disappeared. This was for me my grown-up world-this was my initiation into 'womanhood'. These persistent symptoms continued throughout my teen years and beyond. During those younger years, my mother continuously sought the advice of our small town physician. At one point on one of my many visits to the doctor, he finally suggested that birth-control pills might be my only solution. This was NOT an acceptable answer for my mother and certainly not for me. At age thirteen in 1958 my friends and I were still playing with our dolls. Birth-control was not one of the topics of our conversation.

After my marriage, my symptoms slightly diminished. I was then able to at least tolerate the 'monthly event' with ice packs, a bottle of aspirin, and a very tolerant husband. The years following the birth of my daughter in 1970 brought with it the return of the original discomforts I had experienced. Whenever I scheduled my yearly check-ups, I would always discuss with the gynecologist the symptoms I was again experiencing. This time I was told that "some young mothers are just that way". It was even suggested that I might possibly be experiencing post-partum depression. Huh? I was an elementary school teacher with no time for that! Many years later, a notation was made in my medical record concerning signs of a slight low thyroid, but I was told not to worry about that because "this is to be expected at your age" Oh, really. Thanks (I was only 30 at the time)

My family and I moved to Houston in 1985 and began the creation of an air-conditioning business which became a totally consuming entity for all of our lives. As I quickly approached the ripe old age of 50, I was actually looking forward to what I presumed would be the end of all these many years of unanswered questions and frustrating symptoms. That was not to be! Now I was beginning to experience a whole new realm of problems: hair loss, dizziness, severe night sweats, daytime hot flashes, weight gain, bloating, water retention- O.K., that is enough. I went to several different doctors with these new symptoms only to be told over and over again "this is to be expected at your age" (Where had I heard that before?) The difference this time was my symptoms were given a name-Menopause. With this profound diagnosis came many different prescriptions of various dosages, quantities, shapes, sizes and multi-colors with names such as premarin, provera, cycrin, and climara. Speaking of symptoms! I now had a whole new set as a result of these medications -the most dynamic and climactic being the onset of severe, migraine headaches. When I contacted the physician, he simply prescribed <u>another</u> medication to treat my new symptom without examining me. This ended my connection with prescription drugs whose side effects could have filled volumes.

Fortunately for me I ran across an article in a local magazine concerning a natural approach to healthy bodies and healthy minds. The emphasis was on all natural alternatives to health and preventive measures for maintaining a healthy, active body.

My experience with the Hotze Health and Wellness Center was and continues to be one of the most enjoyable, educational, mind and body- healing events of my lifetime. I spent four and one half hours talking about myself and my body, explaining in detail all of my symptoms and the many synthetic methods that had failed with me. No doctor had ever listened to me for more than 15 minutes: therefore, I really had to think about my problems for the very first time. I began to realize that there was a real emphasis on allowing my body to heal in a very natural and nutritious way with the aid of valuable information given to me about foods and their impact on my body. As I began to talk and ask questions, I soon realized that my health was going to depend on me taking control and accepting some of the responsibility for the health and well-being of the only body I will ever have.

All of the symptoms which I spent a lifetime experiencing and had accepted as just a part of my life, are now just a memory for me. The prescriptions I am presently taking for hormonal balance and for low thyroid are plant derivatives: therefore, no side effects. I no longer have to wonder about which symptom will consume me for the day for I am virtually pain free. There was actually a reason for each of my symptoms and through nutritional training and natural supplements they have all disappeared including the excess weight! My prayer is that every man and woman will have the opportunity to experience such freedom as I have just witnessed in my own life.

Thank you for your interest and for allowing me to share in your valuable time.

Respectfully yours,

Vicki Reynolds

Mr. BURTON. Thank you for that story. It's very, very interesting. Do men get night sweats, too? [Laughter.]

Ms. REYNOLDS. They're contagious. [Laughter.]

Mr. BURTON. Dr. Hotze.

Dr. HOTZE. There is a solution for women in mid-life who experience a host of health problems related to hormonal decline and hormonal imbalances. The solution is natural, biologically identical hormones. They are safe, they are natural and they are effective.

As Vicki so articulately presented her history of problems that she had, in our Health and Wellness Center in Houston, I have seen thousands of women, we see 1,500 new guests every year, we call our patients guests, they're not patients, they're guests. We elevate treatment, we think doctors ought to treat their customers as nicely as other businesses do. So we take care of our guests when they come in.

And 35 percent fly in from across the country. They have sought help in their local areas, New York, Los Angeles, and they can't find physicians that will help them overcome their problems. And their problems can be as simple as breast tenderness, mood swings, fluid retention, weight gain and headaches that may happen premenstrually, irregular menstrual periods, breakthrough bleeding, depressed moods, premenstrual and irritable moods.

Eventually, as Vicki mentions, as they move through their menstrual life, their hormones begin to decline, particularly progesterone. And what do they get? They get loss of energy, they get weight gain, they begin to lose their hair. Their eyebrows start to fall out, their hands are cold, they shiver, they can't think clearly, they're irritable, they're depressed, they're anxious, they get panic attacks, they go to bed, they can't sleep. They channel surf all night long. We channel surf during the day, they gripe at us. But at night, they channel surf all night long because they can't get to sleep. They wake up tired, they go to bed tired and they wake up tired. And they often have to slug it out all week at work so they can get home on Saturday so they can go to bed for 2 days so they can make it through the next week.

They visit their physician and their physician runs a blood test and says, everything is normal. And they go, I'm not normal. Well, you're not normal, but I think there might be a problem. You need a little antidepressant. And they'll put them on Prozac and Effexor and Zoloft and a whole host of them and completely ruin their lives. If they didn't have libido before they start, though, they won't have any libido after that. If they used to say, well, I don't think about sex, now they say, I don't even care that I don't think about it any more when they get on these drugs.

Then they get headaches, so they put them on the headache medication and they put them on sleep medication and anti-inflammatory medication and before you know it, these women, their personalities have been completely changed, and then they may try the birth control pills or the counterfeit hormones, which cause a host of problems, as Dr. Alving so clearly told us. The Women's Health Initiative clearly told us what has been in the literature for over 14 years. Since 1989 there have been five major studies that showed that the counterfeit hormones are dangerous, they cause tremendous side effects.

And any physician that listens to a woman, the woman will tell you, Doctor, these make me feel bad. And I say, if they make you feel bad, don't take them. That's the best sign in the world is how you're feeling. If your energy level is gone, you gain weight, you don't think clearly, get off the stuff. My dad used to tell me, and he wasn't a doctor, beware of doctors, they will poison you to death with their drugs. And do you know that the leading cause of death in America is not cancer, it's not heart diseases, if you look at the facts, it's iatoragenic illness, drug-induced illness from the drugs that doctors give patients. It's the leading cause of death. You'll find it's the third leading cause, but if you do the statistics, it's the leading cause of death.

The drugs that the FDA approves kill Americans every day, 100,000 in the hospital every year. And these are drugs that are given and prescribed by doctors and given in appropriate doses in the hospital and it kills them. My suggestion is, well, why do people get sick to begin with? Well, they get sick because their hormones decline. Just like a diabetic young person may get diabetes when their insulin declines. We would never withhold insulin, we replenish insulin.

When your hormones, Congressman and Congresswoman and staff members, begin to decline, you're going to begin to feel the symptoms of the aging process. Yes, it's natural. Yes, it's common. But it's not healthy. That's when you're going to get heart disease, that's when you're going to get diabetes, that's when you're going to get cancer, you're going to get arthritis.

What can you do to prevent that? You're not going to prevent death, but you can sure improve the quality of life by simply replenishing, in your body, replenishing in your body the same hormones that your body used to make in adequate amounts when you were younger. Keep them at a normal level.

And for gosh sakes, do not take the drugs that the drug companies are putting out. Because they will kill you, and the women's health study has said that, I've been saying that for 10 years. And I was out on the extreme when I said that 10 or 15 years ago on my radio programs and all over town. Well, Dr. Hotze's a little out on a limb, he's saying these drugs are bad for you.

Well, guess what? Now that it turns out I was right, did they say Dr. Hotze was right? No, they went, well, we don't want to bioidentical, let's just put them on some other drugs. So we're going to go on Premarin light. You've heard of Miller and Miller Lite. Dr. Alving told us that now they have offered Prempro light. We'll kill you slower, not as fast as we would have. You'll get cancer, it will take you twice as long to get cancer. Then if that doesn't work, we'll just put you on drugs and drug you up.

So ladies, if you start acting a little bit weird, and you don't feel good and your doctor, most likely it's going to be a man, and the way men look at women, he's going to look at you and say, I just think you're a hypochondriac. But he's not going to say that. He'll go, I think you might have a little problem with depression. Ninety percent of the women between 35 and 55, 90 percent of the antidepressants that are prescribed are prescribed to women. Why do doctors give women all the antidepressants? Why don't the men get the antidepressants?

As to studies, there is a plethora of studies, and I would be glad to forward these to the doctor at the end of the table, who is an academician at a medical school and frankly, with all due respect, should be ashamed that she hasn't read this plethora of literature. I'll be glad, I'm the president of the American Academy for Biologically Identical Hormone Therapy. Dr. Fugh-Berman, I will be glad to forward you catalogs of all this information that you can read and make up your own decision. I'll be glad to send you that. And I will send you that as soon as we get back to Houston. Then you can comment on it after that.

In 1981, the Johns Hopkins Public School of Health did a study published in the American Journal of Epidemiology, a 20 year study. It showed that there was one chemical in a woman, when she lost the chemical, she had a 555 percent increase of breast cancer and a 1,000 percent increase of death of all kinds from cancer. And wouldn't it be nice if you knew what that particular molecule was? The Johns Hopkins School of Public Health determined when it was missing, that women had a 555 percent increase of breast cancer. Dr. Berman, do you know what that was, have you read the article?

Dr. FUGH-BERMAN. Perhaps if you had included a reference in your testimony, that would have been helpful.

Dr. HOTZE. I did.

Dr. FUGH-BERMAN. It's also a epidemiological study, not a randomized control trial, and I am extremely familiar with hormones.

Mr. BURTON. I don't want to lose control of the hearing. [Laughter.]

Dr. HOTZE. Anyway, the hormone was progesterone. So the dramatic increase in risk factor for women getting cancer is the decline in their progesterone levels and progesterone is a naturally occurring hormone that women have and every cell in their body requires it.

Finally, there is a solution for women's health problems in midlife and thereafter. When should a woman start taking bioidentical hormone replacement therapy? As soon as she starts having symptoms, which can happen, in the case of somebody like Vicki, at 13. She may need just a little bit of progesterone.

But this is the solution, and this is safe and it's effective. We have treated thousands of women. I have done numerous clinical studies and presented them at medical conferences. We are now training doctors, OB-GYNs in Houston, TX. We are leading a wellness revolution that will change the way mainstream medicine, and the way men and women in America area treated in mid-life through the use of biologically identical hormones.

And we thank you, Congressman Burton and you, Congresswoman Watson, for your interest in alternative, safe, effective alternatives for health problems. And this would save the country billions of dollars. The last thing that people need when they're older is all these drugs they drug them up with. Why do you think sitting in a nursing home they drool and they can't talk to you and

you go, Mama's losing her mind? They've got her drugged up on anti-anxiety, anti-depressants and sleep medications. Get her off the drugs, get her out of there, she's liable to be normal again. I've seen this happen.

[The prepared statement of Dr. Hotze follows:]

Testimony on Biologically Identical Hormone Therapy
House Subcommittee on Human Rights and Wellness
Washington, D.C.
July 22, 2004

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The U.S. Congress must take action to protect and improve the health of women in America. Congress must stop the FDA from illegitimately attempting to restrict compounding pharmacies from providing women in America with the benefits of natural, biologically identical hormone therapy. Congress should also consider underwriting a study of biologically identical hormones like the one that it funded in the Women's Health Initiative study which clearly demonstrated the adverse effects of drug company counterfeit (non bio-identical) hormones.

The Health Problems of Women in Midlife

Women in midlife experience a host of health problems related to an imbalance and decline of their sex hormone levels. These problems may include one, some or all of the following symptoms: premenstrual breast tenderness, mood swings, fluid retention, weight gain, and headaches, including migraines. They may also experience irregular menstrual cycles, heavy periods, breakthrough bleeding, fibroid tumors, fibrocystic breast disease, osteoporosis, fatigue, weight gain, hair loss, cold extremities, decreased mental sharpness, depressed and irritable moods, joint and muscle aches and pains, insomnia and loss of libido. At menopause, the symptoms of hot flashes, night sweats and vaginal dryness may also occur. These problems have been addressed by conventional medicine using synthetic, counterfeit (non bio-identical) hormones produced by drug companies for hormone replacement therapy (HRT). Additionally, other types of drugs have been prescribed to ameliorate these symptoms, such as, anti-depressants, anti-anxiety and anti-inflammatory drugs, sleep preparations,

diuretics, anti-migraine and headache medications, etc. Often times the menstrual irregularities that women experience lead the physician to recommend a hysterectomy. This surgery of course eliminates the problem of dysfunctional menstrual bleeding but does not address the underlying cause of the menstrual abnormality, that being hormonal imbalance.

Both the **Women's Health Initiative (WHI)** published in the **Journal of the American Medical Society (JAMA)** in July, 2002 and the recent **United Kingdom study on Breast Cancer and Hormone Therapy**, published in the **Lancet**, a premier British medical journal, on August 9, 2003, underscore the harmful effects of conventional, counterfeit (non bio-identical) hormone replacement therapy. In the British study, the treatment using the non bio-identical equine (horse) estrogens (e.g., Premarin, Cenestin and Ogen) with progestin agents proved to be the most dangerous combination. The progestins studied were medroxyprogesterone (Provera), norethisterone, norgestrel and levonorgestrel, all non bio-identicals of human progesterone. The non bio-identical hormone combination that is most commonly used in America is Prempro, which was the primary medication that was studied in the WHI. These drugs caused a significant increase in the incidence of breast cancer, stroke, pulmonary embolism (blood clots to the lungs) and cardiovascular disease.

Biologically identical human estrogens and progesterone were not used in either study.

There have been at least five medical studies, published in major medical journals, since 1989 that had reported the same findings that were found in the WHI and in the United Kingdom study on Breast Cancer and Hormone Therapy.

It was not until the results of the WHI were published on the front pages of the newspapers and magazines across the country that mainstream medicine realized that there was a problem. The pharmaceutical industry and conventional medicine have been promoting these counterfeit (non bio-identical) hormones for decades as essential ingredients to good health for women in midlife and menopause. But all one had to do was to listen to the complaints of the women taking these counterfeit (non bio-identical) hormones to know that these drugs were unhealthy for them.

Women taking these counterfeit (non bio-identical) hormones commonly complain of low energy, weight gain, depressed moods, an inability to think clearly, joint and muscle pain, poor sleep and loss of libido, just to list a few of the symptoms. Doctors have been prescribing drugs, most commonly antidepressants, to mask these symptoms which are caused by conventional HRT.

Due to the widespread dissemination of this information, and often misinformation, on HRT in the press and because of their concern about medical liability, many physicians have begun to recommend that women discontinue HRT or have begun to warn women of the potential risks that their use may cause. This has left a void in the treatment of the numerous health problems that women experience due to the hormonal imbalances and declines that occur in mid life.

What is the drug industry's answer to these studies? Wyeth is now promoting a new low dose Prempro. The drug companies are attempting to fill this void by advertising the use of drugs as an alternative to HRT. Is it really surprising that millions of women have lost faith in mainstream medicine with its multi-drug solution to their problems?

The Prevention of Breast Cancer

The Johns Hopkins University School of Public Health published an article in the 1981 American Journal of Epidemiology demonstrating a 5 fold increase in breast cancer and a 10 fold increase in death from all other types of cancers in women with progesterone deficiency.

What is the unifying principle? Women with low levels of progesterone have a significant increase in breast cancer. Women who take non bio-identical progestins, which turns off the ovaries' production of naturally occurring progesterone, also have a significant increase in breast cancer. The unifying principle is that low levels of human progesterone increase the risk of breast cancer.

It has been clearly demonstrated that the incidence of breast cancer dramatically increases when woman have low levels of progesterone or when they take non bio-identical hormones. It has also been scientifically demonstrated that hypothyroidism, a low thyroid condition, is also

associated with a significant increase in all types of cancer. This is due to the state of low oxidative metabolism, an environment in which cancer thrives, which is caused by hypothyroidism. Counterfeit (non bio-identical) hormone replacement therapy leads to hypothyroidism.

There has been a tremendous push for the "Cure for Breast Cancer" and cancer in general. This slogan accepts the premise that the occurrence of cancer is a foregone conclusion. No woman wants to develop breast cancer, hoping for a cure. Women want and deserve safe, effective measures for the prevention of breast cancer and the other maladies that occur during mid life.

There is a huge, multi-billion dollar cancer industry in America. There is also a multi-billion dollar pharmaceutical and insurance industry in America, as well as a multi-billion dollar medical industry in America. None of these is promoting the prevention of cancer to any significant degree. Exercise, healthy eating and elimination of smoking are encouraged, but there is no money to be made by these industries in the prevention of disease. Healthy people do not need drugs for the relief of symptoms in midlife or for the treatment of cancer. Healthy individuals have minimal requirements for medical services.

The primary goal of medicine should be to prevent disease by enabling people to obtain and maintain health and wellness rather than the treatment of disease. The old adage remains true, "An ounce of prevention is worth a pound of cure." The lion's share of our efforts should be directed toward the prevention of cancer. American woman have an extraordinarily high incidence of breast cancer when compared with women in other areas of the world. This is due in large part to the hormonal imbalances and declines that occur in mid life, as well as to the widespread use of the counterfeit (non bio-identical) hormone agents that have been promoted over the past 40 years. They cause progesterone deficiency in women. Birth control pills contain many of the same progestins, non bio-identical progesterone, which were found to be dangerous to women's health in the WHI. It is the progesterone deficiency caused by non bio-identical hormone agents that has increased the risk factor for breast cancer and other cancers among American women.

Faced with significant health problems in midlife and with an increased risk of breast cancer and cancers of all kind women feel hopeless and helpless. Women are looking for a solution that is safe, effective and natural.

The Solution

The solution is **Biologically Identical Hormone Therapy (BIHT).** First, the use of any counterfeit (non bio-identical) estrogens and counterfeit (non bio-identical) progestins should be immediately discontinued. Secondly, biologically identical progesterone as well as biologically identical estrogens should be given to women when indicated. These biologically identical hormones are indicated when the symptoms of hormonal decline first occur, most commonly around 35 years of age. Premenstrual symptoms such as breast tenderness, headaches, mood swings and depression, fluid retention, weight gain, as well as irregular and heavy periods, are common signs of progesterone deficiency. These should be treated with biologically identical progesterone premenstrually. A significant amount of data already exists in current medical literature, as well as the clinical experience of the physicians at the Hotze Health & Wellness Center in treating thousands of women, to promote further study of the use of **Biologically Identical Hormone Therapy (BIHT)** for treating women's health problems in mid life.

Biologically identical hormones are hormones that have the same molecular structure as the hormones produced by the human body. They are derived from plant sources and are chemically formulated in the lab to be identical in structure to the hormones that humans produce. Drug companies make chemical changes to these biologically identical hormones in order to create a hormone like drug that is patentable. Natural occurring substances, such as human hormones, cannot be patented. This is the reason that the pharmaceutical companies have no interest in investing in the research and development necessary to make these biologically identical hormones commercially available.

Biologically identical hormones are only available through compounding pharmacies which purchase these hormones in bulk from FDA approved pharmaceutical companies. The compounding pharmacies then fill prescriptions, tailored for the individual patient, based upon a physician's prescription.

The review of the literature on human progesterone, published by Bruno de Lignieres, M.D., in **Clinical Therapeutics** in 1999, indicated that biologically identical (human) progesterone has a host of benefits without any significant side effects. The Postmenopausal Estrogen/Progestin Interventions (PEPI) Study, in 1995, recommended biologically identical

progesterone, over the non bio-identical progestins, as the first line of therapy when treating menopausal women with intact uteruses. Of course this recommendation was not followed because the pharmaceutical companies could not patent biologically identical progesterone. Without the ability to patent progesterone and develop a proprietary label, the pharmaceutical companies could not profit from its production. Only by changing the molecular structure of progesterone, in order to create non bio-identical progestins, could the drug companies obtain a patent.

The FDA's Illegitimate Actions

The FDA has recently decided to declare all compounding as manufacturing in order to justify their illegitimate claim of jurisdiction over compounding pharmacy. This action flies in the face of the fact that when pharmacies were exempted from FDA jurisdiction in the 1938 Food, Drug, and Cosmetic Act essentially all pharmacies practiced compounding. Since 1938, the FDA has left regulation of drug compounding to the States. Now the FDA is attempting to intimidate pharmacies and state boards of pharmacy by issuing compliance policy guidelines on compounding which have no force of law. This is a clear case of federal usurpation of states' rights as relates to pharmacy.

The means of distribution of the medications is the point that differentiates compounded pharmacies from drug manufactures. Neither the volume of medications produced nor the type of equipment used is a basis for differentiation between compounding pharmacies and pharmaceutical manufacturers.

Compounded Pharmacy Distribution

Compounded medications are prepared in the pharmacy from bulk active ingredients and distributed based upon an individualized prescription for a patient written by a physician or veterinarian or for the discretionary use by these practitioners in a medical facility. This is known as the pharmacist – physician -patient triad and is what differentiates compounding pharmacy from pharmaceutical manufacturing. The dosage or route of administration of the medication usually varies from that of commercially available products. Compounded preparations may require the customized combining

of different medications as determined by the physician or veterinarian, working directly with a pharmacist.

Pharmacies are governed and licensed by their respective State Boards of Pharmacy and were exempted from the jurisdiction of the Food and Drug Administration (FDA) by the 1938 Food, Drug and Cosmetic Act.

Pharmaceutical Company Distribution

Drugs manufactured by pharmaceutical companies are mass produced and distributed to wholesale distributors for resale. These drugs have limited dosage strengths and means of administration. They are not individualized for a specific patient. There is no direct personal interaction between the pharmaceutical manufacturer and the practitioner, pharmacist or patient.

Pharmaceutical manufacturers are governed and licensed by the FDA.

Pharmaceutical manufacturers are required to pay drug user fees for all new drugs approved by the FDA. This amounts to approximately 15% of the FDA's annual budget. In 2005, drug user fees from pharmaceutical companies are projected to be approximately $ 270,000,000. The pharmaceutical companies are known to have filed complaints with FDA against compounding pharmacies.

There is a legitimate concern that the FDA is being used by pharmaceutical companies to deter the growth of compounding pharmacy.

In November of 2003, the U.S. Congress refused to approve the establishment of an FDA commission that would have investigated and proposed regulations for the practice of compounding pharmacy. Working through its agents in the US Congress, the FDA supported a Senate amendment, Section 626, to the 2003 Medicare Prescription Act. This amendment would have set up a commission, under the auspices of the FDA, to investigate and propose regulations for compounding pharmacies. This amendment was not included in the House version of this bill. In the Joint Conference Committee, which met to reconcile the 2003 Medicare Prescription Act, the House members of that committee refused to allow Section 626 to become part of the act.

Actions

1. Congress must stop the FDA from illegitimately attempting to restrict compounding pharmacies from providing women in America with the benefits of natural, biologically identical hormone therapy.

2. It is imperative that a study be conducted to determine the safety and efficacy of Biologically Identical Hormone Therapy (BIHT). The Federal Government should underwrite this study. The results could spawn a Wellness Revolution in America that would free millions of women from the health problems that develop in mid life, as well as decrease women's risk for the development of breast cancer. In turn this could save billions of dollars in health care expenses.

Mr. BURTON. Thank you, Doctor.

Dr. HOTZE. Thank you, sir.

Mr. BURTON. The one thing I wish you could help me with is, I'm a little bit older now and I've never understood women. And if you could find some way to give me some kind of a hormone replacement that would make me understand women. [Laughter.]

Dr. Brownstein, Dr. Fugh-Berman, I will have some questions for you in a minute. But I have to tell you, after listening to your testimony, it sounds remarkably similar to testimony we've had from people who represent the pharmaceutical companies who have been before me over 4 years. And that's why, and I don't mean to impute your integrity at all, but that's why I asked you where your funding was coming from and what the foundation funding sources were.

Dr. FUGH-BERMAN. Could I respond?

Mr. BURTON. Sure.

Dr. FUGH-BERMAN. I'm really flattered to be accused of that, or even——

Mr. BURTON. You're not accused.

Dr. FUGH-BERMAN. No, no, but I am really flattered, because actually I do a lot of work against pharmaceutical companies. And the National Women's Health Network does as well. Pharmaceutical companies shudder when we come into FDA advisory committee rooms. So yes, it's a novel position to be in.

But I just also wanted to say that actually, I have practiced alternative medicine for many years. I was medical director of two clinics in Washington, and I currently teach in the only masters degree granting program in alternative medicine in the United States at Georgetown, which we just started last year. So I'm normally seen as a sort of nuts and granola, herbs and dietary supplement person. So this is a very interesting position for me to be in.

Mr. BURTON. OK. Dr. Brownstein and Dr. Hotze, what I'd like to know is, where is your practice, Dr. Brownstein?

Dr. BROWNSTEIN. Outside of Detroit.

Mr. BURTON. You're outside of Detroit. Do you have people come in, like Dr. Hotze, that stay for a while and you do a battery of tests on them and then you decide what hormone replacement therapy, natural hormone replacement therapy they should take?

Dr. BROWNSTEIN. We have people come in from all over the country and out of the country. We check levels before we institute any hormonal therapy, pre and post. And we follow our patients closely.

Mr. BURTON. I was looking at your chart here. In the chart there was a picture who looked like she was severely overweight. And then it shows another picture right after that. Is that the same lady?

Dr. BROWNSTEIN. That's the same lady with 6 months of treatment with natural hormones.

Mr. BURTON. Six months? How much weight did she lose?

Dr. BROWNSTEIN. About 75 pounds.

Mr. BURTON. Was this without weight control?

Dr. BROWNSTEIN. She was a lady around 40 years old, had a baby and fell apart during the pregnancy. And she had normal blood tests for thyroid levels. When I put her on a small amount

of thyroid hormone plus a few natural hormones that were imbalanced, her health recovered.

Mr. BURTON. And she lost weight?

Dr. BROWNSTEIN. She lost that weight.

Mr. BURTON. Without any dietary weight loss substances?

Dr. BROWNSTEIN. Took no dietary substances.

Dr. FUGH-BERMAN. Thyroid will make anyone lose weight.

Mr. BURTON. Yes. Thank you, Dr. Berman.

[Simultaneous conversations.]

Dr. HOTZE. That's not correct.

[Simultaneous conversations.]

Dr. BROWNSTEIN. That's not correct.

Mr. BURTON. In any event——

Dr. HOTZE. That's the difference between a clinician and an academician.

Mr. BURTON. Well, I don't want to get into a fight here. I'm glad you're sitting at opposite ends of the table. [Laughter.]

But what I'd like to——

Dr. HOTZE. Well, we'll juice it up a little bit, because we heard your hearings get pretty good.

Mr. BURTON. Well, I've never been known to back way from a fight. [Laughter.]

But in any event, what I'd like to know is, you've spoken in generalities. She mentioned studies, clinical studies, that sort of thing. Do you have any clinical studies or anything that we could—and I don't want you to give me this much——

Dr. HOTZE. Yes, sir, I do, and we will send you those. I have clinical studies from my office, and I will send you the clinical studies also that I promised you.

Mr. BURTON. Has the FDA or HHS ever taken issue with you, come into your office and——

Dr. HOTZE. No. And they can't, because FDA has no authority over the practice of medicine. That's all governed by the State Board of Medical Examiners.

Mr. BURTON. How about HHS or any of the health agencies?

Dr. HOTZE. They have no authority over——

Mr. BURTON. Have any of the State health agencies given you a hard time?

Dr. HOTZE. No.

Mr. BURTON. The reason I ask is because, some people who practice alternative modalities of medicine have had problems with various Government agencies. And they literally put some of them out of business.

Dr. HOTZE. True, they do. Unfortunately, they pick on the little ones that aren't strong. They will pick on people that will back down. But they don't pick on us.

Mr. BURTON. Got that. Ms. Petersen, how do you determine through your pharmacy, how do you determine what substances people need to take, hormone replacement, that will help make them better?

Ms. PETERSEN. Actually, we don't. The practitioners do.

Mr. BURTON. So you work with people like Dr. Brownstein and Dr. Hotze?

Ms. PETERSEN. That's quite right. And as both doctors referred to, there's really a plethora of information out there. There's very much a lot of basic research in the fields of endocrinology, physiology and even medicine that identify what symptoms are related to what hormone. We know that from those basic studies. And then we also have quite a bit of literature on when you use a particular hormone, how much it takes to get to normal blood levels. So there are ranges of these hormones that are used.

And within that paradigm, knowing what clinical response you expect to get, and what the usual dose ranges are and what blood levels or saliva levels or urine levels you can anticipate improving, with all those tools, the clinician is very straightforward, very scientific to determine what people need.

Mr. BURTON. So what you do, Dr. Brownstein, Dr. Hotze, is that you take blood tests, saliva tests, urine tests, and you analyze those and you decide from those tests whether or not there's a deficiency of certain hormones?

Dr. HOTZE. First, everyone in this room, as you age, your hormones are going to decline. There are scientific studies on that. And women know that.

So the first thing we do, I do, I'm a clinician, the first thing we do is take a copious 26 page history. The history tells you everything. If you understand how the hormones work, when a woman walks into your office, she's 38, she had a baby, and now she's experiencing breakthrough bleeding and she's experiencing mood swings, breast tenderness, you know she needs progesterone.

Mr. BURTON. Yes.

Dr. HOTZE. So we don't draw a blood level on progesterone, we will draw a blood level on thyroid and some of the other hormones. But if a woman is menopausal, she's not making any hormones, you don't have to check her blood for that, she's already told you. So you replenish it in the average normal range that is accepted and that relives the symptoms.

Mr. BURTON. How do you determine that?

Dr. HOTZE. Well, you do a physical exam.

Mr. BURTON. Do you do diagnostic tests?

Dr. HOTZE. Yes, we do tests. But if any woman in menopause walks in, I can look at her and know what her size and weight is, and she tells me her symptoms, I'm going to know the dosage that she needs to take. And that's the starting dose. And then we work, we see her back in followup and make adjustments.

Mr. BURTON. How about you, Dr. Brownstein? Do you do it the same way?

Dr. BROWNSTEIN. I check, as I said before, pre and post levels in everyone.

Mr. BURTON. How do you do that, through blood tests, saliva tests, urine tests?

Dr. BROWNSTEIN. Blood and urine tests. And the idea of being a physician is to put the whole picture together for the patient, to look at their physical exam, look at their history, look at their blood work and look at whatever other signs you can come up with and then put the whole picture together, not rely on one aspect only to treat people.

And when you look at the whole picture, I think you can get a better treatment regimen together for somebody.

Mr. BURTON. I see, and then you prescribe pretty much all holistic hormonal replacements?

Dr. BROWNSTEIN. If someone has strep throat, I'll prescribe penicillin. There is a place for drug therapies.

Mr. BURTON. I know, but I'm talking about as far as the deficiencies in people.

Dr. BROWNSTEIN. I will only prescribe natural hormones.

Mr. BURTON. What about men? You've been talking a lot about women.

Dr. HOTZE. I'll speak specifically. Men also, as they age, lose, their testosterone level declines. So a man at 40 will have one-half the testosterone level he had in his 20's, at 50 a third, at 60 a quarter. Testosterone is essential. It affects your initiative, your assertiveness, sense of well-being, self-confidence, moods, goal orientation, your drive, direction, decisiveness, analytical ability——

Mr. BURTON. I feel sick already. [Laughter.]

Dr. HOTZE. Your analytical ability, and we know this because if a man loses his testicles from cancer or injury, he has difficulty, he can't read a map, he can't think in three dimensional terms.

Mr. BURTON. But you treat——

Dr. HOTZE. So when you give them testosterone, oh, my gosh, it's huge, and I take it myself, and I have for 7 years. It's remarkable.

Dr. BROWNSTEIN. Mr. Chairman, you mentioned that heart disease, or somebody mentioned heart disease was the No. 1 killer in the United States. I have yet to see a patient with severe heart disease have a normal testosterone level, man or woman. They all have low levels. And when you look at the literature on testosterone and heart disease, there is tons of it. I have file cabinets at work of testosterone and heart disease relationships.

Mr. BURTON. So for men, you will check their testosterone levels and you'll compensate?

Dr. HOTZE. Prescribe, yes.

Dr. BROWNSTEIN. Check all their hormone levels, but yes, testosterone is one of the things.

Mr. BURTON. Ms. Watson.

Ms. WATSON. I want to thank all the witnesses, and sorry to be late coming in. We're always conflicted.

Dr. Hotze, I believe in holistic medicine. What do you see are the problems today, when I say today, I mean today, in the use of naturally occurring biological methods for addressing the hormone loss? What is the problem? Is the problem with the FDA?

Dr. HOTZE. There is a potential coming problem with the FDA. Pharmacies, just like medical doctors, are all governed and regulated by their various State boards of pharmacy. The FDA has recently tried to extend, and we believe illegally attempted to extend its jurisdiction to govern pharmacies, particularly compounding pharmacies. They have already issued a compliance policy guideline that would prohibit compounding pharmacies that make products for veterinarians where they prohibit them from buying it in bulk. That's what their compliance policy is, which has no force of law, but people think it does, and they intimidate people.

Now, what they want to do, and all compounding pharmacies buy their products in bulk from a pharmaceutical manufacturer, whether their products are synthetic or whatever. Compounding pharmacies don't just make bioidentical hormones, they make a plethora of drugs based upon a doctor or pharmacist patient relationship.

So the FDA wants now to restrict bulk use of ingredients in that pharmacy. That shuts them down. They can't do it any more. That's how you make a compounded product, you buy in bulk. They will next move to humans and say, we're going to restrict you doing this in humans, you can't buy the bulk product.

And then Vicki won't be able to get hormones any more, because the way they want to control the doctors that are practicing alternative medicines is shut down the compounding pharmacies. That's their goal.

So what we would like to ask you, we need your help, Congresswoman Watson and Chairman Burton. We need to ask you if you would consider writing a letter to the FDA, asking them to focus their efforts on tracking all these dangerous drugs from the pharmaceutical companies, which they say they don't have enough money to do, and leave the pharmacies under the jurisdiction of the State boards of pharmacies, in other words, stop the intervention. They are intimidating the little guys.

Now, I'm big enough, I can go out and hire a lawyer and spend hundreds of thousands of dollars. I haven't had to do this, but I've joined in coalitions that have fought the FDA. I'm willing to do that. But a little guy on the corner can't do it. And they're going to shut all the little people down.

Ms. WATSON. Let me ask you, what is the FDA's position on intervening? Do they feel that maybe the studies have not been——

Dr. HOTZE. They don't intervene on biologically identical—they haven't intervened on biologically identical hormones. They haven't done that. But they want to shut down compounding pharmacies.

Ms. WATSON. Why is this?

Dr. HOTZE. Because, with all due respect to the FDA, they're regulatory bureaucrats. Every regulatory agent wants to control things. And when Kesler got into power, he wanted to control dietary supplements. He wanted—you couldn't get a vitamin unless you went to your doctor and your doctor wrote a prescription.

What are the odds of your doctor writing you a prescription for vitamins? In most people, they'll never do it, because when my dad asked me, when he had heart disease in 1988, he said, son, I read about vitamins, the doctor says I need to take vitamins. He said, what do I take? I said, Dad, what the hell do I know? I'm a doctor. I don't know anything about vitamins. And he said, will you find out? And I did. That's how I got into alternative medicine. Very similar story to Dr. Brownstein's, my dad's heart disease and health problems got me into alternative medicine.

Ms. WATSON. Well, do they lean more toward the synthetics?

Dr. HOTZE. Yes, of course. Yes, they do.

Ms. WATSON. Is it to the benefit of the pharmaceutical companies?

Dr. HOTZE. Voila! If something doesn't seem logical, like, you mean, I can get something, I can replenish my body with water if

I'm thirsty, but you want me to drink Coke when I'm thirsty, but all I need, I'm dying in the desert and all I want is water, and you're going to do a double blind study, well, you're trying to sell me that Coke.

The same thing with the hormones. We have available, as we age, the ability to replenish our hormones with the same identical hormones your body used to make in adequate amounts. Oh. But you can't patent those.

Dr. FUGH-BERMAN. Could I clarify something about bioidentical hormones? This is important.

Bioidentical hormones are available in commercial pharmaceutical preparations. Compounding pharmacies buy them from drug companies. You can get 17 beta estradiol, the exact bioidentical estrogen that is in our bodies, in patches, in pills, in vaginal tablets, inc reams. Is that not correct?

Ms. PETERSEN. That's absolutely correct, it's only partial.

Dr. HOTZE. It's partial.

Dr. FUGH-BERMAN. What is different? What is different in the preparations that you use than in the commercially available pharmaceutical versions of estrone, estradiol and testosterone?

Ms. PETERSEN. I can tell you that in a minute. Say prometreium progesterone comes in 100, 200 milligrams. I have many, many people who use 10 milligrams, 15 milligrams, 50 milligrams, 250 milligrams. You cannot do it with a commercial product and it's not appropriate for them.

Also the fillers and the binders in some things, our pharmacy does a lot of work with environmentally sensitive people. We pay attention to that. Commercial products are not appropriate. There's dyes and fillers that will cause severe reactions with them.

Dr. BROWNSTEIN. The other thing that Carol is pointing out is that, all these therapies need to be individualized.

Ms. PETERSEN. Yes.

Dr. BROWNSTEIN. You require a different dose than the lady next to you. And when you're relying on pharmaceutical companies, they only have a couple of doses fits all size.

Ms. WATSON. Let me just say this. I'm an example——

Mr. BURTON. Hold on a second.

Dr. FUGH-BERMAN. We tailor medications in conventional medicine. What my problem with this is not that these people are too alternative, but that they're too conventional. These are the same sorts of claims that were made without data by the company that made Premarin.

Mr. BURTON. Would you yield?

Ms. WATSON. I'll yield to the Chair.

Mr. BURTON. Let me just say this. As we age, and I know you're very young, we take a lot of pills. Can you imagine me breaking these pills apart and trying to see? You can't do that. You'd go crazy first of all, and you'd probably kill yourself.

I think what Drs. Brownstein and Hotze are trying to say is that this is going to be, they're going to try to find out what your deficiencies are and tailor it to the individual. And a one size fits all commodity coming out of a pharmaceutical company won't cut it.

Dr. FUGH-BERMAN. Right. And it's fine to tailor therapy. We do that in conventional medicine, we do it in alternative medicine, and I consider myself a practitioner of both.

Mr. BURTON. Well, my doctors don't.

Dr. FUGH-BERMAN. But the idea that there are known normal levels of all hormones is actually not true. That we don't know what the normal age levels are of, for example, estrogen. You cannot tell from blood levels of estrogen who's having hot flashes and who isn't. So blood levels of 20 year olds are higher in estrogen than blood levels of 70 year olds, but you can't tell who's having hot flashes, you don't know what a normal level of estrogen in a 70 year old is.

So this is an aura of science over something that is not scientific. Also saliva is not an appropriate, salivary hormone tests are not appropriate for several hormones, including progesterone, and that's been shown in scientific studies.

Ms. WATSON. Can I get my time back? [Laughter.]

Mr. BURTON. Ms. Petersen, do you want to respond real quick, and then it's back to my good buddy.

Ms. PETERSEN. I did. It's like looking at one thing, and none of the practitioners look at an estradiol level without looking at the clinical picture. Some women normally have very high estrogen levels throughout their whole lifetime. And when they drop, they may not drop very much, but they notice a huge difference. You have to tie the two.

You can't rely on a test, and I agree, saliva tests are not the best tests. And there is some possibility of its use for some diagnostics, but not across the board. I agree entirely. It's just a tool. You can't just use one tool. You can't take a saliva test, no matter how good the test, or the blood test, and you can't figure out how many milligrams of this or that will do it for you. It's trial and error. You have to work with the patient and the clinical response.

Dr. HOTZE. And that's scientific. That's the history of medicine. Evaluate, make a diagnosis. Start on preparation of medications, see how the guest or the patient does. Make adjustments. That's scientific. That's the science of medicine.

Ms. WATSON. Dr. Fugh-Berman, I wasn't here for all the testimony, so let me direct this to you. In describing the condition of my own health, I have difficulty with patent medicines. I have side effects, and I have to continue to change. I use holistic medicine most often, because it has been customized to my own system. I can't take anything harsh and I usually have to break down prescriptions because they're just too strong for my system.

Can you explain what problems you might have with seeking the natural hormones that are customized and will help an individual? I find that in patent medicine, there are so many additives, and I remember my doctor said, read labels. So I read labels on everything. When I see the additives, I know I'm going to be in trouble. And I'm trying to find the right kinds of foods that will go with my system. I don't know if that's a hormonal thing or not. But as I age I become more and more allergic to almost everything.

So can you describe for me why you think the natural kinds of hormonal treatments are not as good as the others?

Dr. FUGH-BERMAN. I wouldn't actually say that. I would say that the use of estriol, Bi-Est, Tri-Est or commercially available pharmaceutical preparations are effective for hot flashes and vaginal dryness. Those are the only things that they have been proven to be effective for.

It's important to individualize any of these medications to a woman, especially now that we know that estrogens don't provide other health benefits, and that they do provide risks. However, there is no evidence that natural bioidentical hormones, whether they are in pharmaceutical drugs or in compounded prescriptions, are safer than synthetic estrogens.

Ms. WATSON. You said there is no evidence?

Dr. FUGH-BERMAN. There is evidence that they are——

Ms. WATSON. Hold on. How do we gather evidence?

Dr. FUGH-BERMAN. From observational studies or randomized controlled trials. We have randomized controlled trials showing that estradiol increases stroke risk. We have information from epidemiological studies that estriol increases endometrial cancer risk.

This is not an unknown. This is known, and it's consistent with what we know about other estrogens. In my testimony, while you were away, I pointed out that even higher levels of naturally occurring estrogens in our own body are actually associated with higher levels of breast cancer risk. So there's no such thing as a harmless hormone. Hormones have risks.

Sometimes it's worth it taking those risks for somebody who has very severe hot flashes, taking a risk of a slightly increased chance of having breast cancer might be worth it. But there is no evidence that these have other health benefits and it's really bothersome to me as a public health physician, as a physician concerned about public health, that there are claims being made that these compounded prescriptions will increase quality of life or prevent any disease. There is no evidence to support that, and there is evidence to support that they are harmful.

Ms. WATSON. I heard you say twice there is no evidence. And it would seem to me that if we did short term and long term studies across the board, maybe it would yield some empirical evidence that then we can base claims on both sides on.

I would think, and in my own case, as I said, I chose to go to a holistic provider because the patent medicines were not helping me. I was becoming allergic to them.

So would you not agree that we need to go into the studies and try using these hormones beyond just the hot flashes and the dryness in the uterus? Would you not agree that we really need to do some studies to see in what levels, in what dosages and so on they could or could not work?

Dr. FUGH-BERMAN. You know, for many years, the medical profession thought that hormones were going to be helpful.

Ms. WATSON. No, no, no, no. Let me direct—my time is getting short. Let me get you on point.

Dr. FUGH-BERMAN. There have been studies already done about these natural hormones.

Ms. WATSON. But I thought you said there was no evidence, no empirical evidence.

Dr. FUGH-BERMAN. No. I said that there are randomized controlled trials showing that estradiol increases stroke risk.

Ms. WATSON. OK, time.

Dr. FUGH-BERMAN. They're referenced in my written testimony.

Ms. WATSON. Dr. Fugh-Berman, what would you have against, starting today, I think it's July 22nd, going forward to do some in-depth kinds of studies to see about the effects of using these natural hormones and customizing them to the individual? Would you be, as an educator, as a clinician, as a doctor, would you be against that kind of research?

Dr. FUGH-BERMAN. It depends on what the indications were for, Congresswoman Watson.

Ms. WATSON. Will you write a hypothesis——

Dr. FUGH-BERMAN. There already have been studies of estriol for hot flashes and bone. It helps them.

Ms. WATSON. Hold on. I was very clear in giving you a date. And I——

Dr. FUGH-BERMAN. What's the position you're studying?

Ms. WATSON. Well, that's your hypothesis, you know. And I have a Ph.D in education, I don't have one in medicine. But I do know how you formulate a study. What I'm saying to you is, would you have, would you object to studies going forward? Not what they've already done, but going forward to then be able to present empirical evidence?

Now, let me tell you, I've been in this business of making policy for many, many years. For 17 years, I headed up the health and human services committee in the State Senate in California. We decided many years ago that smoking was bad for your health. So I came in with proposals, and I would have to convince my own colleagues that we ought to look and do research. They laughed, and they said, oh, no, and they were looking at the tobacco industry and protecting them and so on.

So I found that education was the thing. And it took us 14 years, but we were the first State that prohibited smoking in California air space, and now it's pretty universal. So I know what it takes to educate, when you make policy, that does no harm and does the best good.

And so I would think that you've got tremendously compelling arguments on the other side, and I hear you kind of stuck in what was. I'm wondering if you could be flexible to see what could be.

Dr. FUGH-BERMAN. I wouldn't be against doing long term studies with a reasonable hypothesis. However, it's generally considered unethical to study a drug with no proven benefit when we have evidence of harm.

Ms. WATSON. That is why you do a hypothesis. You make a proposal. And I also established bioethics committees in every hospital in the State of California, because we were having problems with the HMO movement and so on.

So I was, what I wanted to hear from, and anyone can response to this, maybe Dr. Brownstein, would you feel that it was ethical to start doing some short and long term studies to be able to determine with empirical evidence if this was an effective kind of treatment?

Dr. BROWNSTEIN. Well, certainly we need to do studies and answer as many questions as we can. I would agree with Dr. Berman, I think estrogens are a major problem in the environment. They're in pesticides, they're fattening up the animals with estrogens, they're in plastics. The natural estrogens are the least of any natural hormone that I use. I don't use them in most women, I don't use them in men. And I use a lot of the other natural hormones to reverse or improve people's health and help them get over their chronic illness.

Dr. HOTZE. And Congresswoman Watson, I have already initiated studies, and there are a lot of clinical studies. In fact, the PEPI study, which was completed in 1995, which is the Postmenopausal Estrogen Progestin Intervention study, and I think that was Government funded as well, first line of treatment for women on estrogen therapy, postmenopausal, the first line of treatment they said they needed natural progesterone first. But very few doctors prescribe natural progesterone, they all prescribe the counterfeit—provera, medroxyprogesterone and the other counterfeits, because that's what the drug companies sell.

The drug companies can't patent anything biologically identical. They can't do it. You can patent the strength or the formula, but you can't patent the hormone. There's no money in it for the drug companies. That's the way it is.

If there's no money in it, they're not going to promote it. And that's why we in private practice, like Dr. Brownstein and myself and hundreds and thousands of other doctors across the country and compounding pharmacists have embraced, we've seen what it's done to our patients, and I would say for Dr. Berman, I would be glad to offer her a one person test, I invite you to come to our office in Houston, be worked up, be evaluated, do a 2-month trial and see how you feel.

Dr. FUGH-BERMAN. Thank you. That would save me $3,000.

Dr. HOTZE. Yes, it would, it would save you that. I'd be glad to. Then you could do it from personal experience, see how you feel and then talk about it. Because I've been on both sides of the aisle. I was over on your side of the aisle at one time, too. But I decided to challenge it, think out of the box, think unconventionally. And believe it or not, the world would always be the same if people never thought out of the box and thought conventionally. Thank God you all didn't.

Congresswoman Watson, if you hadn't been willing to challenge the tobacco industry and everybody said, you're crazy as you can be——

Ms. WATSON. Do you know what my last proposal to my colleagues was? I was commissioning the University of California to research the connection between wrinkling and smoking. Well, the guys almost laughed me off the floor.

Dr. HOTZE. And they're doing it now probably.

Ms. WATSON. The bill passed. Three years later, they came back and made the connection and the rest is history.

Dr. HOTZE. There you go. And of course, Congressman Burton too, with the mercury problem.

Mr. BURTON. I thought you were going to talk about my wrinkles. [Laughter.]

Go ahead, I'm just kidding.

Dr. HOTZE. But you thought out of the box and challenged the conventional thinking on mercury, both of you have. And to your credit. That's wonderful. Thank God for you all being willing to do that. And that's what we need, people in the medical community to challenge it. All you have to do is listen to women and the way they're treated and how they feel and they're not being taken care of.

There's a revolution coming. The doctors in this room and across the country, they don't even know it's coming. But there are going to be women like Vicki Reynolds that go, Doctor, guess what, I'm firing you, good-bye, click.

Mr. BURTON. In any event, what I'd like to do, because it's getting late and some of you have to catch planes and so forth, I'd like to have your recommendations on what we can do to make holistic medicine and these complementary and alternative therapies more available and also, any information you have on the safety of them and the efficacy of them.

Dr. HOTZE. I will send you that.

Mr. BURTON. We would like to have that.

And you said something about a letter earlier.

Dr. HOTZE. A letter to the FDA. And if I could have your permission to visit with one of your staff members——

Mr. BURTON. Yes. I think Mindi and Brian, Brian is my right arm in the office. Brian and Mindi will be happy to sit down with you and talk with you about that.

Dr. HOTZE. Thank you very much.

Ms. PETERSEN. Chairman Burton, if I might say something.

Mr. BURTON. Sure.

Ms. PETERSEN. I would like to propose that we have a money back guarantee.

Mr. BURTON. What?

Ms. PETERSEN. A money back guarantee.

Mr. BURTON. On what?

Ms. PETERSEN. On health care. If you go to your doctor and he doesn't get you healthy and that prescription you got doesn't make you better, money back.

Mr. BURTON. You know, I want to tell you, that's a very interesting statement. We have 600 lobbyists in Washington that represent the pharmaceutical industry, 600. There's 535 Members of Congress and the Senate. They outnumber us. And any time we talk about, Congresswoman Watson and myself, or anybody else talks about anything, you would not believe the attacks and everything else that takes place.

Just to give you a little aside, so you'll know why I'm saying that what you're talking about is crazy, because it's never going to happen, is that in Canada, a woman who buys tamoxifen can buy it for $50, $60, and it's a very big help for women that have had cancer. In the United States, it costs as much as $350 for a 30 day supply. And yet the Food and Drug Administration and the pharmaceutical companies and everybody else have said, oh, my gosh, we don't want reimportation. And they come up with a million reasons why we can't have it.

That's just one example. There are hundreds and hundreds and hundreds of pharmaceutical products that cost four, five, six, seven times as much here as they do elsewhere. And yet the pharmaceutical companies have been fighting like crazy to stop reimportation. They are a very, very powerful lobby. And doctors, I think a lot of doctors probably would not be aware of a lot of things, so I'm not sure they're going to give you a money back guarantee on things they're not aware of, so I don't think that's going to happen.

In any event, I would like to have from you, including you, Dr. Fugh-Berman, I'd like to have any recommendations that you have that you think we could utilize to help the health of women. And don't forget the men. You haven't talked much about the men today, and you know, I'm getting up there, I'd kind of like to know how I can be more virile and keep my hair and keep the color down. So if you have any testosterone with you, throw a couple packages up here for me before you leave. [Laughter.]

In any event, thank you all for being here. Did you have any other questions, Ms. Watson?

Ms. WATSON. No, thank you, Mr. Chairman.

Mr. BURTON. But I would like to have anything you think we should be doing in writing, so we can followup on it, because we will do that.

Thank you very much. We stand adjourned.

[Whereupon, at 5:35 p.m., the subcommittee was adjourned, to reconvene at the call of the Chair.]

[Additional information submitted for the hearing record follows:]

August 2, 2004

The Honorable Dan Burton
U.S. House of Representatives
Committee on Government Reform
Washington, DC 20515

Dear Congressman Burton:

Thank you very much for holding the hearing on natural hormones in the Human Rights and Wellness Subcommittee. You provided an unusual opportunity to explore the complicated issues that these products raise for consumers and the very important implications they have for the health of women and men. And thank you, as well, for giving me the opportunity to testify before the committee on this topic. I hope you will consider the information that I provided in the context of advancing public health in this area.

As you requested, I'm writing to follow-up on some of the questions and concerns that you and Congresswoman Watson raised and also to offer my recommendations of future actions that might help ensure consumers' access to safe and effective complementary and alternative therapies.

I deeply appreciate and applaud your strong criticism of past use of synthetic hormones for women at menopause. As you know too well, the history of menopause hormone therapy has been a triumph of marketing over science. Over the decades that drug companies and doctors have spent telling women to take estrogen/progestin without doing long-term studies to determine whether the claims they were making were supported by evidence, the National Women's Health Network (NWHN) has persistently questioned this practice. (As you requested, I've enclosed information about the funding sources of the NWHN.)

Since its founding in 1975, the NWHN has criticized routine hormone therapy, pushing for better patient information warnings about risks and leading the advocacy for independent research to uncover the truth about the risks and benefits of these drugs. We pushed the National Institutes of Health (NIH) to fund the Women's Health Initiative (WHI) at a time when some doctors argued that the benefits of menopausal hormone therapy were so well known that it would be unethical to do a randomized controlled trial of hormones, and we petitioned Congress successfully to fund a large NIH study to

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look at whether or not birth control pills increase breast cancer risk. We've been a unique source of reliable, science-based information about hormone therapy for consumers, publishing the sixth edition of our book *The Truth About Hormone Replacement Therapy: How to Break Free from the Medical Myths of Menopause* in 2002. (Our first edition was in 1989.) Since the Women's Health Initiative results have come out, we've debunked criticism by doctors and drug company-supported organizations that want to undermine its findings.

I am very concerned that women may be about to go through a very similar experience with natural hormones. Just as drug companies made unproven safety and efficacy claims for synthetic hormones, claims made for natural hormone products are not supported by evidence. Representative Watson was right to point out that there haven't been studies of natural hormones on the scale of the WHI yet, but what studies have been done (abstracts enclosed) are worrisome. Natural hormones seem to carry the same risks as synthetic hormones – increased breast cancer and endometrial cancer – and research to date shows them to be effective only for hot flashes, not for cardiovascular disease prevention or other health promotion claims that compounding pharmacies and clinicians are making. While my testimony focused on natural estrogens, no better evidence supports the routine use of progesterone, testosterone, DHEA, cortisol, or thyroid hormone in healthy people, and all of these hormones carry health risks.

I wouldn't consider it a priority to advocate for a study to look further at natural hormones, because the data we have to date shows that natural hormones and synthetic hormones have similar risks. I'm disturbed to see the same women who have been misled for years by synthetic hormone promoters being targeted by natural hormone marketers in the same absence of evidence demonstrating safety and effectiveness.

At the close of the hearing, you asked for suggestions about how to improve access to alternative therapies. The recommendations below address that as well as how to ensure that alternative therapies that consumers have access to are safe and effective.

1) Ask the Federal Trade Commission (FTC) to look into false marketing claims being made for some natural hormones. For the sake of space, I will provide two examples here and would be glad to send information about others if you or the FTC would like more. **Examples:** Premier Pharmacy states on its website (http://www.premier-pharmacy.com) that the BellaFem® hormones it sells protect against breast cancer, endometrial cancer and heart disease. Signature Pharmacy similarly states on its website (http://www.signaturepharmacy.com) that the natural hormone therapy it sells protects against heart disease and "is safe, sensible, effective and free from side effects caused by synthetic hormones."

2) Ask FDA to require compounding pharmacies to enclose information about the known risks of hormones with compounded prescriptions of those hormones.

3) Recognizing your concern about the NIH budget, I respectfully suggest that one of the best ways to support greater access to complementary and alternative medicine is to encourage research and education on the safety and effectiveness of complementary and alternative medicine. The National Center for Complementary and Alternative Medicine and the Office of Dietary Supplements both do that and are worthy of your support.

If you have any questions about these recommendations, please don't hesitate to contact me. The staff of the National Women's Health Network and I would be happy to work with you and your staff on any of them. Thank you again for holding the hearing, for giving me the opportunity to testify and for accepting these suggestions regarding next steps.

Sincerely,

Adriane Fugh-Berman M.D.
Associate Professor, Department of Physiology and Biophysics
Georgetown University School of Medicine
Medical Advisor, National Women's Health Network

cc: The Honorable Diane Watson
U.S. House of Representatives
Washington, DC 20515

Following are a few abstracts from MEDLINE that refute the claim that "natural" estrogens are safe. The abstracts are reproduced from MEDLINE (National Library of Medicine's international database). I have underlined some key points, and the summaries in italics are mine. I have also enclosed articles on progesterone.

Natural hormones and breast cancer risk

An analysis of eight studies, and two studies since that analysis, have consistently found that higher levels of naturally-occurring estrone and estradiol are associated with increased breast cancer risk in menopausal women. Estrone was most strongly associated with risk. Breast tissue from women with breast cancer has higher levels of estriol, estrone, estradiol, than breast tissue from women without breast cancer. In breast cancer cell lines, estriol stimulated breast cancer cell growth more than other estrogens.

Postmenopausal levels of oestrogen, androgen, and SHBG and breast cancer: long-term results of a prospective study. Zeleniuch-Jacquotte A, Shore RE, Koenig KL, Akhmedkhanov A, Afanasyeva Y, Kato I, Kim MY, Rinaldi S, Kaaks R, Toniolo P. Br J Cancer. 2004 Jan 12;90(1):153-9.

We assessed the association of sex hormone levels with breast cancer risk in a case-control study nested within the cohort of 7054 New York University (NYU) Women's Health Study participants who were postmenopausal at entry. The study includes 297 cases diagnosed between 6 months and 12.7 years after enrollment and 563 controls. Multivariate odds ratios (ORs) (95% confidence interval (CI)) for breast cancer for the highest quintile of each hormone and sex-hormone binding globulin (SHBG) relative to the lowest were as follows: 2.49 (1.47-4.21), P(trend)=0.003 for oestradiol; 3.24 (1.87-5.58), P(trend)<0.001 for oestrone; 2.37 (1.39-4.04), P(trend)=0.002 for testosterone; 2.07 (1.28-3.33), P(trend)<0.001 for androstenedione; 1.74 (1.05-2.89), P(trend)<0.001 for dehydroepiandrosterone sulphate (DHEAS); and 0.51 (0.31-0.82), P(trend)<0.001 for SHBG. Analyses limited to the 191 cases who had donated blood five to 12.7 years prior to diagnosis showed results in the same direction as overall analyses, although the tests for trend did not reach statistical significance for DHEAS and SHBG. The rates of change per year in hormone and SHBG levels, calculated for 95 cases and their matched controls who had given a second blood donation within 5 years of diagnosis, were of small magnitude and overall not different in cases and controls. The association of androgens with risk did not persist after adjustment for oestrone (1.08, 95% CI=0.92-1.26 for testosterone; 1.15, 95% CI=0.95-1.39 for androstenedione and 1.06, 95% CI=0.90-1.26 for DHEAS), the oestrogen most strongly associated with risk in our study. Our results support the hypothesis that the associations of circulating oestrogens with breast cancer risk are more likely due to an effect of circulating hormones on the development of cancer than to elevations induced by the tumour. They also suggest that the contribution of androgens to risk is largely through their role as substrates for oestrogen production.

Postmenopausal breast cancer risk in relation to sex steroid hormones, prolactin and SHBG (Sweden). Manjer J, Johansson R, Berglund G, Janzon L, Kaaks R, Agren A, Lenner P. Cancer Causes Control. 2003 Sep;14(7):599-607.

OBJECTIVE: High levels of sex steroid hormones and prolactin have been suggested to enhance breast cancer development. Low levels of SHBG may indicate high levels of (bio-available) steroid hormones. The present study investigates whether high levels of sex steroid hormones and prolactin, and/or low levels of SHBG, are associated with high breast cancer risk. METHODS: Blood samples were collected in about 65,000 women participating in two population-based prospective cohort studies in Sweden. Follow-up yielded 173 postmenopausal breast cancer cases who had not been exposed to HRT. Levels of estrone, estradiol, SHBG, FSH, prolactin, testosterone, androstenedione and DHEAs were analysed in cases and 438 controls. Logistic regression analysis yielded odds ratios (ORs), with 95% confidence intervals, adjusted for potential confounders. RESULTS: The risk of breast cancer was associated with the

highest versus lowest quartiles of estrone, OR: 2.58 (1.50-4.44), estradiol (dichotomised: high versus low) (1.73: 1.04-2.88), and testosterone (1.87: 1.08-3.25). High risks, although not statistically significant, were seen for androstenedione (1.58: 0.92-2.72) and DHEAs (1.62: 0.89-2.72). No strong associations were seen between SHBG or prolactin and risk of breast cancer. CONCLUSIONS: High levels of estrone, estradiol, testosterone, and possibly androstenedione and DHEAs, in postmenopausal women are associated with a high risk of subsequent breast cancer.

Sex steroid hormones in serum and tissue of benign and malignant breast tumor patients. Mady EA, Ramadan EE, Ossman AA. Dis Markers. 2000;16(3-4):151-7.

The ability of breast tumors to synthesize sex steroid hormones is well recognized and their local production is thought to play a role in breast cancer development and growth. The aim of this study was to estimate local intra-tumoral and circulating levels of Estrone (E1), Estrone Sulfate (E1S), Estradiol (E2), Estriol (E3), and Testosterone (T) in 33 pre- and postmenopausal women with primary breast cancer in comparison to 12 pre- and postmenopausal women with benign breast tumors. The mean levels of the studied sex hormones were higher in serum and tumor tissue of breast cancer women than those with benign breast tumors apart from Testosterone which showed a significant decrease in pre- and postmenopausal women with breast cancer ($P<0.001$for follicular phase, $P<0.05$ for luteal phase, and $P<0.005$ for postmenopausal). The levels of the five hormones were significantly higher intra-tumoral than in serum of both benign and malignant breast tumor women with E1S as the predominant estrogen. There was only a positive significant correlation between serum and tumor tissue levels of E1 ($rs=0.52$, $P<0.05$ for follicular; $rs=0.63$, $P<0.05$ for luteal and $rs=0.58$, $P<0.05$ for postmenopausal) and a significant correlation between serum and tumor tissue of T ($rs=0.64$, $P<0.05$ for follicular; $rs=-0.51$, $P<0.05$ for luteal and $rs=-0.81$, $P<0.04$ for postmenopausal).

Urinary endogenous sex hormone levels and the risk of postmenopausal breast cancer. Onland-Moret NC, Kaaks R, van Noord PA, Rinaldi S, Key T, Grobbee DE, Peeters PH. Climacteric. 2001 Mar;4(1):42-8.

To assess the relation between urinary endogenous sex steroid levels and the risk of postmenopausal breast cancer, a nested case-cohort study was conducted within a large cohort (the DOM cohort) in the Netherlands (n=9,349). Until the end of follow-up (1 January 1996), 397 postmenopausal breast cancer cases were identified and a subcohort of 424 women was then taken from all eligible women.
Women using hormones were excluded, leaving 364 breast cancer cases and 382 women in the subcohort for the analyses. Concentrations of oestrone, oestradiol, testosterone, 5alpha-androstane-3alpha, 17beta-diol and creatinine were measured in first morning urine samples, which had been stored since enrolment at –20 degrees C. A Cox proportional Hazards model was used, with Barlow's adjustment for case-cohort sampling, to estimate breast cancer risk in quartiles of each of the, creatinine corrected, hormone levels, the lowest quartile being the reference group. Women with higher

levels of all four of the hormones were at increased risk for postmenopausal breast cancer (highest vs lowest quartile: incidence rate ratio for oestrone (IRR(oestrone)=2.5, 95% CI: 1.6-3.8; IRR(oestradiol)=1.5, 95% CI: 1.0-2.3; IRR(testosterone)=1.6, 95% CI: 1.0-2.4; IRR(5alpha-androstane-3alpha, 17beta-diol)=1.7, 95% CI: 1.1-2.7). In conclusion, women with higher excretion levels of both oestrogens and androgens have an increased risk of breast cancer.

The effect of endogenous estradiol metabolites on the proliferation of human breast cancer cells. Lippert C, Seeger H, Mueck AO. Life Sci. 2003 Jan 10;72(8):877-83.

Evidence is accumulating that estradiol metabolites may be involved in carcinogenesis as some metabolites exert proliferative and others anti-proliferative properties on human cancer cells. The present study is the first to investigate the effect of 14 endogenous estradiol metabolites on the proliferation of the human breast cancer cell line, MCF-7, in comparison with the effect of the parent substance 17beta-estradiol with special concern on high pharmacological concentrations. The steroids were tested in the range from 10(-8) to 10(-5) M on MCF-7 cells which were incubated for nine days. Estradiol and almost all A-ring metabolites displayed biphasic reactions on cell proliferation, i.e. stimulatory at low concentrations and inhibitory at the highest concentration, 10(-5) M. The D-ring metabolites did not show such clear biphasic patterns, in most of them the stimulatory effect prevailed at the highest dosage used. The strongest inhibitory effect was seen for the A-ring metabolite 2-methoxyestradiol at the concentrations of 10(-6) and 10(-5) M and the strongest stimulatory effect was noted for the D-ring metabolite estriol at the same concentrations.The results indicate that some A-ring metabolites might be suitable for breast cancer treatment when used in high dosages. This is of special interest, since many of these metabolites have very weak estrogenic activity.

Natural hormones and cardiovascular disease

In randomized controlled trials, estradiol did not reduce stroke in women at high risk and did not reduce heart attack in women with a previous heart attack. In the observational Danish Nurse Study, in which most women on hormones used estradiol, hormone therapy was associated with increased stroke in hypertensive women and increased heart disease and death in diabetics.

A clinical trial of estrogen-replacement therapy after ischemic stroke.
Viscoli CM, Brass LM, Kernan WN, Sarrel PM, Suissa S, Horwitz RI. N Engl J Med. 2001 Oct 25;345(17):1243-9.

BACKGROUND: Observational studies have suggested that estrogen-replacement therapy may reduce a woman's risk of stroke and death. METHODS: We conducted a randomized, double-blind, placebo-controlled trial of estrogen therapy (1 mg of

estradiol-17beta per day) in 664 postmenopausal women (mean age, 71 years) who had recently had an ischemic stroke or transient ischemic attack. Women were recruited from 21 hospitals in the United States and were followed for the occurrence of stroke or death. RESULTS: During a mean follow-up period of 2.8 years, there were 99 strokes or deaths among the women in the estradiol group, and 93 among those in the placebo group (relative risk in the estradiol group, 1.1; 95 percent confidence interval, 0.8 to 1.4). Estrogen therapy did not reduce the risk of death alone (relative risk, 1.2; 95 percent confidence interval, 0.8 to 1.8) or the risk of nonfatal stroke (relative risk, 1.0; 95 percent confidence interval, 0.7 to 1.4). The women who were randomly assigned to receive estrogen therapy had a higher risk of fatal stroke (relative risk, 2.9; 95 percent confidence interval, 0.9 to 9.0), and their nonfatal strokes were associated with slightly worse neurologic and functional deficits.
CONCLUSIONS: Estradiol does not reduce mortality or the recurrence of stroke in postmenopausal women with cerebrovascular disease. This therapy should not be prescribed for the secondary prevention of cerebrovascular disease.

Oestrogen therapy for prevention of reinfarction in postmenopausal women: a randomised placebo controlled trial. Cherry N, Gilmour K, Hannaford P, Heagerty A, Khan MA, Kitchener H, McNamee R, Elstein M, Kay C, Seif M, Buckley H; ESPRIT team. Lancet. 2002 Dec 21-28;360(9350):2001-8.

BACKGROUND: Results of observational studies suggest that hormone replacement therapy (HRT) could reduce the risk of coronary heart disease (CHD), but those of randomised trials do not indicate a lower risk in women who use oestrogen plus progestagen. The aim of this study was to ascertain whether or not unopposed oestrogen reduces the risk of further cardiac events in postmenopausal women who survive a first myocardial infarction. METHODS: The study was a randomised, blinded, placebo controlled, secondary prevention trial of postmenopausal women, age 50-69 years (n=1017) who had survived a first myocardial infarction. Individuals were recruited from 35 hospitals in England and Wales. Women received either one tablet of oestradiol valerate (2 mg; n=513) or placebo (n=504), daily for 2 years. Primary outcomes were reinfarction or cardiac death, and all-cause mortality. Analyses were by intention-to-treat. Secondary outcomes were uterine bleeding, endometrial cancer, stroke or other embolic events, and fractures. FINDINGS: Frequency of reinfarction or cardiac death did not differ between treatment groups at 24 months (rate ratio 0.99, 95% CI 0.70-1.41, p=0.97). Similarly, the reduction in all-cause mortality between those who took oestrogen and those on placebo was not significant (0.79, 0.50-1.27, p=0.34). The relative risk of any death (0.56, 0.23-1.33) and cardiac death (0.33, 0.11-1.01) was lowest at 3 months post-recruitment. INTERPRETATION: Oestradiol valerate does not reduce the overall risk of further cardiac events in postmenopausal women who have survived a myocardial infarction.

Increased risk of stroke in hypertensive women using hormone therapy: analyses based on the Danish Nurse Study. Lokkegaard E, Jovanovic Z, Heitmann BL, Keiding

N, Ottesen B, Hundrup YA, Obel EB, Pedersen AT. Arch Neurol. 2003 Oct;60(10):1379-84.
BACKGROUND: Recent randomized clinical trials suggest an increased risk of stroke with hormone therapy (HT), whereas observational studies have suggested mixed results. Differences in design, definitions of HT exposure, and stroke outcome may explain these discrepancies. Little attention has been paid to identifying subgroups of women who are particularly sensitive to HT. OBJECTIVES: To investigate the risk of various stroke outcomes among women using HT based primarily on estradiol-17beta (unopposed or combined with norethisterone acetate) and to assess the potential modifying effect by presence of risk factors for stroke. DESIGN: Prospective cohort study. SETTING: In 1993, the Danish Nurse Study was established, and questionnaires on lifestyle and HT use were sent to all Danish nurses older than 44 years, of whom 19,898 (85.8%) replied. PARTICIPANTS: Postmenopausal women (n = 13,122) free of previous major cardiovascular and cerebrovascular disease and cancer. MAIN OUTCOME MEASURE: Ischemic or hemorrhagic stroke (n = 144) identified in the national registries of hospital discharges and cause of deaths in the total follow-up through December 31, 1998. RESULTS: In 1993, 28.0% of the 13 122 were current HT users, 14.3% were past users, and 57.7% were never users. Overall, HT exposure was not consistently associated with stroke. However, subdivision based on the presence of hypertension showed a significantly increased risk of stroke among hypertensive women. Compared with hypertensive never HT users, an increased risk of total stroke was found with current use (hazard ratio, 2.35; 95% confidence interval, 1.16-4.74) and especially with current use of estrogen-progestin (hazard ratio, 3.00; 95% confidence interval, 1.33-6.76). Normotensive women had no increased risk of stroke with HT. CONCLUSIONS: We found an increased risk of stroke among hypertensive but not normotensive women using HT. The present study suggests that HT should be avoided in hypertensive women.

Relation between hormone replacement therapy and ischaemic heart disease in women: prospective observational study. Lokkegaard E, Pedersen AT, Heitmann BL, Jovanovic Z, Keiding N, Hundrup YA, Obel EB, Ottesen B. BMJ. 2003 Feb 22;326(7386):426.

OBJECTIVE: To investigate the risk of ischaemic heart disease and myocardial infarction among women using hormone replacement therapy, especially the potential modifying effect of cardiovascular risk factors. DESIGN: Prospective observational study. SETTING: Denmark. PARTICIPANTS: 19 898 nurses aged 45 and over completing a questionnaire on lifestyle and use of hormone replacement therapy in 1993. MAIN OUTCOME MEASURES: All cases of death and incident cases of ischaemic heart disease and myocardial infarction until the end of 1998. RESULTS: Current users of hormone replacement therapy smoked more, consumed more alcohol, had lower self rated health, but were slimmer and had a lower prevalence of diabetes than never users. In current users compared with never users, hormone replacement therapy had no protective effect on ischaemic heart disease (hazard ratio 1.2, 0.9 to 1.7) or myocardial infarction (1.0, 0.6 to 1.7), whereas current users with diabetes had

an increased risk of death (3.2, 1.4 to 7.5), ischaemic heart disease (4.2, 1.4 to 12.5), and myocardial infarction (9.2, 2.0 to 41.4) compared with never users with diabetes. CONCLUSION: Hormone replacement therapy showed no protective effect on ischaemic heart disease, but there was a significantly increased risk of death from all causes and ischaemic heart disease among women with diabetes.

Natural hormones and endometrial cancer

Low-potency oestrogen and risk of endometrial cancer: a case-control study.
Weiderpass E, Baron JA, Adami HO, Magnusson C, Lindgren A, Bergstrom R, Correia N, Persson I. Lancet. 1999 May 29;353(9167):1824-8.
BACKGROUND: Urogenital symptoms are common among postmenopausal women. Such symptoms may be alleviated by low-potency oestrogen formulations administered orally or vaginally. Although low-potency oestrogen formulations are assumed to have few, if any, adverse effects on the endometrium, risk of endometrial neoplasia has not been quantified. METHODS: In a nationwide population-based case-control study in Sweden of endometrial cancer among postmenopausal women, we obtained detailed information on hormone replacement from 789 cases of endometrial cancer and 3368 population controls. In a histopathological review, 80 cases were reclassified as having endometrial atypical hyperplasia. Odds ratios and 95% CI were calculated with unconditional logistic regression.
FINDINGS: After multivariate adjustment, oral use of oestriol 1-2 mg daily increased the relative risk of endometrial cancer and endometrial atypical hyperplasia: the odds ratios for at least 5 years of use compared with never use were 3.0 (95% CI 2.0-4.4) and 8.3 (4.0-17.4), respectively. The association was stronger for well-differentiated cancers and those with limited invasion. The excess relative risk was lost rapidly after cessation of treatment. Only weak associations were observed between vaginal application of low-potency oestrogen formulations and relative risk of endometrial neoplasia.
INTERPRETATION: Oral, but not vaginal, treatment with low-potency oestrogen formulations increases the relative risk of endometrial neoplasia. Thus close surveillance of patients is needed, and addition of a progestagen should be considered.

NATIONAL WOMEN'S HEALTH NETWORK

2003 Annual Report

NATIONAL WOMEN'S HEALTH NETWORK | Strategic Framework

MISSION

The National Women's Health Network improves the health of all women by developing and promoting a critical analysis of health issues to influence public policy and support consumer decision-making. The Network aspires to a health care system that is guided by social justice and reflects the needs of diverse women.

CORE VALUES:

- We value women's descriptions of their own experiences and believe that health policy should reflect the diversity of women's experiences
- We believe that evidence rather than profit should drive the services offered and information that is made available to women to inform their health decision-making and practices
- We value analysis of science that takes into consideration systems of power and oppression
- We believe that the government has an obligation to safeguard the health of all people
- All women should have access to excellent health care
- Women's normal physiological changes over the lifespan should not be unduly medicalized

LONG-RANGE GOALS:

- The establishment of universal health care that reflects the values of the Network and meets the needs of diverse women
- To create a cultural and medical shift in how menopause is currently perceived and addressed
- Ensure that women have self-determination in all aspects of their reproductive and sexual health

DEAR NWHN MEMBERS AND SUPPORTERS,

In 2003 NWHN celebrated important successes on menopause and silicone breast implants, for which we worked long and hard. These proud moments reminded us that our fights for women's health take forward thinking and long-term commitment. We invested this year in intensive strategic planning to establish three priority policy goals. We would like to share with you the highlights of our 2003 successes and our ambitious plans for the future.

After decades of NWHN's work, women now have information vital to deciding whether to take hormones after menopause. NWHN's insistence that important questions about the safety and effectiveness of menopause hormone therapy had not been answered led the federal government to undertake the Women's Health Initiative. Now women know hormones don't prevent heart disease or Alzheimer's, but do increase the risk of blood clots, stroke and breast cancer.

Also for decades, NWHN insisted that women who wanted to use breast implants deserved devices proven to be safe, pointing out that careful studies of implants used by women for many years had not been done. The FDA now requires that manufacturers meet higher, scientifically-proven safety standards, and conduct more research on the risk of implant rupture and leakage before they will approve silicone gel-filled implants.

In 2003, NWHN's board of directors looked ahead 10–15 years to determine the most important goals we need to accomplish to improve the health of all women. Our long-term goals are ambitious: universal access to health care that meets the needs of diverse women; respect and support for the reproductive health choices of all women; and a shift away from treating women going through menopause (and other natural bodily processes) first and foremost as targets for drug company marketing campaigns.

To achieve these goals in the years to come NWHN will need to remain active and vigilant in defending women's health from attacks and setbacks. Our continued strength as an independent voice for women's health depends on your help. Your support of NWHN and your actions on behalf of important women's health issues make all the difference. Thanks to all of you, for you are the Network.

Sincerely,

Cynthia A. Pearson
EXECUTIVE DIRECTOR

Sonja Herbert, M.P.H.
CHAIR, BOARD OF DIRECTORS

NATIONAL WOMEN'S HEALTH NETWORK

Year in Review

OUR GOALS AND ACCOMPLISHMENTS

To ensure that women have self-determination in all aspects of their reproductive and sexual health.

In support of this goal, NWHN's program brings together our recent work on women's sexual health with our long-standing commitment to abortion rights, informed consent and choice in family planning, and integration of STD/HIV prevention with contraceptive concerns.

ACCOMPLISHMENTS IN 2003

- Throughout this year, NWHN has been a leading voice sounding the alert about the Bush Administration's politicization of science, being quoted in January by one of the first mainstream editorials commenting on the problem, published in the *San Francisco Chronicle.*
- In advance of the Food and Drug Administration's advisory committee meeting on emergency contraception (EC), NWHN conducted a petition campaign in support of making EC available without prescription, collecting more than 8,700 signatures.
- At the International Consultation on Erectile and Sexual Dysfunction, NWHN participated in a debate attended by more 1,000 conference participants on how the pharmaceutical industry is medicalizing treatment of women's sexual problems.
- NWHN participated in a meeting held by the National Cancer Institute on the alleged connection between abortion and breast cancer, serving as the primary liaison from the meeting to the reproductive health advocacy community.
- With the introduction of Seasonale, the new contraceptive pill that suppresses monthly menstruation, NWHN produced an analysis of the safety of the product, highlighting our concerns about misleading and over-promising promotion efforts.
- NWHN's *Network News* published an interview with a leading U.S. medical abortion provider about her success in establishing medical abortion services at her clinic, the important role played by mid-level providers in the practice, and her frustrations at the resistance among private practice physicians to offering women a medical abortion option.

To create a cultural and medical shift in how menopause is currently perceived and addressed.

In support of this goal, NWHN's program builds on our long history of work as a critic of the medicalization and marketing of menopause. This year in particular, we've sought to take advantage of the opportunities for change created by the release of results from the Women's Health Initiative (WHI), the first large, long-term study of hormone therapy for healthy women.

ACCOMPLISHMENTS IN 2003

- NWHN has been a leading media spokesperson on hormone therapy as the WHI results continued to emerge this year. We were quoted in stories appearing in numerous publications including *The Washington Post, The New York Times,* the *Los Angeles Times* and *The Boston Globe.*
- Responding to women's questions and concerns about the new research findings on hormone therapy, NWHN disseminated information on this topic to many thousands of women through our information clearinghouse, by making presentations at numerous health and women's conferences, and by distributing our new fact sheet series on hormone therapy. We were able to reach an international audience when our critical analysis was featured in a major documentary produced by the Canadian public television company.
- NWHN presented testimony supporting changes in the regulation of menopause hormone therapy drugs at an FDA meeting on the "Women's Health Initiative Study Results: Implications for the use of hormone therapy."

NATIONAL WOMEN'S HEALTH NETWORK

2003 Financial Statement*

REVENUES	
Foundations	$333,164
Membership	$370,255
Other	$39,383
Total Revenues	**$742,782**

2003 REVENUE BREAKDOWN

The establishment of universal health care that reflects the values of the Network and meets the needs of diverse women.

In support of this goal, NWHN's program supports efforts to make health care accessible to all women and identifies and advocates for health care system changes that are needed to make the health care system responsive to the needs of diverse women.

Accomplishments in 2003

- At the SisterSong Women of Color Collective's first National Conference on Reproductive Health and Sexual Rights, NWHN presented a panel on *Not Just About "Choice": Barriers, Restrictions and Abuses and Health Access for Women of Color*
- NWHN's *Network News* published "Operation Medicaid: the War on Women," an article detailing the efforts underway to undermine the capacity and effectiveness of the Medicaid program to meet the medical needs of low-income women.
- NWHN led a lobby team of breast cancer activists who advocated with members of the Congress for increased access to health care.
- At the invitation of the National Institutes of Health Office for Research on Women's Health, NWHN addressed a scientific workshop about Recruitment and Retention of Women in Clinical Studies on making research responsive to consumer needs and priorities.

Interns pictured above: Katie O'Connor, Shireen Tawil, Sarah Gutin, Sinduja Srinivasan.

Helen Rodriguez-Trias Women's Health Leadership Program

NWHN continues to cultivate future leaders in women's health through our Helen Rodriguez-Trias Health Leadership Program. 11 bright and enthusiastic interns from all over the country enriched work in 2003. The interns ranged from ages 20–26, and three were women of color. Their fields of study included: anthropology, biology, economics, history, medicine, psychology, public health and women's studies. The interns updated 10 of NWHN's informational packets on topics ranging from Alternative Medicine to Female Orgasm. Interns also provided instrumental assistance with numerous program and policy projects including school nutrition, consumer-directed promotion of prescription drugs, and silicone gel breast implants. 2003 brought new opportunities for NWHN interns: Sarah Gutin, a summer intern, conceived our empowering new slogan, "A Voice For Women, A Network For Change," and our fall interns wrote the first "Young Feminist" feature, a section which will appear in every issue of NWHN's newsletter *The Women's Health Activist*.

NWHN 2003 Board of Directors

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Theresa Rust Smith, Ph.D.
Mariamne Whatley, Ph.D.
Jane Sprague Zones, Ph.D.

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Amy Allina *Program Policy Director*
Stephanie Donne *Program Coordinator*
Tara Edwards *Development specialist*
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Natalie Moss *Financial Manager*
Leah Thayer *Newsletter Editor*
Beverly Thomas *Membership Coordinator*
Joi Washington *Office Coordinator*

Interns:
Carmel Anderson, Jennifer Cook, Linda Galib, Sarah Gutin, Kiersten Hoskisson, Rachel Kiesel, Katie O'Connor, Devon Quasha, Grace Shih, Sinduja Srinivasan, Shireen Tawil

EXPENSES PROGRAM SERVICES

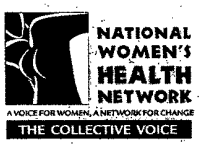
Public Policy Programs	$228,411
Member Services	$225,051
Information Clearinghouse & Women's Health Leadership	$55,530
Total Program Services	**$508,992**

EXPENSES SUPPORT SERVICES

Administrative	$56,426
Resource Development	$78,791
Total Support Services	**$135,217**

2003 EXPENSES BREAKDOWN

NWHN does not accept funding from pharmaceutical companies, medical device manufacturers or tobacco companies.
*Note: These are preliminary figures based on NWHN's internal year end bookkeeping. Audited financial statements will be available from NWHN.



NWHN's *Collective Voice* is comprised of a special group of supporters who go a little above and beyond, people who make special contributions to NWHN through their creativity, time, or financial giving. You can become part of our *Collective Voice* by engaging in any of the following: donate $250 or more; enroll as monthly sustainer; host a party benefiting NWHN; circulate NWHN materials; intern at NWHN, or serve on our Board of Directors.* As always, NWHN thanks you for your ongoing support!

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