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## **PRESS RELEASE & ACTION ALERT**

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**PBS's "The New Medicine" Draws Ire of Female Patients Over Sponsor Wyeth's Attempt to Limit Women's Health Options : FDA Comment Deadline Approaches**

Croton on Hudson, NY

The Bravewell Collaborative, originator of the PBS documentary "The New Medicine" (aired 3/29 /06), posts a 'Declaration for A New Medicine' on its website ([www.bravewell.org](http://www.bravewell.org)), deeply honoring patients. However, it's fifth principle, 'We support truly integrative medicine that offers the highest standards of excellence in a full and complete array of care modalities'. At the same time, one of the of the documentary's sponsors, Wyeth (NYSE: WYE , <http://www.wyeth.com>), is seeking to eliminate access to Bio Identical hormones used for female hormone replacement therapy which compete with their products through an FDA 'Citizen's Petition'.

Urgent action is required since the deadline for comments to the FDA on this issue is April 4, 2004. [Testimony](#) and opinions can be offered electronically at

[http://www.democracynaction.org/dia/organizationsORG/healthfreedomusa/campaign.jsp?campaign\\_KEY=3246&t=wyethpage.dwt](http://www.democracynaction.org/dia/organizationsORG/healthfreedomusa/campaign.jsp?campaign_KEY=3246&t=wyethpage.dwt)

Wyeth manufactures and markets two synthetic hormone products, Premarin and Prempro. Bioidentical hormones are a natural hormone replacement option used by

large numbers of women following the highly publicized dangers of Premarin and Prempro which led to the early termination of a massive National Institutes of Health clinical study when Premarin and Prempro were found to increase life threatening conditions in menopausal and older women without conferring any protective benefit. Natural hormones provide protection without the risks associated with the synthetic hormones.

Women taking compounded bio-identical hormones have been actively organizing in recent weeks to combat Wyeth's attempt to eliminate patient's right to buy, and doctor's right to prescribe, low-risk, inexpensive, natural, bio-identical, plant-based hormones. Consumer and physician comments on Wyeth's petition to eliminate competition to their higher-risk, patented drugs must be received by the FDA by April 4, 2006.

Rima Laibow, MD, Medical Director of The Natural Solutions Foundation (<http://www.HealthFreedomUSA.org>), an international health freedom watchdog organization based in NY dedicated to preserving patients' right to choose natural health solutions, says "It may come as a shock to the millions of women using these safer, gentler, natural hormones that the 3/29 PBS documentary "The New Medicine" was sponsored in part by Wyeth". She adds, "Wyeth is deeply entrenched in the 'old medicine'. Consumers have to wonder when a company uses corporate sponsorship opportunities to position an organization as 'patient friendly' while simultaneously seeking to limit patients' options in the interest of their bottom line".

Evelyn Timmons, RPh, President of Arizona Apothecaries/dba Mountain View Pharmacy in Paradise Valley, AZ, Former President of the American College of Apothecaries and past Board Member of the (International Academy of Compounding Pharmacists, [www.iacprx.org/site/PageServer?pagename=home\\_page](http://www.iacprx.org/site/PageServer?pagename=home_page)), adds "While we applaud the production of "The New Medicine", we suspect its originators may have been misled about the intentions of Wyeth with regard to patient health care options and health freedom. Wyeth, with its FDA Citizens Petition, is trying to seriously erode women's rights to choose the safest, most natural care".

"Its not new that the drug industry tries to protect and expand its turf", Mrs. Timmons says, "But there has been an increase in 'junk science' debunking the value of both nutritional supplements and compounded medicines in direct proportion to the growth and tremendous acceptance of Complementary & Alternative Medicines over the past five years. Right now we're at a critical juncture where patient rights are being seriously challenged on many fronts—from hormones to supplements. We need to wake up fast."

Timmons, a five decade veteran of the compounding industry says, "Never before has there been a time of greater urgency and concern where patients and physicians need to come together to protect their rights".

**It is well known that Wyeth, with brands such as Premarin (c)—the conjugated estrogen made from pregnant mare's urine—and Prempro (c), the conjugated estrogen and synthetic progesterone drug (known as 'progestin'), has seen sales of these drugs fall dramatically in recent years due to the 2002 Women's Health Initiative (WHI) report which indicated Premarin and Prempro cause a significant increase in breast cancer, blood clots to the lungs, heart attacks and strokes. "Because of these shocking revelations", Dr. Laibow says, "women have been shifting in recent years in very large numbers to doctors who can support their health by prescribing natural hormones."**

**Camilla Rees, San Francisco based Integrative Care Counselor and founder of The Wide Angle Health Network predicts even more efforts to limit patients' rights in the future, especially if this one succeeds. "With growth in consumer driven health care, where both financial and health responsibility is shifting back to patients, people everywhere are becoming more active in taking back their health choices, which will be very good for outcomes and costs. So it's not surprising the pharmaceutical industry may want to disparage other forms of competition at this time". She adds, "If enough practitioners and patients alike voice their concerns before the April 4th, 2006 FDA deadline, I trust the FDA will do the right thing to support women."**

**Leading New York City OB/GYN, Allan Warshowsky, M.D., who has used bioidentical hormones successfully with thousands of patients over two decades, explains "There are entire assortments of natural hormones which are made in the lab from soy or wild yam. These food-based hormones are 'bio-identical' to the hormones that were produced in the women's ovary before menopause, and because of this they are much less likely to cause problems. Since they are the same hormones in chemical structure that the body has been detoxifying and excreting for years, they are less likely to stimulate either breast or uterine cancer. The synthetic hormones, in contrast, are not able to be thoroughly and efficiently detoxified from the body, and this leads to a plethora of negative effects women think are related to menopause but are really related to their treatment".**

**Most importantly, he says, women should be aware of the risks of synthetic hormones leading to other diseases. "There are two recent studies showing not only an increase in breast cancer with synthetic HRT, but an even higher risk when the so-called protective effects of Provera (synthetic progesterone, called 'progestin') are added in". Dr. Warshowsky, the former director of the Women's Program at Beth Israel Medical Center's Center for Health and Healing and author of "Healing Fibroids: A Doctor's Guide to a Natural Cure," says "There is enough information at this time to recommend all women on HRT be switched to the natural alternative".**

**With 80 million women either in or approaching menopause, Dr. Warshowsky indicates Wyeth's attempt to eliminate the safest options for women presents a**

**"major national health issue".**

**Ana Micka, President of Citizens for Health (www.citizens.org) , Washington, D.C. , says "It's possible the Wyeth challenge will be a catalyst for a patient uprising the likes of which we have never seen before. Already, grass roots women's groups are planning a march on Washington to protest Wyeth's behavior". She says Citizens for Health has called on its greater than 100,000 activists who have taken action on natural health issues in the past to oppose the Wyeth petition to the FDA. "We at Citizens do not believe women will ever let the Wyeth petition succeed", says Micka.**

**Julianne Bergdale, RNP, of Camelback Women's Health in Phoenix, AZ, has been involved in women's health treatment as a practitioner for 30 years. She says it is rare in her large practice that women are not overwhelmingly satisfied with the effects of bioidentical hormones, and that most women find them "a godsend". She comments, "Since I've been prescribing natural hormones, I have been delighted to discover how much more pleased patients have been and how few side effects they report. It is a rather strange circumstance when a pharmaceutical company is trying to eliminate the competition—when that competition is working especially well for patients!"**

**Backlash to the Wyeth petition to the FDA that attempts to limit women's freedom of choice has hit Wyeth hard. In recent weeks, many physician groups and patient advocate organizations, including Women's International Pharmacy; The Schwarzbein Institute, Julian Whitaker, MD, The Health Sciences Institute, Citizens for Health, Wide Angle Health Network, the Natural Solutions Foundation and many others have been communicating actively with patients across the country, encouraging them to offer their personal testimony on natural hormones to the FDA by the April 4 deadline. [Testimony](http://www.democracynaction.org/dia/organizationsORG/healthfreedomusa/campaign.jsp?campaign_KEY=3246&t=wyethpage.dwt) can be offered electronically at [http://www.democracynaction.org/dia/organizationsORG/healthfreedomusa/campaign.jsp?campaign\\_KEY=3246&t=wyethpage.dwt](http://www.democracynaction.org/dia/organizationsORG/healthfreedomusa/campaign.jsp?campaign_KEY=3246&t=wyethpage.dwt) (if this link does not work, please cut and paste in your browser)**

**CEO of Seattle activist group (CodeBlueNow, www.codebluenow.org), Kathleen O'Connor, says "This move by Wyeth to take choices away from women under the secrecy of an FDA petition is the very reason CodeBlueNow! was founded—to give voice and choice to the American people who are kept at arms' length in health care decision-making and health policy". O'Connor says, "Until 'we the people' claim our right to shape our health care system, including equal access to health care from every type of licensed complementary and alternative health care provider, we are doomed to be constantly fighting health decisions on our behalf that are made without proper transparency. It's past time for the American public to stand up for what we want and not accept the dictates of bitterly toxic party politics and very entrenched special interests."**

**"There's no doubt about it, women suffer terribly on the synthetic hormones", says Leilani Tejada of Dallas, author of a book on hormones called "S.H.E.". She has traversed the country for ten years to research this problem and counsel women, and is now organizing a march in D.C. for the fall called "The Health of Women". Tejada says, "Often the suffering is the result of an unnecessary hysterectomy, which lands women in surgical menopause, where they wake up from the operation surprised to find a synthetic estrogen patch on their skin. Women's lives can be miserable from there on out—breast tenderness and lumps, heart disease, extreme mood swings, depression, strokes, nausea and migraines. And they think it's menopause. It's really devastating how we are deceiving women. Natural, Bio Identical hormones are the far better option. I've witnessed the difference in many thousands of women."**

**Major General Albert N. Stubblebine III (U.S. Army, Ret.) President of the Natural Solutions Foundation ([www.HealthFreedomUSA.org](http://www.HealthFreedomUSA.org)), says while the U.S. has focused on liberties abroad we have been relinquishing our freedom to corporations and government agencies here at home, especially when it comes to health care. "It's totally inappropriate that a company selling synthetic drugs proven to increase heart disease, cancer and stroke in women should bring pressure on the FDA to ban its natural, safe and inexpensive competitors. This is not the free market, but attempted restraint of trade. The FDA should not bow to this pressure to the detriment of women it is tasked to protect".**

**He adds, "Health freedom means the freedom to make your own health choices, which includes treatments and practitioners. No person, government or corporation should dictate or limit these choices. Today we are facing a challenge to natural hormones, as well as to supplements and even clean food through the CODEX legislation. If there ever was a time for consumers to take a stand for health freedom, that time is now." North Carolina physician John L. Wilson, Jr., M.D., CEO of the Great Smokies Medical Center of Asheville says "Only a pharmaceutical company would believe estrogenic compounds derived from horses' urine (marketed under the trade name Premarin by Wyeth Laboratories, Inc.) would be the safest or preferred product for use in humans. Of 17 known estrogens found in horse's urine, only two are identical to human estrogens. Premarin use has long been known to put women at risk for breast and uterine cancer in addition to blood clotting that results in heart attacks, blindness, and strokes. Utilizing the FDA's Citizen Petition process, Wyeth is attempting to bring down their competition, the custom-compounding industry, and is moving to preserve profits from what I consider less-than-optimal treatment options for women with hormonal replacement needs."**

**Several times over the years the pharmaceutical industry has attempted to displace this mainstream part of pharmacy practice that the medical establishment relies on day in and day out to treat both common and rare conditions, including preparing**

**individualized, compounded hormones.**

**L. D. King, Executive Director of the International Academy of Compounding Pharmacists, says, “Pharmacy compounding is a long-standing part of pharmacy practice on which millions of patients and their physicians rely today. Prescribed by doctors and prepared by pharmacists, compounded medicines are customized to treat the unique needs of each individual patient. Wyeth’s campaign to restrict access to these medications is anti-doctor, anti-pharmacist, and most of all, anti-patient.”**

**Preserving the ability to individualize care is considered an essential aspect of effective health care by the overwhelming majority of health practitioners.**

**Leading D.C. regulatory lawyer, Jim Turner, Esq. of Swankin-Turner, who is Chair of Citizens for Health ([www.citizens.org](http://www.citizens.org)), says “Wyeth’s petition to the FDA is a cynical manipulation of the legal process, designed to undermine the laws intended to protect people. It’s very important people object to the Wyeth petition before the April 4 deadline so it can be successfully derailed.**

**He adds, “Wyeth and the pharmaceutical industry have a long history of undertaking projects and producing products that harm the health of women. It is time for women and the men who love them to undertake action to put a stop to this cynical behavior”**

**Rima Laibow, MD says "Wyeth’s actions are part of a systematic attack on a mainstay of Integrative Medicine—on natural, effective compounds which are free from the risk and expense of patentable drugs. Wyeth and other patent medicine companies that manufacture synthetic drugs are pushing dangerous, but highly profitable, substitute molecules over safer, less expensive ones, for their financial best interest—in this case not at all in the patient’s best interest”.**

**She adds, "The rapidly expanding corporate ethics and social responsibility fields should take careful note of this industry's maneuvers and hypocrisy. As Integrative (often called “Complementary & Alternative”) Medicine physicians know well, deception like Wyeth’s in the case of “The New Medicine” documentary sponsorship is not an isolated incident but instead reflects an industry-wide pattern to mislead consumers regarding their best health care options, just as with ‘direct to consumer’ drug ads."**

**Berkley Bedell, Former Congressman, and Chairman of the National Foundation for Alternative Medicine ([www.nfam.org/](http://www.nfam.org/)) confirms, “It is ridiculous for a pharmaceutical company to file a Citizen’s Petition to quash their competition at a time when people are rightfully demanding freedom in health care choices and more and more problems are being experienced with pharmaceutical drugs. I hope the**



people will make their voices heard on this matter.”

To submit comments to the FDA go to

[http://www.democracyinaction.org/dia/organizationsORG/healthfreedomusa/campaign.jsp?campaign\\_KEY=3246&t=wyethpage.dwt](http://www.democracyinaction.org/dia/organizationsORG/healthfreedomusa/campaign.jsp?campaign_KEY=3246&t=wyethpage.dwt)

To bring this to Congress’s attention go to

[http://www.democracyinaction.org/dia/organizationsORG/healthfreedomusa/campaign.jsp?campaign\\_KEY=3246&t=campaigns.dwt](http://www.democracyinaction.org/dia/organizationsORG/healthfreedomusa/campaign.jsp?campaign_KEY=3246&t=campaigns.dwt)

To support leading activist and educational groups protecting health freedom of choice, the quality of our air, water and food and the ability of consumers to see any licensed health care professional, go to:

[www.healthfreedomusa.org](http://www.healthfreedomusa.org) - Natural Solutions Foundation

[www.AAEM.com](http://www.AAEM.com) - American Academy of Environmental Medicine

[www.citizens.org](http://www.citizens.org) - Citizens for Health

[www.friendsofhealth.org](http://www.friendsofhealth.org) - Friends of Health

[www.nfam.org](http://www.nfam.org) - National Foundation for Alternative Medicine

[www.humanhealthproject.org](http://www.humanhealthproject.org) - The Human Health Project

[www.codebluenow.org](http://www.codebluenow.org) - Code Blue Now

To support the compounding industry's defense and prevent Wyeth’s petition from shutting down compounding pharmacies, go to International Academy of Compounding Pharmacists at

<http://www.iacprx.org/site/PageServer?pagename=Donate>

>>>>END.

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