

Hormone Replacement Therapy and Wyeth

A Notre Dame case study
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Wyeth

Case Study Overview

- Background of Wyeth.
- Menopause.
- Hormone Replacement Therapy(HRT).
- The Controversy.
- Women's Health Initiative.
- Timeline of Events.
- Critical Issues.
- Questions?



Background of Wyeth

- Founded in 1860 as a drug store by John Wyeth.
- Acquired by American Home Products (AHP) in 1931.
- AHP changed its name to Wyeth and its ticker to WYE in March 2002.
- Four divisions: Wyeth Pharmaceuticals, Wyeth Research, Wyeth Consumer Healthcare, and Fort Dodge Animal health.
- Premarin and Prempro key HRT products at Wyeth Pharmaceutical.

Background of Wyeth

- Premarin family of products earned more than US\$2 billion dollars in revenues in 2001, accounting for 14% of total net revenues of Wyeth.
- More than 11 million women took a Premarin product in 2001 in the U.S.
- Over 80% of HRT sales are in the U.S.
 - Tremendous international expansion potential estimated in near future.
- Share price has been steady at around US\$60 per share for past three years.

Internal Communications at Wyeth:

- Corporate Communications:
 - Team of six people (includes PR and Public Affairs).
 - Reports directly to CEO.
 - Led by Natalie de Vane, Director of Public Relations.
- Investor Relations:
 - Team of three people.
 - Reports directly to CFO, who reports to CEO.
 - Led by Justin Victoria, Vice President of Investor Relations.

What is Menopause?

- A baby girl comes into the world with 2 million eggs.
- By age 12, the count is down to 300,000 eggs.
- By her late 30's, the count has fallen to 25,000.
- By middle-age, the ovaries are eggless.
- No one in the scientific/medical community truly understands this phenomenon.



The Unspoken Side Effects

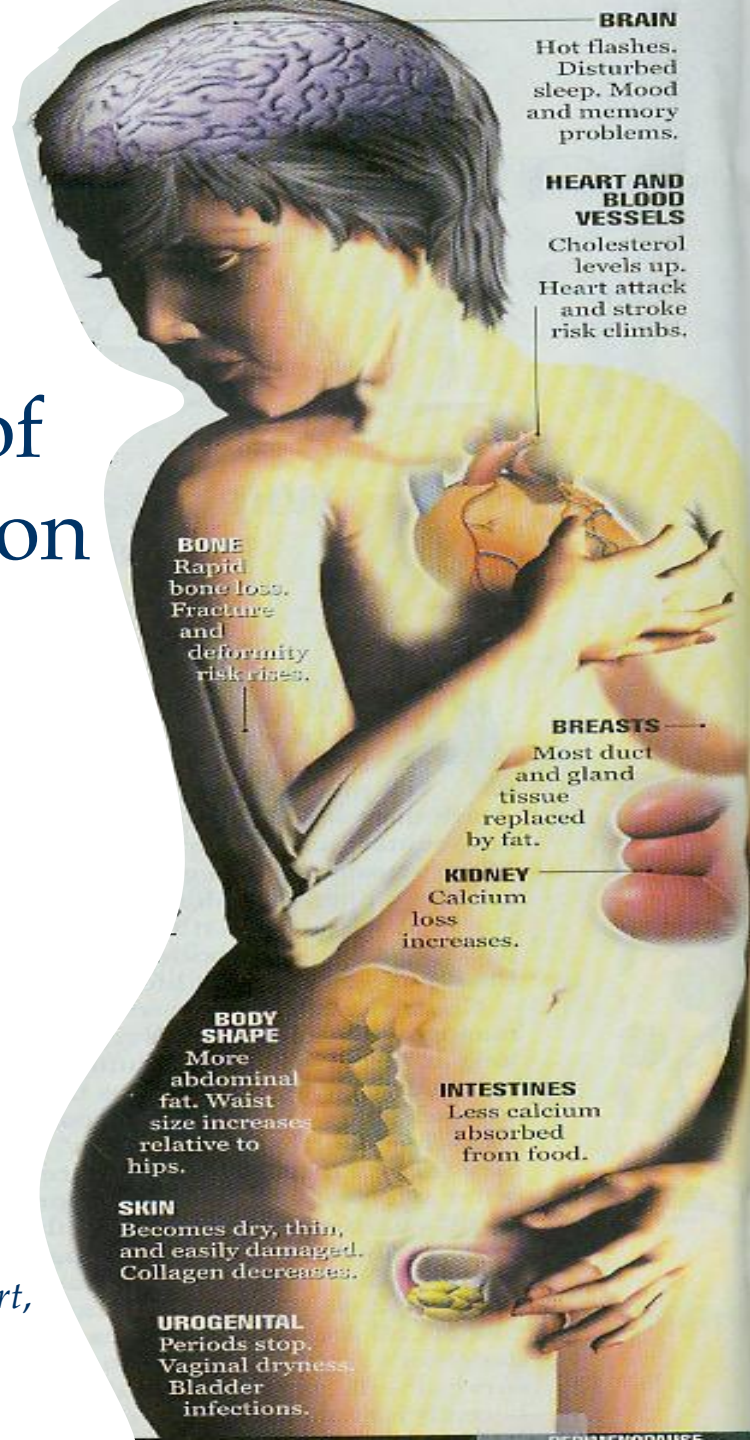
- Hormone output has decreased significantly.
- The reduction of estrogen in a women's body has wide ranging effects including:
 - Night sweats.
 - Fatigue, irritability and mood changes.
 - Increased risk of Osteoporosis.
 - Hot flash.

The Dramatic Hot Flash

- Varies in intensity, lasts from seconds to minutes
 - A sudden flush makes a woman feel overwhelmingly hot, sometimes with drenching perspiration, palpitations, and a wave of anxiety.
 - Hot flashes usually subside over a year or two.



The Effects of Menopause on the Body



BRAIN

Hot flashes.
Disturbed sleep. Mood and memory problems.

HEART AND BLOOD VESSELS

Cholesterol levels up. Heart attack and stroke risk climbs.

BONE

Rapid bone loss. Fracture and deformity risk rises.

BREASTS

Most duct and gland tissue replaced by fat.

KIDNEY

Calcium loss increases.

BODY SHAPE

More abdominal fat. Waist size increases relative to hips.

INTESTINES

Less calcium absorbed from food.

SKIN

Becomes dry, thin, and easily damaged. Collagen decreases.

UROGENITAL

Periods stop. Vaginal dryness. Bladder infections.

Wyeth

Source: *US News & World Report*,
November 18, 2002

HRT

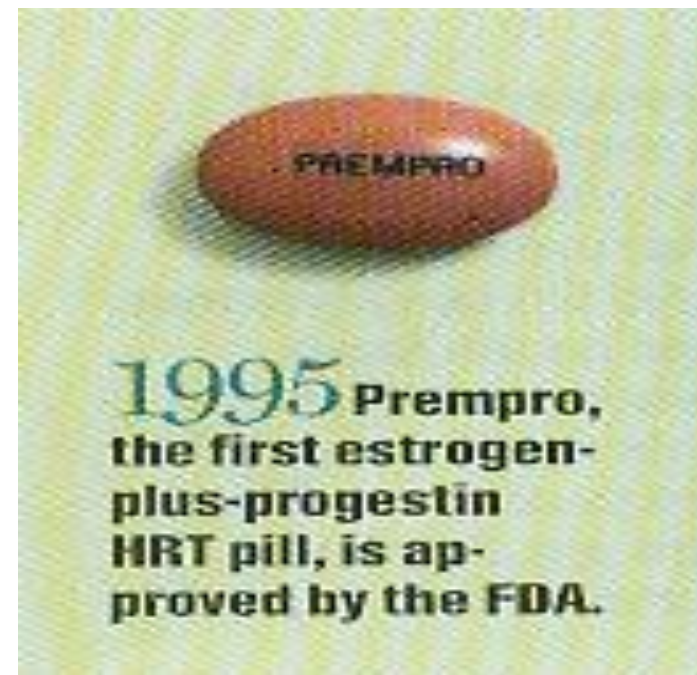
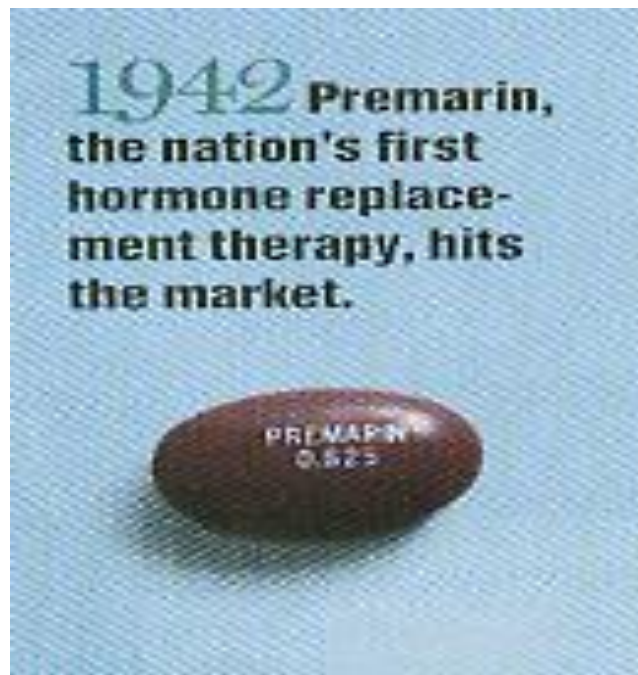


I feel the hormone replacement therapy kicking in.

- HRT has been used since the 1940s.
- Short term use:
 - Used to treat symptoms associated with menopause.
 - Helps postmenopausal women maintain healthy hormone levels.
- Long term use:
 - Often prescribed to prevent osteoporosis, hip fractures, and colon cancer, and heart disease.
- Pill or tablet, vaginal creams, vaginal ring insert, implants, or patches.

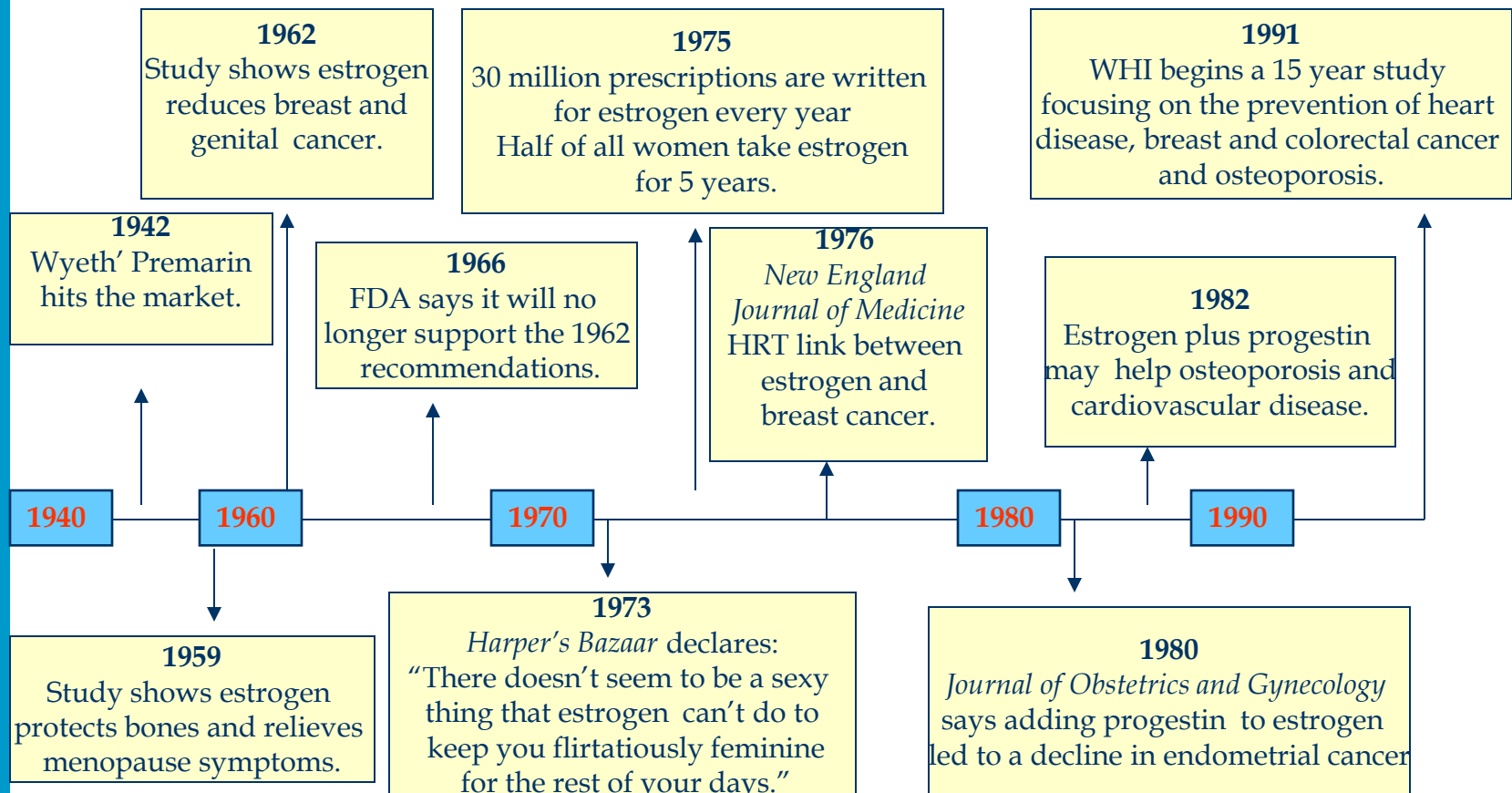
Wyeth

Wyeth's Premarin Family of Products Help Women to Conquer Menopause

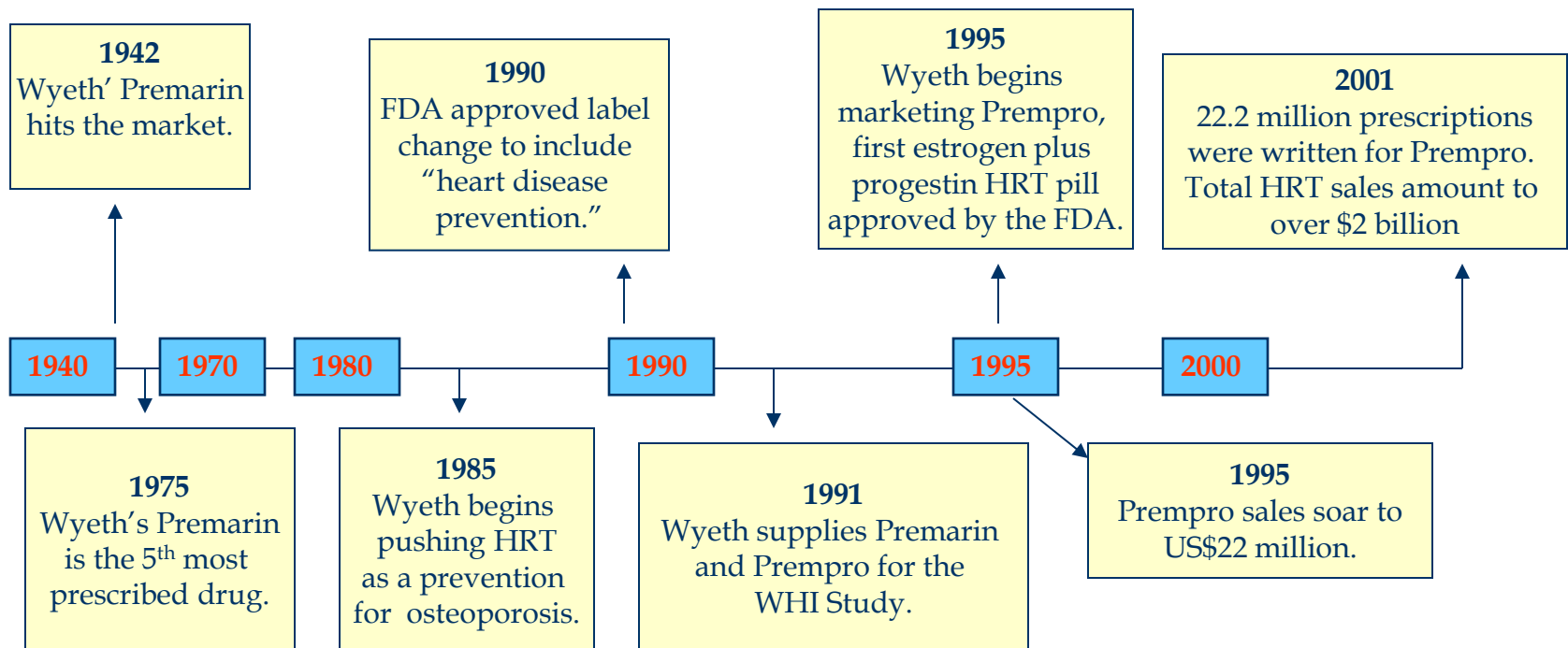


Source: *US News & World Report*, November 18, 2002

HRT Over the Years



New Uses of HRT



Controversy of HRT

- Contradictive and confusing clinical results of numerous tests by reputable organizations.
- Decades of disagreement amongst the medical community.

For women who've had a
hysterectomy
PREMARIN <<
(conjugated estrogens tablets, USP)

For women at
menopause
>> **PREMPRO**[™]
(conjugated estrogens/medroxyprogesterone acetate tablets)

What Happened with the WHI?



Women's Health Initiative (WHI)

- 15-year study to of ways to prevent heart disease, breast and colorectal cancer, and osteoporosis by NIH.
- Designed in 1991 and enrolled over 161,809 women between 1993-1998; it was scheduled to end in 2005.
- The Prempro arm of the study involved 16,608 women who took either Prempro (combination HRT) or placebo.
- In May 2002, The DSMB recommended that the Prempro arm of the trials be stopped.
- Research stopped due to high risks:
 - 26% increase in breast cancer
 - 41% increase in strokes
 - 29% increase in heart attacks
 - Doubled rates of blood clots



How Bad Is The Problem?

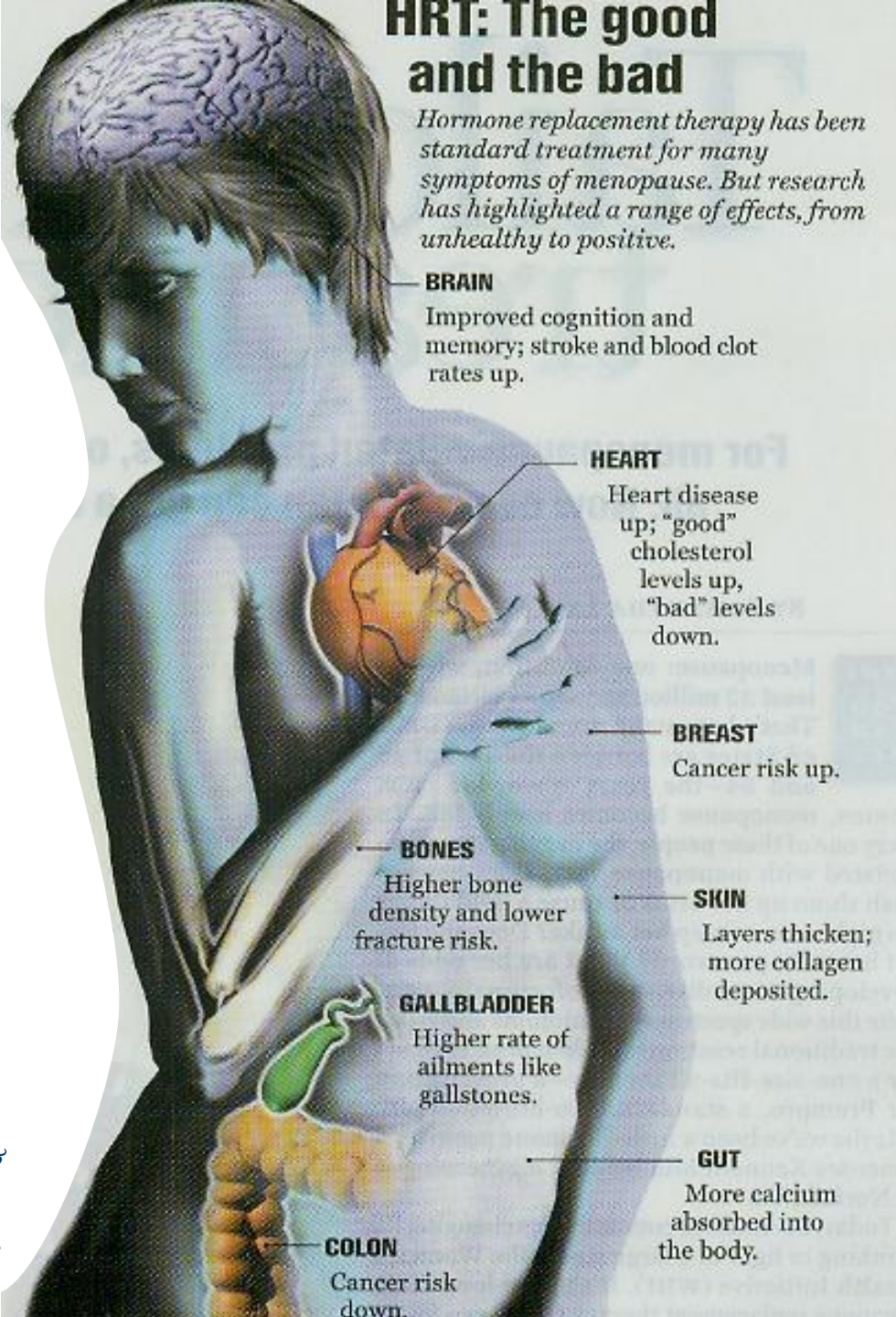
- Risks outweighed the benefits:

Health Event	Relative Risk vs. Placebo Group at 5.2 Years	Increased Absolute Risk per 10,000 Women/Year	Increased Absolute Benefit per 10,000 Women/Year
Heart Attacks	1.29	7	
Strokes	1.41	8	
Breast Cancer	1.26	8	
Blood Clots	2.11	18	
Colorectal Cancer	0.63		6
Hip Fractures	0.66		5

HRT: The good and the bad

Hormone replacement therapy has been standard treatment for many symptoms of menopause. But research has highlighted a range of effects, from unhealthy to positive.

Wyeth



BRAIN

Improved cognition and memory; stroke and blood clot rates up.

HEART

Heart disease up; "good" cholesterol levels up, "bad" levels down.

BREAST

Cancer risk up.

BONES

Higher bone density and lower fracture risk.

SKIN

Layers thicken; more collagen deposited.

GALLBLADDER

Higher rate of ailments like gallstones.

GUT

More calcium absorbed into the body.

COLON

Cancer risk down.

Source: *US News & World Report*,
November 18, 2002

Timeline


- May 15, 2002 – Share price around \$60 per share.
- May 31, 2002 – Termination of Prempro arm of WHI. Share price drops to \$55 per share.
- July 1, 2002 – Notified by NIH of termination of study.
- July 2, 2002 – “emergency meeting” with NIH on results of findings of WHI.
- July 9, 2002 – Issued public press release after company sends over 550,000 letters to doctors on WHI findings. Significant media coverage begins. Lawsuits filed.

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07/09/2002

WYETH INFORMS PHYSICIANS OF WHI FINDINGS – COMPANY REAFFIRMS ROLE OF COMBINATION HRT IN MENOPAUSAL TREATMENT – ESTROGEN-ONLY ARM TO CONTINUE

Madison, N.J., July 9, 2002 --Wyeth Pharmaceuticals is informing health care providers of important results on combination hormone replacement therapy (HRT) from the Women's Health Initiative Study (WHI). Results from this trial provide physicians and the public with more definitive information regarding the risks and benefits associated with the long-term use of estrogen plus progestin therapy (or combination HRT). However, the study did not evaluate the use of combination HRT for the treatment of menopausal symptoms or vaginal atrophy.

"These are valuable new data with significant implications. However, it is also important to recognize the critical role that combination HRT plays in treating the symptoms of menopause, the number one reason that women start therapy," says Victoria Kusiak, M.D., Vice President, Clinical Affairs and North American Medical Director. In a recent survey, doctors report that management of symptoms is a treatment goal for 9 out of 10 new patient starts with combination HRT.

In the WHI trial, the primary endpoints were prevention of coronary heart disease and the incidence of breast cancer. The study found that combination HRT increased the risk of cardiovascular disease (CVD) and, over time, increased the risk of breast cancer. The WHI also found that combination HRT reduced the risk of hip and other fractures and reduced the risk of colon cancer. The National Institutes of Health (NIH)

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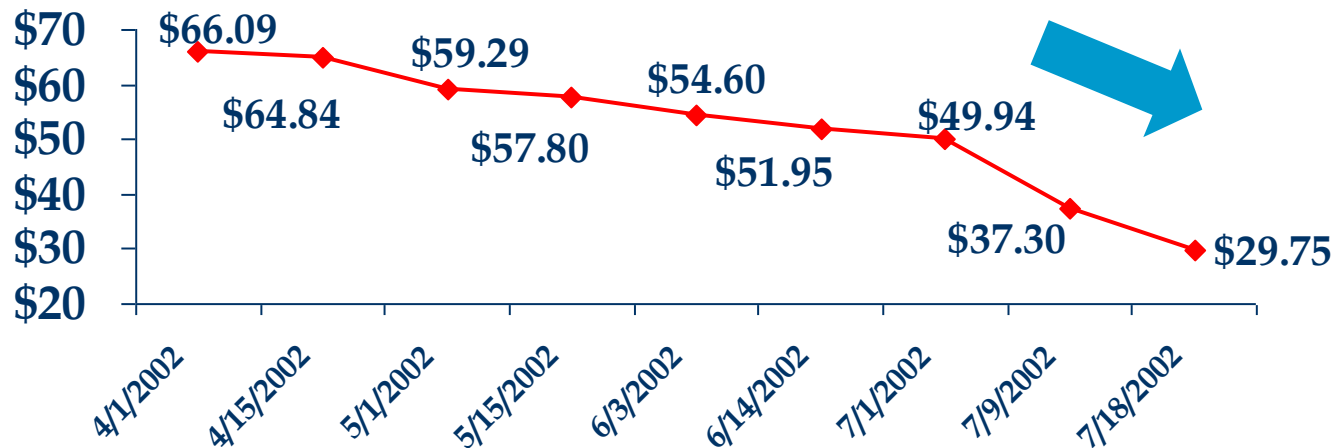
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Media Responds to WHI Findings

- “Hormone Therapy Harm Found Risks for Women Seen in Long Term” (*The Boston Globe*, July 10, 2002).
- “Wyeth Stock Falls 24% after Report” (*The New York Times*, July 10, 2002).
- “Dangers of Popular Prempro Worry Doctors and Patients” (*The Houston Chronicle*, July 10, 2002).
- “HRT Trial Cancelled Over Cancer and Stroke Fears” (*The Guardian*, July 10, 2002).

Timeline

- July 10, 2002 - Share price drops below \$36 per share.
- July 17, 2002 - Release of *JAMA* article on WHI findings; share price drops to \$30 per share.
- July 18, 2002 - Share price drops to \$29.75 per share.



Wyeth Share Price



Physicians Put HRT in Perspective

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“The NIH study in question showed a slight increase for the risk of cancer and heart disease in less than one tenth of one percent of the women studied,” responded Dr. Judith Reichman, author of “Relax, This Won’t Hurt.” “We thought that estrogen was going to help protect our hearts. What we found out was that Prempro does not; there are questions if estrogen, in general, will. But the thought of just giving everyone hormones and saying, ‘Here, dear, take this forever and this will prevent all diseases,’ we now realize is not true.

Physicians Put HRT in Perspective

“This study hasn’t changed my practice. We’ve known of breast cancer risk associated with HRT for some time, and we’ve known that women with heart disease didn’t get much benefit from HRT,” said Steven Goldstein, professor of obstetrics and gynecology at NYU School of Medicine.

“This study never addressed the women who come to menopause with terrible symptoms. Women should still take HRT in the short term, but on a case-by-case basis. Patients are individuals and should be treated one at a time.”

Key Stakeholders

- Wyeth Pharmaceuticals
- Physicians who prescribe HRT
- Patients who take combination HRT
- Pre-menopausal women considering HRT
- Women on estrogen only treatment
- Investors of Wyeth
- National Institute of Health
- Government agencies
- Competitors

Critical Issues

- Disseminating and educating the public and media of research findings.
- Protecting the corporate image.
- Protecting brand equity of all HRT products.
- Managing relations with doctors, patients, government agencies, research institutes, and investors.
- Limiting further negative media focus and negative impact on share price.

Discussion Questions

- How should Wyeth respond to findings of the WHI?
- What are the issues for the corporate communications team to address at this point?
- Who are the key audiences that Wyeth should try to reach and through what means?
- Who are the relevant stakeholders?
- Over the years, numerous scientific and medical sources have reached different conclusions on HRT. Armed with the new WHI data, how should Wyeth move forward?
- What are the corporate ethical issues involved when a pharmaceutical company attempts to market its product into market segments that have not been scientifically or medically founded?