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Wyeth Pharmaceuticals

Premarin®, Prempro® and Hormone Replacement Therapy

In the days following the announcement of the Women's Health Initiative (WHI) findings and the release of the JAMA article, Wyeth's shares tumble and sales sharply decline.

The Legal Challenge Begins

On July 22, 2002, law firms across the country rush to capitalize on the just-released findings by filing complaints for class-action lawsuits against Wyeth. Several law firms revamp their websites to attract women who think their current health problems stem from taking Prempro. Wyeth's Natalie de Vane describes the lawsuits as baseless, "We don't believe there is any legal or factual basis for the claims filed against Wyeth related to Prempro."[1]

"We're Not Exactly Sure What This Means for Wyeth"

Also on July 22, Wyeth has a conference call to discuss quarterly earnings. In the call, Wyeth's CEO Mr. Robert A. Essner said the company could not yet estimate what might happen to sales of Prempro, which accounted for $900 million of Wyeth's revenue in 2001. "Wyeth is much more than a one-product company," Essner said as he tried to reassure journalists and analysts. "Once the media sensationalism over the study subsides, the data will speak for themselves and hormone replacement therapy (HRT) will remain an important part of women's health care."

[1] Rubin, Rita. "Here Comes the Legal Wrangling over Prempro," *USA Today*, July 22, 2002.

This case was prepared by Research Assistants Kathryn I. C. Huang and Megan E. Vanaelstyn under the direction of James S. O'Rourke, Concurrent Professor of Management, as the basis for class discussion rather than to illustrate either effective or ineffective handling of an administrative situation.

The following day Wyeth issues a quarterly earnings press release. Wyeth acknowledges that a great deal of media attention has focused on the WHI suspending the combination HRT arm of the study. Wyeth says that the company is currently monitoring the situation, including prescription trends for the Premarin family of products and other relevant information, but is not able yet to estimate the impact of this data on future sales or operating results. After sufficient information is obtained and assessed, Wyeth promises to issue earnings guidance to the public.[2]

On July 24, Mr. Essner publicly criticized the media in the *New York Times* for what he termed its "sensationalizing" of a study. Mr. Essner also said that he did not think that the lawsuits filed against the company on behalf of women who took Prempro would be successful. "The vast majority of women who unfortunately develop breast cancer or cardiovascular disease would have done so regardless of whether or not they took H.R.T."[3]

Changing the Labels

On September 4, Wyeth announces that it has updated its product labels for its Premarin family of postmenopausal hormone therapies to reflect the WHI's findings. Wyeth initiates this action so physicians can have up-to-date information in order to counsel their postmenopausal patients on the appropriate use of hormone therapies. In addition to including the WHI findings, the updated labels also state that:

1. These products are not indicated and should not be used to prevent coronary heart disease.

2. These products should be limited to the shortest duration consistent with treatment goals and risks for the individual woman and should be periodically reevaluated.

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[2] www.wyeth.com

[3] URL:http://www.businessweek.com/bwdaily/dnflash/sep2002/nf20020926_0907.htm

3. The products should be used solely for the prevention of postmenopausal osteoporosis, alternative treatments should be carefully considered.

4. The labels also mention that due to the potential increased risk of heart attack, stroke, breast cancer and blood clots, the use of a Premarin product should be limited to the shortest duration consistent with the treatment goals and risks for the individual women.[4]

Dr. Janet Woodcock, who heads drug approvals for the FDA later mentions that it was not yet clear whether the risk of taking Prempro apply to other hormone therapies on the market. "How can we generalize to the other products? We are evaluating this whole area. There are implications of this study for new drug development of estrogens and they are going to have to be taken into account."[5]

"It Is *Our* Data!"

"We simply want to evaluate the data. It is our product. And we thought it would be appropriate for the WHI to share all the data with us," said Wyeth spokesperson Douglas Petkus.

Companies frequently ask researchers for data from completed studies that contain negative findings about their products. On October 19, in a move that angered researchers in the WHI, Wyeth requests to see the WHI data. Given the severity of the recent findings, some researchers and medical experts believe that Wyeth may use the data to try to undermine the study's conclusions about the risks of hormone therapy. Initially, the National Institute of Health (NIH) is reluctant to share the data because its researchers did not feel all of the findings had been thoroughly evaluated. Additionally, the Premarin portion of the study was continuing and researchers did not feel it was appropriate to turn over the data to Wyeth when the entire study had not yet concluded.

Under the Freedom of Information Act (FOIA), an act that states a federal agency must disclose requested records, Wyeth demands to see the WHI findings from the NIH. While WHI researchers continue to analyze the finding, NIH officials agree it is in the best interest of their partnership with Wyeth to provide the data voluntarily. In turn, Wyeth withdraws the FOIA

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[4] www.weyth.com

[5] Kolata, Gina. "Drug Agency Weighs Role Of Hormone Replacements," *The New York Times,* October 25, 2002.

request and signs an agreement not to publish articles on the new data.[6]

Wyeth now begins referring to HRT as simply "hormone treatment."

US Experts Consider the Future of HRT

On October 23, nearly 1,000 doctors, researchers, and drug company officials gather at the NIH in Bethesda, Maryland, for the Scientific Workshop on Menopausal Hormone Therapy to consider how to advise a growing population of middle-aged women -- now that the most popular brand of HRT has been show to cause cancer and heart disease. Since the release of the findings, there is little news to report to anxious women wanting to know if they should throw away their hormone pills.

"Although the results were somewhat unexpected, it was a good example of evidence-based research replacing conventional wisdom." Dr. Elias Zerhouni, director of the National Institutes of Health, said at the start of a two-day workshop on the future of HRT. Despite all the media attention, Dr. Zerhouni said that, "'What should I do?' is still the most common thing we hear from patients. Patients out there…are still confused."[7]

Wyeth's Uncertain Future on Wall Street

While some on Wall Street have been expecting Wyeth's earnings to grow well above the industry average over the next few years, concern is mounting that the company's performance could fall short. In the past four months after the release of WHI findings, Wyeth shares have plummeted more than 30%. "It's a bit of a crapshoot as to what earnings will look like over the next few years," warns Lloyd S. Kurtz, senior vice-president at money management firm Harris Bretall Sullivan & Smith, which sold all its Wyeth stock after the Prempro data was released.

Despite an aggressive damage-control effort, including a blitz by Wyeth's sales representatives, prescriptions for Wyeth's Premarin family of products have plummeted more than 20% since the study was released.[8]

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[6] Okie, Susan. "NIH to Give Hormone Maker Data," *Washington Post*, October 19, 2002.

[7] Kolata, Gina. "Drug Agency Weighs Role Of Hormone Replacements," *The New York Times,* October 25, 2002.

[8] Barrett, Amy. "Why Wyeth Still Has the Sweats," *BusinessWeek,* September 27, 2002.