Publication Program

In late 1997, DesignWrite initiated a comprehensive, peer-reviewed publication program in support of the PREMARIN Family of Products. To date, 36 papers, one supplement (containing 5 individual papers), and 2 extended abstracts/newsletter articles have been published or accepted for publication. A variety of scientific topics have been covered over this 5-year span and these publications have taken into account the evolving HRT marketplace. In 2002, our proposed publications focused on the impact of ERT/HRT in early postmenopausal women. We plan to work closely with the Issues Management Team of Women's Health Care to continue this publication plan for 2003 with the development of additional research articles including review papers that highlight the areas below.

Key Issues/Message Strategies

Low-Dose ERT/HRT

1. Clinical Trial Data:

DesignWrite will continue to develop 3 papers from the Women's HOPE study that are in progress. These include bone responder data, 2-year endometrial safety, and the impact of BMI on efficacy outcomes. Preliminary data for these papers have been presented at national or international scientific meetings.

2. Supplemental Papers

We suggest an updated literature review (a 2001 review of low-dose therapy was published in *Climacteric*) that supports the beneficial effects of low-dose therapy, highlighting the 1st and 2nd year data from the Women's HOPE study.

The Importance of Treating Menopausal Symptoms

We propose 2 papers, one for primary care physicians, one for allied health professionals. The papers will include information on CNS changes with hot flashes as well as the cascade effects of sleep loss and disruption of family relationships. The primary message will be the importance of quality of life issues that are improved with HRT use. In addition, the benefits of HRT on skin and sexuality will be included in the reviews.

Counseling Issues for the Postmenopausal Patient

The importance of treating menopausal symptoms, highlighting appropriate counseling methods based on the patient's individual needs and new prescribing information, will be the focus of a paper(s) targeted for a variety of audiences.

A paper that addresses absolute versus relative risk of disease will be developed for clinicians with the aim of providing practical information for sharing with patients in order to clarify this very confusing, but important topic.

HRT and Prevention of Hip Fractures

We would propose 2 review papers: 1) A comparative review of osteoporosis therapies that highlights the data from WHI indicating HRT is currently the only treatment that has been shown to prevent hip fractures; and 2) The beneficial effects of HRT when combined with other osteoporosis therapies (bisphosphonates, PTH) in preventing hip fractures.

Blunt Competitive Inroads of Other Products

Our goal will be to continue to effectively diffuse the use of raloxifene as an alternative to HRT, as well as highlight the class-effect of all HRT products. This objective can be achieved through papers developed on other topics as well.

An additional paper will focus on the issue of alternative therapies that include an increase in usage since WHI without any evidence that these remedies are effective or safe (based on a suggestion from Michael Kleerekoper).

Primary Audience

- Family Practice/General Practice Clinicians
- Nurse Practitioners/Physician Assistants
- Related health care providers

Key Journals to Be Targeted

Key Medical Journals for General Practitioners (First tier, high circulation)

Journal	Circulation	Comments
JAMA	372,000	Weekly
New England Journal of Medicine	228,000	Weekly
The Lancet	50,000	Weekly
British Medical Journal	117,000	Weekly
Annals of Internal Medicine	95,000	Monthly
Archives of Internal Medicine	110,400	Monthly
American Journal of Medicine	53,000	Monthly
American Family Physician	186,948	Biweekly
Annals of Family Medicine	New in 2003	Bimonthly
Journal of Family Practice	86,163	Monthly
Mayo Clinic Proceedings	126,000	Monthly
Postgraduate Medicine	132,700	Monthly

Key Medical Journals for Nurses, Nurse Practitioners, Physician Assistants

Journal	Circulation	Comments
The Nurse Practitioner	27,000	Monthly
American Journal of Nursing	233,000	Monthly
CNS: The Journal for Advanced Nursing Practice	3,600	Bimonthly
Journal of Advanced Nursing	2,685	Monthly
Journal of Obstetric, Gynecologic, and Neonatal Nursing	25,000	9 issues/year
Nursing Clinics of North America (Invitation only)	6,200	Quarterly
Public Health Nursing	1,000	Bimonthly
RN	275,000	Monthly
Nursing (Year)	325,000	Monthly
Journal of the American Academy of Nurse Practitioners	15,000	Monthly
Advance for Nurse Practitioners	41,000	Monthly
Clinician Reviews	112,000	10 issues/year
Physician Assistant	20,935	Monthly
Advance for Physician Assistants	33,826	Monthly
Journal of the American Academy of Physician Assistants	38,500	Monthly

Types of Publications

The following are some specific types of publications that may be prepared for the publication program:

Review Articles

We recommend that full-length review articles (2500-5000 words) be published and that these reviews consist of two types:

- Awareness-type articles dealing with current issues in HRT, along with reviews of pharmacoeconomic and quality of life issues

- Reviews of the clinical data on the PREMARIN Family of Products, other estrogens, and competitive products

Clinical Trials/New Data

DesignWrite will assist with the publication of clinical trials that are sponsored by Wyeth-Ayerst Pharmaceuticals in leading peer-reviewed journals. The timing of the publications will be planned so that physicians will frequently come across new information on the PREMARIN Family of Products.

Case Reports

Case reports offer a means of discussing the use of the PREMARIN Family of Products in patients with comorbid conditions or in those whose cases are unusual in some other respect. Often case reports can be published more quickly than full-length original reports. This type of publication would also support the case report interactive sessions that are proposed in the Medical Congress Activity section of this proposal.

Posters/Abstracts

DesignWrite will produce abstracts and posters from clinical data for national and international congresses. We will work closely with marketing, medical affairs, and clinical research departments to ensure that the scientific content and messages are optimized and that the presentation materials are uniform for all Wyeth research presented at each meeting.

2003 Council on Hormone Education Estimated Budget

	Estimated Total
December Meeting	$200,000
January Meeting	$400,000
Development costs (eg slide kit, unless this is the January meeting budget)	$250,000
2 Faculty development meetings with 150 attendees each	$1,200,000
150 dinner meetings	$1,250,000
200 dinner meetings	$1,650,000
20 regional symposia	$2,600,000
Speakers website	$250,000
4 newsletters	$250,000
Virtual factory CD-ROM	$520,000 (assumes 50,000 distribution)
External website	TBD

Medical Congress Activity: Satellite Symposia

DesignWrite specializes in creating, developing, and implementing scientific symposia in conjunction with national congresses. Our highly trained staff ensures professionally produced and attractive meeting materials (invitations, signage, coursebooks, etc), extensive on-site experience, and well-positioned strategic spin-offs. We have conducted symposia at national organizations such as AACE, AAFP, ACOG, ASBMR, ASRM, AGS, APS, ASHP, and Pri-Med, among others.

In 2002, we coordinated symposia at AACE, ACOG, and ASBMR, and were responsible for content at an IMS symposium. These meetings focused on the impact of hormone replacement in early postmenopausal women. We plan to continue this theme in 2003. The benefits of low-dose therapy and the importance of treating menopausal symptoms will also be highlighted in 2003.

Proposed Conferences and Topics

The American College of Obstetrics and Gynecology (ACOG)
April 26–30, 2003
New Orleans, Louisiana
Demystifying Hormone Replacement: The Importance of Menopause Counseling and Tailored Therapy

- Emphasize the significant impact of menopausal symptoms on quality of life, CNS effects, and relationships
- Review the importance of individualizing HRT, recognizing the class effects of all forms of HRT
- Review the beneficial effects of low-dose therapy, highlighting the 1st and 2nd year data from the Women's HOPE study
- Present case studies of difficult patients, including helpful tips for patient management
- Provide practical information for physicians to share with their patients, including methods of emphasizing that the absolute risk with HRT is small

American Association of Clinical Endocrinologists (AACE)
May 14–18, 2003
San Diego, California
Preventing the Menopause Cascade: HRT and the Early Postmenopausal Women

- Stress the impact of the cascade of symptoms associated with hot flashes
- Emphasize the importance of treating menopausal symptoms
- Discuss the effects of HRT on other factors reducing the quality of life of menopausal women
- Provide practical information for physicians to share with their patients regarding the safety of HRT

Endocrine Society
June 18–21, 2003
Philadelphia, Pennsylvania
New Trends in Menopausal Health: The Emergence of Low-Dose HRT

- Emphasize the importance of treating menopausal symptoms
- Review the importance of individualizing HRT
- Review the beneficial effects of low-dose therapy, highlighting the 1st and 2nd year data from the Women's HOPE study
- Present case studies of patients considering low-dose HRT, including helpful tips for patient management

North American Menopause Society (NAMS)
September 18–20, 2003
Miami Beach, Florida
The Current Role of HRT: Reconciling Evidence from Observational and Clinical Studies

- Discuss the importance of treating menopausal symptoms
- Review the epidemiological evidence on the effects of HRT
- Review evidence on the effects of HRT in clinical trials
- Evaluate the similarities and differences between the results of observational and clinical studies
- Provide practical information for physicians to share with their patients regarding absolute versus relative risk

[or, if this is not on target...]

The Role of HRT in Postmenopausal Osteoporosis Prevention: Timing, Efficacy, and Economic Cost

- Evaluate the impact of early postmenopausal bone loss
- Review the pathophysiology of early postmenopausal bone loss
- Discuss the effects of HRT on BMD in early postmenopausal women and compare them to those of other therapies
- Evaluate the effects of osteoporosis therapies on fracture in early postmenopausal women and women with established osteoporosis
- Discuss the risks and costs of the various therapies, including practical information for physicians on the relative and absolute risks associated with HRT

American Society for Bone and Mineral Research (ASBMR)
September 19–23, 2003
Minneapolis, Minnesota
Simplifying the Complexity of Postmenopausal Osteoporosis Prevention [or]
Fracture Prevention: A Review of the Evidence

- Review the pathophysiology and impact of bone loss
- Discuss the effects of HRT and other therapies on BMD in early postmenopausal women and women with established osteoporosis