A Proposal for
Jeffrey A. Solomon
Sr. Product Manager, ERT/HRT
and
Howard E. Rofsky, M.D.
Sr. Director, Clinical Development Division
Medical Affairs Department
Wyeth-Ayerst Laboratories

PREMARIN®
Publication Program

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I. INTRODUCTION

At the request of Jeffrey Solomon and Dr. Howard Rofsky of Wyeth-Ayerst Laboratories, DesignWrite has prepared this proposal for a comprehensive publication program in support of PREMARIN. The specific objective of this program is to 1) increase physician awareness on the multitude of benefits that hormone replacement therapy provides for postmenopausal patients, 2) diminish the negative perceptions associated with estrogens and cancer, and 3) blunt the competitive threat of raloxifene, a selective estrogen receptor modulator, expected to be approved early next year for osteoporosis.

We have described a publication strategy that will be targeted to specific audiences audiences such as gynecologists, primary care physicians, physician assistants, nurse practitioners as well as other related specialties (i.e., cardiovascular, bone disease specialists, neurologists, oncologists, and pharmacists).

The rationale for a planned publication program is:

X Research shows high clinician reliance on journal articles for credible product information.

X Integration of clinical data publication into the overall product development and marketing plan is essential for maximizing product potential.

X Competitive factors and other considerations require acceleration of product awareness, differentiation, and acceptance through clinical data dissemination.

X Promotional campaigns rely to a great extent on published clinical data; even great creativity is not a substitute for poor or nonexistent data.

X Client resources are often prioritized on achieving regulatory submission goals.

X Marketing staff often has priorities other than focusing on development and publication of clinical data.

X DesignWrite provides the bridge between marketing and clinical disciplines and assures that benefits of publication planning are achieved.

DesignWrite is pleased to have the opportunity to offer Wyeth-Ayerst Laboratories its medical marketing services. Our expertise and experience in the organization and development of scientific and technical communications will provide the support required for the continued success of PREMARIN, despite competitive launches.

II. OBJECTIVES

This plan proposes support for a combination of peer-reviewed, freestanding primary research articles, opinion-leader-endorsed review articles and journal supplements.

The PREMARIN publication plan will satisfy the following business strategies:

- Identify key data for publication content in conjunction with the client.
- Consider the most influential publication sources for landmark data.
- Identify, select, and recruit targeted authors.
- Assure publication of key available data for PREMARIN and conjugated estrogen therapy.
- Present substantial documentation to key prescribing audiences and decision-makers.
- Enhance thought leader support and increase awareness of key healthcare audiences about product advantages.
- Identify abstracts and posters for submission to major national and international congresses.
- Publish interim study results of ongoing clinical trials in targeted peer-reviewed journals and journal supplements.
- Position the product appropriately to influence prescribers.

III. KEY ISSUES/MESSAGE STRATEGIES

Based on input from Wyeth-Ayerst, DesignWrite has assembled a list of key issues and message strategies that will be addressed through the publication plan. Short term and long term strategies will determine the specific focus of the plan and which articles will be submitted for journal publication first.

1. Value of Estrogen Therapy (or Bundle of Benefits)

Define the serious nature of menopause-related illness and demonstrate the *clinical* benefits of instituting hormone replacement therapy in the treatment of multiple disorders including cardiovascular, osteoporosis, vasomotor, Alzheimer's, and colon cancer.

2. Bolster PREMARIN's Perception as the "Original SERM"

There will be a need to ensure that PREMARIN's image as the cornerstone of hormone replacement therapy be maintained by touting the:

- Uniqueness of PREMARIN's blend of conjugated estrogens to clinically improve a host of postmenopausal diseases.
- Intricate science associated with PREMARIN's composition as recently defined by FDA.
- Long history of physician use and confidence.
- Cost-effective therapy

3. Blunt Competitive Inroads of Raloxifene

Raloxifene will be introduced into the market early next year for osteoporosis. It is expected that it will be marketed as a "perfect SERM" and compete with PREMARIN for use in postmenopausal conditions, highlighting its greater selectivity in breast tissue receptors.

The goal will be to effectively pre-position raloxifene and defuse it as a threat by:

- Niching raloxifene as an anti-estrogen
- Linking raloxifene to the "tamoxifen experience"-it took 5-10 years for tamoxifen's connection with uterine cancer to become apparent. Human studies with raloxifene have lasted only 8 weeks. What we don't know <u>can</u> hurt us. Will it increase the risk of uterine cancer?
- Stressing that raloxefine does not relieve hot flashes and may even exacerbate them. Raloxefine is a CNS antagonist, which is supported by Britton's data.
- Questioning the use of specific peroxidase testing methodology to evaluate raloxifene's uterine activity.
- Exploiting raloxifene's weaknesses with specific surrogate markers (i.e. lipids)

- Evoking the memory of DES-Lilly is still dealing with the aftermath of diethylstilbesterol, generations after its use.

4. Dispel the Perception of Estrogen Causing Cancer

Fears of breast or ovarian cancer, as well as side effects such as bleeding or weight gain, contribute to reluctance on the part of physicians and patients to use. We will utilize available data to deal with this issue.

IV. METHODOLOGY/PROGRAM DESCRIPTION

1.Manuscript Preparation

The editorial staff of DesignWrite offers more than 100 years of cumulative experience in preparing manuscripts for peer-reviewed submissions to medical journals throughout the world.

The DesignWrite management team has extensive experience in developing integrated, strategic publication programs. DesignWrite will provide a full spectrum of support, from strategic analysis and planning to submission of developed manuscripts.

DesignWrite will:

- Work closely with investigators and marketing, regulatory, medical, and clinical departments during every phase of manuscript preparation and approval.
- Handle liaisons with investigators and journals.
- Provide a back-up plan so a valued paper always has another publication option.
- Continuously provide management oversight through final publication and distribution, including reprints.
- Provide updates and frequent reports to keep the client informed of the status on all publication activities.

DesignWrite would substantially increase the perceived amount of published data on a product by:

- preparing/submitting abstracts and posters to major national and international congresses
- prepackaging appropriate non-US and US data for international publications
- publishing the interim study results of ongoing clinical trials in targeted journal supplements
- accelerating the publication of data from multicentered clinical trials
- publishing bylined articles targeted to key prescribing audiences and decision makers.
- To implement a plan, a close working relationship is required between DesignWrite and Wyeth-Ayerst Laboratories' Marketing, and Clinical Research departments. As indicated earlier, DesignWrite has an established track record of working with the various internal groups that will be involved in a communication program, and our INFO*Link* program supports the needs of these varied groups.

The success of a publication plan will be affected by many factors, including adherence to schedules for study completion and data analyses, the overall direction of the study

results, and the impact of other communication programs on the overall timing of specific publication dates for each article. However, the client will benefit from DesignWrite's experience in managing these variables to ensure the successful completion of the communication plan.

2. Journal Submission

The editorial staff of DesignWrite is highly experienced in preparing manuscripts for journal submission.

The first step is to choose the target journal best suited to the manuscript's content, thus avoiding the possibility of manuscript rejection. We will then analyze the data and write the manuscript, recruit a suitable well-recognized expert to lend his/her name as author of the document, and secure his/her approval of its content. After the client has reviewed and released the manuscript for submission, DesignWrite will see it through the necessary production stages—creating camera-ready figures and tables and the text according to the journal guidelines—and submit the package (manuscript, art, cover letter, and any required forms and checklists) to the appropriate journal editor. Any revisions requested by the journal will be handled by DesignWrite in conjunction with the client and the author. Should the journal reject the manuscript, DesignWrite will restyle it for submission to another journal within 10 working days.

From receipt of the internal summary report for a given study, a time frame of 1 to 2 months is estimated for manuscript development. The time frame between submission of draft and the client approval is subject to internal review. Subsequent revisions based on the client, author, or reviewer comments are typically addressed in 2 to 3 weeks. A period of 6 to 16 months is projected for actual publication once the manuscript has been accepted by the journal. This latter time frame is a function of individual journal policies.

The following is a typical work flow plan for developing a manuscript for submission to a peer-reviewed journal:

Client provides data report	TBD
DesignWrite prepares first draft	4-8 weeks
Client internal review	TBD
DesignWrite addresses consolidated Client comments (second draft)	2-3 weeks
Second draft reviewed by selected author	TBD
DesignWrite incorporates author comments (third draft)	2 weeks
DesignWrite assists in journal submission	TBD
Journal provides peer-reviewer comments	TBD
DesignWrite addresses comments; resubmits	2 weeks
Journal acceptance and publication	TBD

Manuscripts will be submitted to peer-reviewed journals directed at the target audiences. Where appropriate, articles dealing with pharmacological aspects of the drugs will be placed in journals with a pharmacology orientation. These articles could combine updates on study results as well as information comparing the product with other selected

therapeutic agents. In addition, they could address trends in treatment and complete disease management issues.

3. Journal Supplements

The value of journal supplements is that it allows you to better tailor your marketing message since it is a manufacturer-sponsored publication form. Additionally, reprints of supplements may be purchased and distributed widely among health care professionals via sales representatives and direct mail.

Selected data derived from individual studies could be published together as supplements to target journals within a particular therapeutic specialty. Should the client wish to pursue this publication option, the following guidelines are applicable. A turnaround time of 6 months is generally adhered to for producing the supplement. This includes all editorial components, including interactions with invited authors, and the target journal. Timing of the publication is ultimately predicated by the individual journal's supplement schedule. Journal supplements could be published before launch, targeted to specific audiences.

4. Acceptance Rate Experience

Based on an analysis of manuscripts developed by the DesignWrite team for submission to peer-reviewed medical journals, we have determined that approximately 80% of these articles were accepted by the journal of first choice in the submissions. Fifteen percent of the manuscripts prepared by the DesignWrite team have been accepted for publication by the second journal to which they were submitted. The remaining 5% of articles required other publication considerations (e.g., placement in lower caliber or non-peer-reviewed journals).
A number of principles serve as the foundation of our publication plan. Following are some of the essential components:

- A comprehensive strategy should be developed and agreed to by all members of the product/publications team at the inception of the program. Although it is inevitable that changes to the strategy will be made as additional clinical data and additional competitive information become available, key representatives from the clinical and marketing functions should come to consensus about overall program goals before a definitive timetable of publications and presentations is discussed.

- Provision should be made for reviewing the overall strategy on a periodic basis. As mentioned above, it will be necessary to modify the original strategy as further data about PREMARIN and its competitors become available. A timetable for periodic review of the overall strategy by the full publications team should be agreed to at the beginning of the program.

5. Targeting Key Audiences

Target audiences consist of the names of physician specialty groups or other healthcare professionals who should receive information about the preclinical and clinical trial program for a drug through primary publications, review articles, or presentations at scientific meetings. As part of the publication plan we will identify and prioritize primary, secondary and tertiary audiences.

Although preliminary, the following is a prioritized list of target audiences:

Primary Audiences

- OB/GYN
- High Prescribing Primary Care physicians (FP/GP/DO/IM)

Secondary Audiences

- Orthopedic/Bone Specialists
- Cardiovascular Specialists
- Oncologists
- Other Primary Care physicians
- Consultant, hospital, and retail pharmacists
- Nurse Practitioners/Physician Assistants

Tertiary Audiences

- Payers (government, managed care)
- Related healthcare providers

6. Targeting Key Journals

We will research and prepare a profile of all specific worldwide publications used in disseminating information and data on hormone replacement therapy and osteoporosis as well as relevant OB/GYN publications that would be interested in PREMARIN's advantages vs. newer hormones on the market. As part of the journal analysis, details of all journals relevant to this therapeutic area will be provided. Some of the elements will include a focus on the journal's content and circulation, time to publication, peer review status, rejection rate, target audience, prestige and sphere of influence, professional editorial staff, and country of publication.

In addition, as part of the PREMARIN publication plan, strategic recommendations about the overall quantitative aims will be highlighted including:

- Total number of journal publications

- Ideal ratio of clinical: preclinical publications

- Ideal ratio of primary: review publications
- Total number of meeting-related presentations to be aimed for, including satellite symposia and abstracts and poster sessions
- Identification of high-quality medical and health-related journals

The selection and identification of the key journals is based in part on their *Science Citation Index®* (SCI) ranking. Tactical recommendations for primary and secondary target journals for a specific manuscript including cuts of the data and review articles, case studies, or short reports will be based on a number of factors including:

- the type and relative timing of the study
- the importance and quality of the data
- the investigators involved
- the impact of the journal in specific therapeutic areas

*6.1 Key Medical Journals**

Journal	Circulation	Comments
New England Journal of Medicine	228,000	Weekly, peer-rev.
The Lancet	50,000	Weekly, peer-rev.
Annals of Internal Medicine	95,000	Monthly, peer-rev.
JAMA	372,000	Weekly, peer-rev.
Archives of Internal Medicine	100,000	Monthly, peer-rev.
American Journal of Medicine	53,000	Mthly, peer rev./supp.
American Family Physician	149,000	Monthly, peer rev.
Archives of Family Medicine	51,000	Monthly, peer-rev.
Postgraduate Medicine	127,000	Monthly, peer rev.
Hospital Physician	90,000	Monthly, peer rev.
Hospital Practice	175,000	18/yr.
Internal Medicine	92,770	Monthly, peer-rev.
Journal of Family Practice	74,000	Monthly

*First tier, high circulation, general and internal medicine journals.

6.2 Key OB/GYN Journals

Journal	Circulation	Comments
American Journal of Obstetrics and	16,700	Monthly, peer-rev.

Gynecology		
Clinical Obstetrics and Gynecology	9,400	Quarterly, peer-rev.
Contemporary OB-GYN	10,800	Bimonthly
Menopause	N/A	Quarterly, peer-rev.
Obstetrics and Gynecology	N/A	14 issues/year, peer-rev.

6.3 Key Orthopedic/Bone Disease Journals

Journal	Circulation	Comments
The American Journal of Orthopedics	25,000	Monthly
Bone	N/A	Monthly
Journal of Bone and Joint Surgery	38,000	Monthly
Journal of Bone and Mineral Research		
Orthopedics	28,000	Monthly
Osteoporosis Report	10,000	Quarterly

6.4 Cardiovascular/CNS Journals

Journal	Circulation	Comments
American College of Cardiology Journal	31,733	14 issues/yr, peer-rev.
American Heart Journal	11,100	Monthly, peer-rev.
American Journal of Cardiology	32,000	Bi-monthly, peer-rev.
Cardiovascular Drugs and Therapy	800	6 issues/yr, peer-rev.
Clinical Cardiology	31,700	Monthly, Peer-rev.
Arteriosclerosis and Thrombosis	2,000	Bi-Monthly, peer-rev.
Cardiovascular Reviews and Reports	68,000	Monthly, peer-rev.
Current Opinion in Lipidology	6,450	Bi-monthly, peer-rev.
American Journal of Geriatric Cardiology	20,000	Bi-monthly, peer-rev.
Annals of Neurology	10,000	Monthly, peer-rev.
Alzheimer's Disease and Associated Disorders	1,000	Quarterly, peer-rev.
Archives of Neurology	17,500	Monthly, peer-rev.
Annals of Neurology	10,000	Monthly, peer-rev.

6.5 Key Endocrinology Journals

Journal	Circulation	Comments
Endocrinology	5,800	Monthly, peer-rev.

The Endocrinologist	N/A	Bi-monthly, peer rev.
Journal of Clinical Endocrinology and Metabolism	9,500	Monthly, peer-rev.

6.6 Key Gerontology and Geriatric Journals

Journal	Circulation	Comments
Journal of the American Geriatrics Society	9,400	Monthly
Geriatrics	56,000	Monthly, peer-rev.

6.7 Key Oncology Journals

Journal	Circulation	Comments
Cancer	16,600	Monthly, peer-rev.
Cancer Research	7,000	Monthly, peer-rev.
Journal of the National Cancer Institute	5,000	Monthly, peer-rev.
Blood	14,000	Monthly, peer-rev.
Journal of Clinical Oncology	14,000	Monthly, peer-rev.
Seminars in Oncology	8,000	Bi-monthly, peer-rev.
Oncology	1,500	Monthly, peer-rev.

6.8 Key Pharmacology Journals

Journal	Circulation	Comments
Pharmacological Reviews	2,400	Qrtrly., ASPET jnl.
Journal of Pharmacology and Experimental Therapeutics	2,700	Monthly
Clinical Pharmacology and Therapeutics	5,200	Monthly
Journal of Clinical Pharmacology	2,500	Monthly
Pharmacotherapy	3,900	Bi-mnthy,ACCP.jl.
American Pharmacy	48,800	Monthly, peer-rev.
Formulary	45,000	Monthly

6.9 Key Pharmacy Journals

Journal	Circulation	Comments
American Druggist	83,600	Monthly, Peer-rev

Drug Topics	80,000	Bi-Monthly, Peer-rev.
Pharmacy Times	100,000	Monthly, Peer-rev
U.S. Pharmacist	104,000	Monthly, Peer rev
Pharmacy Today	95,000	Weekly, Peer-rev
The Consultant Pharmacist	6,000	Monthly, Peer-rev

6.10 Key Managed Care Journals

Journal	Circulation	Comments
Medical Interface	33,000	Monthly, peer rev.
American Journal of Managed Care	56,320	Monthly
Managed Healthcare	30,100	Monthly
Managed Healthcare News	65,300	1-2 mo., peer-rev.
Managed Care Pharmacy Practice	53,200	Bi-monthy
American Journal of Health-System Pharmacy	28,000	Monthly
*Corporate Health***	17,000	Bi-monthly
Journal of Managed Care Pharmacy	13,000	Bi-monthly

** Employer Publication

6.11 Key Experimental/Research Journals

Journal	Circulation	Comments
Clinical Research (now Journal Invest. Medicine)	12,000	Qtrly., Proceedings of Clinical Research
Journal of Experimental Medicine	3,900	Monthly
Journal of Clinical Investigation	6,400	Monthly
Journal of Laboratory and Clinical Medicine	3,500	Monthly

6.12 Rapid Acceptance Journals

Journal	Circulation	Comments
Advances in Therapy	1,500	Bi-monthly, non-p.r.

Clinical Therapeutics	6,000	Bi-monthly, non-p.r.
Current Therapeutics Research	6,000	Monthly
Today's Therapeutic Trends	4,000	Qtrly.,non-p.r.

6.13 Other Health Care Professional Journals

Journal	Circulation	Comments
Physician Assistant	18,000	Monthly
Advance for Physician Assistants	27,500	Monthly
Clinician Reviews	66,000	10 issues/year
The Nurse Practitioner: American Journal of Primary Care	20,000	Monthly
American Journal of Nursing	314,000	Monthly

7. Types of Publications

Following are some specific types of publications that can be prepared for the PREMARIN publication program.

Primary Papers

Upon receiving a complete list of clinical studies at the beginning of our work on the publications program, we would be in a position to make specific recommendations for primary publications, their timing and placement.

Journal Supplements

We recommend that supplements be considered for the following key audiences;

- The international community of OB/GYNs
- Primary care physicians and internists
- Consultant and clinical pharmacists

Journal supplements can be developed from CME/Convention spin-off activities.

Review Articles

We recommend that a number of full-length review articles (2500-3500 words) be published and that these reviews consist of two types:

- Awareness-type articles dealing with current hormone therapies, along with reviews of pharmacoeconomic and quality of life issues
- Reviews of the clinical data on PREMARIN, estrogens, and competitive products.

Additional reviews could be developed to support potential indications.

Mini-Reviews

In addition to the full-length reviews previously discussed, we recommend that a number of mini-reviews be prepared. These reviews, from 1000-1500 words in length, are intended to give a comprehensive review of PREMARIN for various audiences.

Case Reports

Case reports offer a means of discussing the use of PREMARIN 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. We recommend that Wyeth-Ayerst Laboratories advise its investigators that there is an interest in publishing such reports and offer them technical assistance in preparing the appropriate manuscripts for submission.

Letters, Editorials, Comments

We have found that substantive editorials, letters and comments of approximately 400 words are a means of placing important information about the therapeutic profile of an agent into the hands of influential physicians who read the most prestigious and selective journals. These letters might be submitted to the *New England Journal of Medicine, JAMA, Lancet, Annals of Internal Medicine* or OB/GYN journals.

In general, the publication target date is determined by considering the required times:

- For an investigator or medical writer to produce the manuscript of a scientific paper after receipt of the final study report
- For reviews by the authors whose names are to appear on the published paper
- For obtaining corporate reviews and clearances
- For the target journal to review the submitted manuscript
- For peer reviewers' suggestions to be incorporated in the manuscript and for these changes to be approved by all appropriate persons, or for a rejected manuscript to be reworked for another target journal and submitted
- For the target journal to publish the accepted paper

8. Overall Topics for Review

A comprehensive list of recommended manuscripts, titles, authors, timelines and journals will be developed for Wyeth-Ayerst Laboratories upon assignment of this project and a

review of the clinical operating plan.

The following services are included in the cost of developing each original paper, review article, or other publication:

- Submitting a written work plan, confirming the nature of the project, due dates, and any special concerns.
- Styling the publication to meet the requirements of the target journal, meeting sponsor, etc.
- Submitting the manuscript, on the agreed-upon date, to all appropriate investigators and to designated reviewers at Wyeth-Ayerst Laboratories.
- Making two rounds of reasonable changes to the manuscript
- Submitting the manuscript to the target journal in the form of a journal submission package (usually using the letterhead of the principal investigator/author)
- Incorporating the peer reviewers' suggested changes, once these changes have been authorized by the designated author(s) of the paper.

RECOMMENDED JOURNAL ARTICLES AND STUDIES

1. VALUE OF ESTROGEN THERAPY (BUNDLE OF BENEFITS)

Article	Journal	Timing
Estrogen or Anti-Estrogen: That is the Question.	*Contemporary OB/GYN*	4Q97
The pharmacologic and non-pharmacologic approaches to treating the complications of menopause	*Journal of Family Practice*	1Q98
Hormone Replacement Treatment Guidelines for Postmenopausal Women	*American Journal of Medicine*	2Q98
Estrogen Therapy: Expanding the Clinical Horizon	*American Family Physician*	2Q98
HRT: The Pharmacist's Role in Improving Patient Compliance	*U.S. Pharmacist*	1Q98
Long-term Sequelae of Postmenopausal Complications	*Geriatrics*	3Q98
Pharmacologic Factors associated with Estrogen's Effect in Coronary Heart Disease	*Pharmacotherapy*	1Q98

2. BOLSTER PREMARIN's PERCEPTION AS THE ORIGINAL SERM

Article	Journal	Timing
Long-term efficacy, safety, and tolerability of Conjugated Estrogens	*Postgraduate Medicine*	2Q98
Costs associated with hormone replacement therapy in the HMO	*Journal of Managed Care Pharmacy*	3Q98
Conjugated Estrogens: Clinical Overview and Literature Evaluation	*Endocrinology*	2Q98
Economic and Human Toll of Untreated Menopausal Complications in the Managed Care Environment	*American Journal of Managed Care*	2Q98

3. BLUNT COMPETITIVE INROADS OF RALOXIFENE

Article	Journal	Timing

Clinical Evaluation of Selective Estrogen Receptor Modulators (SERMs)	*American Journal of Cardiology*	2Q98
Hormone Surveillance Studies: Do we have the data we need?	*American Journal of Health-System Pharmacy*	1Q98
Steroid Misadventures: What can history tell us?	*Pharmacy Times*	4Q97
The Connection between Uterine Cancer and Estrogen Therapy: Fact vs. Fiction.	*Cancer*	2Q98
Review of tamoxifen, raloxifene, and estrogen on reproductive tissue.	*American Journal of Obstetrics and Gynecology*	2Q98
Primary Studies		
Raloxifene and Uterine Weight Study	*Endocrinology*	1Q 98
Progesterone Receptor Activity Study	*Endocrinology*	1Q98
Hot Flush Model Study	*Endocrinology*	1Q98
Neuronal Cell Study	*TBD*	4Q97
Endothelial Cell-Oxidized LDL Study	*TBD*	2Q98
Anti-Oxidant Study	*TBD*	2Q98
Vasomotor Activity Study	*TBD*	2Q98

4. DISPEL THE PERCEPTION OF ESTROGENS CAUSING CANCER

Article	Journal	Timing
Estrogen and Cancer: The Debate Continues	*Current Therapeutics Research*	1Q98
Quantifying the Real Risk of Cancer in Postmenopausal Women on HRT Therapy	*Journal of Clinical Oncology*	2Q98
Relative vs. Absolute Risk in Breast Cancer	*Seminars in Oncology*	1Q98
Retrospective Analysis of the Association between HRT and Endometrial Cancer	*Geriatrics*	1Q98
Clinical significance of SHBG as a surrogate marker in breast cancer	*Journal of Investigative Medicine*	1Q98