

American Society
of Breast Disease

Advisor

Summer 2003

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LETTER FROM THE PRESIDENT

Barbara Rabinowitz, PhD

Dear Fellow ASBD Members:

Members of the American Society of Breast Disease share a passion that starts with a commitment to excellence in breast care and includes a dedication to the true interdisciplinary nature of that care. Our mission at the organizational level matches your mission as individual practitioners who collaborate on behalf of every woman who struggles with breast disease.

That is not to suggest that working in an interdisciplinary fashion is a given and easy to implement and execute in all settings. You might assume that it is easier in "comprehensive breast centers," and you would often be correct – but not always. There are a multitude of issues in healthcare – both for individual practitioners and for those providing care in breast centers in the modern era – that may make it difficult for you to provide care using an interdisciplinary model.

Part of our focus as a membership organization is to listen to the challenges that you face in working collaboratively and in the interdisciplinary model. Identifying those issues may help drive the agenda for written articles, website pieces and conference offerings that can facilitate productive, cross-specialty fertilization.

One such example is the use of hormone therapy, which has made front-page news as a result of the Women's Health Initiative's work and has raised concerns among ASBD members as to how to respond to patient needs and questions. The viewpoints expressed in this issue of the Advisor reflect the ASBD's mission of encouraging open exchange and debate. We know that this discussion will continue and look forward to your input.

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From the Executive Director

In her letter in this issue, ASBD President Barbara Rabinowitz refers knowingly to the challenges that clinicians and healthcare professionals may encounter in serving patients in a comprehensive and interdisciplinary breast center. Among those challenges is communicating information that is not always black-white or yes-no.

Breast health is indeed complex, and more is being learned each day. Genomics, less invasive procedures, earlier diagnosis, improved imaging techniques, and more intensive and less destructive therapeutics are changing the ways in which clinicians and patients face both illness and health. Breast cancer is not just a disease requiring multi- and interdisciplinary attention. It is also a nuanced disease in which the physician and medical community must continually apply judgment and provide expertise to each patient individually.

The content of this issue of the Advisor demonstrates the ways in which professionals may differ. The diversity of views that are voiced here and raised regularly in ASBD conference calls and at our education programs also reflects the breadth of perspectives needed to move our shared agenda forward.

And our agenda is moving forward in exciting ways. In the coming year, the ASBD will continue the kind of locally based education programming that was launched in 2003. Your Education Program Committee welcomes your suggestions as to the content of those programs. So please let us know what topics are of interest to you. As Dr. Rabinowitz notes, "When you identify the needs as you see them, you empower us to be partners with you in seeking solutions."

In 2004 we will work with the Global Summit, with the WSBH, with the Society of

Surgical Oncology, with the American Society of Breast Surgeons, with the American College of Radiology, and other organizations to ensure that the ASBD's unique multidisciplinary voice is heard.

Internally we will keep intensifying our agenda as well. Your Consensus Committee recently formed a subcommittee to consider existing data on the screening of high-risk women with the goal of issuing a statement by early 2004. Your Public Policy Committee regularly reviews the national legislative agenda and comments, as appropriate, on policy issues that affect the ASBD's membership. And with the leadership of your Membership Committee, that membership is expanding. You can support that expansion easily. If you have a colleague who is not yet a member, point them to our website for easy access to an application.

Brooke Breslow

Letter from the President

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For the ASBD at large, it's not difficult to stay the course in spreading the message regarding the interdisciplinary nature of breast care. It is who we are. We have the vehicles to accomplish our growing agenda. We can provide information shared by members regarding how they push to make interdisciplinary care an ongoing reality in daily practice. When members have questions, other members often have experience that can address those dilemmas. The ASBD's desire is to help and to help through action.

We are fortunate that so many members have responded to our calls to action. Currently, 10 percent of ASBD members are engaged in committee work of some kind. As our agenda grows, we need and welcome increased member participation. We are currently seeking your ideas to support our work with the World Society of Breast Health. (This issue includes an article on the Global Summit that we will support in 2004.) And we look forward to your submissions for poster presentations at next spring's annual symposium in Boston.

Members of the American Society of Breast Disease share a passion that starts with a commitment to excellence in breast care and includes a dedication to the true interdisciplinary nature of that care. . . . As our agenda grows, we need and welcome increased member participation.

We encourage your on-going suggestions on ways to improve our communications and our policy and consensus statement activities. When you identify the needs as you see them, you empower us to be partners with you in seeking solutions. We stand ready.

*Barbara Rabinowitz, PhD
President, ASBD*

Boston 2004

The 28th Annual Symposium of the American Society of Breast Disease will be held at the Westin Copley Place Hotel, Boston, Massachusetts from April 23 to 25, 2004. The keynote address by Craig Henderson, MD, will set the stage for a comprehensive and dynamic program to include pro-con debates, special topic lectures, a set of focused, hands-on workshops, exhibits, and an expanded poster review and discussion session.

The following are some of the topics currently scheduled for debate.

- screening mammography – over-diagnosis versus the value of early detection
- risk assessment and prevention – who should be targeted?
- aggressive vs. conservative management of DCIS and microinvasive breast cancer
- maximizing adjuvant chemotherapy: what agents, how long and how much?
- strategies for the management of metastatic breast cancer

Special lectures will include:

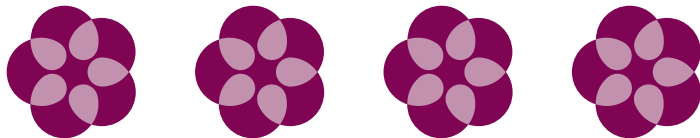
- Molecular profiling in breast cancer: present and future
- Standards and controversies in hormonal therapy for breast cancer
- Are trials really necessary to advance breast care?
- Pathology and clinical decision-making

In addition, five concurrent workshops will offer hands-on practical experience for participants.

- Economics of Breast Cancer
- Successful Survivorship
- Radiologic/Pathologic Correlation in Core Biopsies
- Applying Innovations in Surgical and Radiation Oncology
- Using Targeted Therapeutics

The Symposium will close with a rapid-fire session of late-breaking news in all areas of breast cancer treatment including imaging, pathology, radiation oncology, surgery, and medical oncology with an advocate's report card on how well we are doing as healthcare professionals.

Keep up-to-date with the latest information on Symposium planning by visiting the ASBD website (www.asbd.org) regularly. Online registration will be available in December.



Breast Fellowship Guidelines

In an effort to standardize the breast fellowship training curriculum nationally and make the application and acceptance process more structured, a collaborative effort involving the American Society of Breast Disease, the American Society of Breast Surgeons and the Society of Surgical Oncology has developed comprehensive guidelines for training breast fellows.

To support this effort, the ASBD has established a Breast Specialty Training Committee that will oversee our involvement, develop a comprehensive reading inventory, and coordinate ASBD participation in the site inspection process. Elizabeth Naftalis, MD, of the UTSW Center for Breast Care, Dallas, will chair the Committee whose members include: Michael J. Ullissey, MD, Women's Diagnostic and Breast Health, Plano, Texas; Daniel Hayes, MD, University of Michigan, Ann Arbor; Shahla Masood, MD, University of Florida, Jacksonville; Victor G. Vogel, MD, Magee-Women's Hospital, Pittsburgh, Pennsylvania; Helen Alexandra Pass, MD, William Beaumont Hospital Breast Care Center, Royal Oak, Michigan; Gladys Giron, MD, Memorial Sloan-Kettering Cancer Center, New York; and Kathy-Ann Joseph, MD, Columbia Presbyterian Medical Center, New York, NY.

The first breast fellowship match is scheduled to take place December 1, 2003, with candidate applications due two weeks' earlier. Because of its prior experience in conducting matches, the SSO's training committee, chaired by Scott Kurtzman, MD, will administer the match and accreditation process with continuing guidance from the ASBD's committee.

Each breast fellow will receive experience in breast imaging, breast surgery, community service and outreach, genetics, medical oncology, pathology, plastic and reconstructive surgery, psycho-oncology, radiation oncology and breast research.

Currently, 23 standing breast training programs have confirmed that they meet the criteria outlined in the guidelines and have agreed to be inspected within the next three years. These institutions are: Anne Arundel Medical Center, Annapolis, Maryland • Arkansas Cancer Research Center, Little Rock • Baylor University Medical Center, Dallas, Texas • Beth Israel Medical Center, New York • Bryn Mawr Hospital, Pennsylvania • Carol Frank Buck Breast Care Center/ University of California at San Francisco • Center for Breast Care at the University of Texas Southwestern Medical Center, Dallas • Cleveland Clinic Breast Center, Ohio • Columbia University, New York • Gillette Center for Women's Cancer, Boston, Massachusetts • Grant Medical Center, Columbus, Ohio • H. Lee Moffitt Cancer Center, Tampa, Florida • Helen F. Graham Cancer Center, Newark, Delaware • John Wayne Cancer Institute, Santa Monica, California • Loyola University Health Systems, Maywood, Illinois • Massachusetts General Hospital, Boston • Memorial Sloan-Kettering Cancer Center, New York • Norris Cancer Center at the University of Southern California, Los Angeles • Northwestern University, Chicago, Illinois • St. Luke's-Roosevelt Hospital Center, New York • Stanford University Medical Center, California • University of Massachusetts Memorial Healthcare, Worcester, Massachusetts • University of Michigan, Ann Arbor • University of Texas M.D. Anderson Cancer Center, Houston • Washington Hospital Center, Washington, DC • William Beaumont Hospital, Royal Oak, Michigan.

Conference Round Up

2nd Congress of the World Society of Breast Health

JUNE 24-28, 2003

The 2nd Congress of the World Society of Breast Health (WSBH) convened in Budapest, Hungary, from June 24 to 28, 2003. For ASBD members unable to enjoy the sites of Budapest while reviewing the more than 70 papers and 50 abstracts that were featured in the multidisciplinary program, this summary provides a glimpse of a program that included sessions reflecting the WSBH's global reach. The keynote lecture addressed the genetics of breast cancer in central and eastern European populations, with other sessions targeted at early stage breast cancer diagnosis and treatment in Turkey and Japan.

ASBD's president-elect, Ben Anderson, along with Ute Albert (Marburg, Germany), Shahla Masood (Jacksonville, USA), Klaus-Dieter Schulz (Marburg, Germany), and Roman Shyyan (Lvov, Ukraine) reported on the Global Summit, chaired by Dr. Anderson. (See the article on the Global Summit in this issue.) Board member Susan Braun led the first of several public meetings that centered on breast cancer and breast health issues from the consumer and/or patient perspective.

Ian Tannock, MD, of the Princess Margaret Hospital and University of Toronto, Toronto, Canada, described the phenomenon of "chemobrain" and noted that there is "increasing recognition that fatigue, menopausal symptoms and cognitive changes are associated with chemotherapy, and influence the quality of life of cancer patients." He then reported on the first year results of a longitudinal study to evaluate these symptoms in women receiving adjuvant chemotherapy for breast cancer and encouraged further study of strategies that might reduce the toxic effects observed.

Throughout the Congress, the multidisciplinary nature of the WSBH was on display in the breadth of topics including: Impact of breast screening on the quality of life of the participant; Axillary lymph node involvement, sentinel node biopsy, and sentinel node pathology; Possibilities and limitations of ultrasound; DNA damage and repair in breast cancer; Quality assurance in breast pathology; MRI as state of the art; Preoperative chemotherapy and its impact on breast conservation; Role of prognostic and predictive markers in the selection of optimal systemic adjuvant therapy. The third WSBH congress is scheduled for Japan in 2005.

The Global Summit Consensus Conference on International Breast Health 2002

Guidelines for Countries of Limited Resources

How can breast-cancer morbidity and mortality in poorer countries be reduced? The Global Summit Consensus Conference on International Breast Health convened to find answers to this complex global public-health issue and to produce specific outcomes in the form of Guidelines for Countries of Limited Resources.

Convened in 2002, this international conference was a public and private

alliance initiated by the Fred Hutchinson Cancer Research Center, the University of Washington, and the Susan G. Komen Breast Cancer Foundation to produce practical written guidelines that address screening, diagnosis and treatment of breast cancer in countries with limited resources. Guidelines developed at the first Global Summit in Seattle by an international group of experts were published in the May/June 2003 supplemental issue of The Breast Journal and shared with all ASBD members.

A Systematic Approach to a Global Attack on Breast Cancer

The American Society of Breast Disease is pleased to be joining this effort with 2004 Global Summit, which will expand its vision beyond development of international breast healthcare guidelines to create strategic, multifaceted public and private partnerships. Leading this global initiative is ASBD president-elect and Global Summit Chair, Benjamin O. Anderson, MD, Joint Associate Member, Public Health Sciences, Fred Hutchinson Cancer Research Center, Public Health Sciences Division, and Director, Breast Health Center, Breast Care and Cancer Research Program, University of Washington, and ASBD Board member and Global Summit co-chair, Susan Braun, President and CEO, The Susan G. Komen Breast Cancer Foundation.

The alliances created through the Global Summit will support advancement of breast health programs and mechanisms to share knowledge and expertise across borders. Guidelines will address ways to implement breast healthcare measures in countries where healthcare access is a challenge, where awareness is limited, and where cultural barriers to diagnosis and treatment exist. "There has been a great deal of research defining how to do breast care when resources are without limit," said Dr. Anderson. "As a result, we know a lot about breast disease and can make a significant impact when we have the resources. What has never been done is sorting out, at a basic level, what to do when you don't have those resources."

The practical written guidelines are a crucial end-product that offer a vital medical tool and flexible framework for implementing and expanding healthcare programs, which can be tailored to each country and region's unique circumstances. "We recognize that populations differ, social environments differ,

The alliances created through the Global Summit will support advancement of breast health programs and mechanisms to share knowledge and expertise across borders.

the types of resources that can be made available differ around the world," Anderson said, "and so the solutions in two different parts of the world as to what is the next step may well be different."

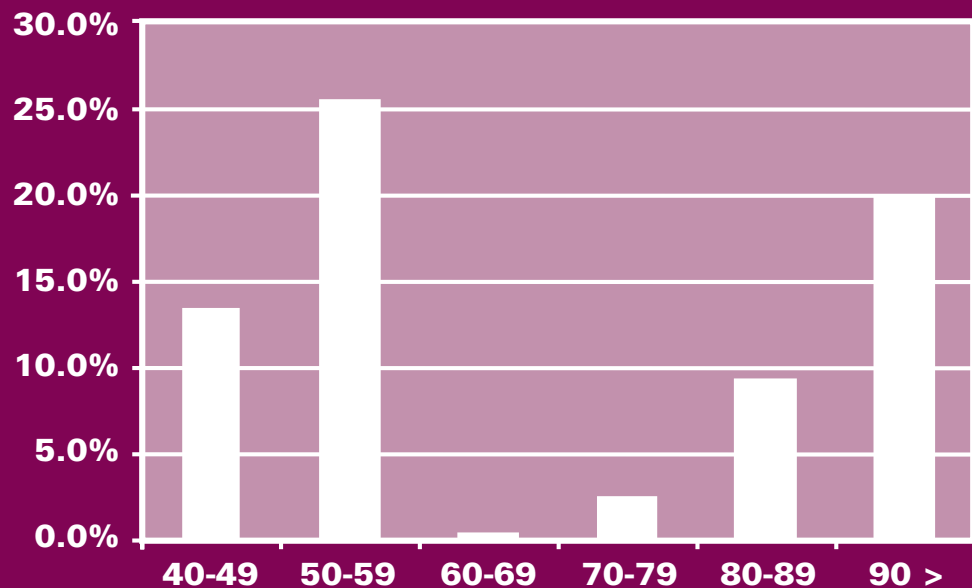
Women commonly or even typically present with stage III disease in many countries. "Current guidelines apply to breast cancer care for developed nations, but they are not practical tools or relevant when you talk about rural

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The Changing Demographics of Breast Cancer

Percent Change in US Population of Women by Age Range (1995-2000)*

*Data are drawn from the US Census Population Estimates Program. All population figures are based on the 1990 Census; they do not reflect Census 2000 counts.



Conference Round Up

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China or Senegal. It's clear that we will not be able to solve the global breast-cancer problem in a single large step," said Dr. Anderson. "It is going to be small incremental steps in different parts of the world at different times that allow us to make advances. The Global Summit guidelines will provide a framework by which these incremental steps can be made."

The Global Summit functions as a vehicle for international awareness, communication, collaboration, and collective engagement, and creates a 'linkage hub' of three essential public and private entities:

- Clinical Communities (health care systems, physicians, government agencies);
- Public Health Research (outcomes analysis, economic modeling and pilot projects); and
- Advocacy and Non-Governmental Organizational (NGO) Community (through communications, implementation, and patient education).

These linkages are essential to cultivate lines of communication for a deeper appreciation of the complexities of the global environment, and initiate fundamental research and pilot projects in developing regions.

The guidelines are being disseminated through national and international health care and medical organizations and government health ministries. They will be updated in alternate years, with the next Global Summit slated for fall 2004 in Washington, DC. "The universal objective of the Global Summit is as a continuing international alliance and inquiry into the challenge of improving breast health care around the world. We plan to bring other people and organizations on board to help us with the next round of guidelines development," Dr. Anderson said.

To view an international briefing held in Washington, DC in June on the Global Summit on International Breast Health visit on the Komen website at: www.komen.org.

For information on the 2004 Global Summit, visit: www.fhcr.org/phs-global_summit/.

To Our Readers:

The American Society of Breast Disease is committed to providing healthcare professionals and the public with current information regarding specific topics of concern in the field of breast healthcare. Thus, as part of our educational mission, the ASBD publishes and distributes the Advisor on a quarterly basis.

Certainly we all understand that medicine is both an "art" and a "science," and rarely is there only "one right answer" on any medical multiple-choice question. With that in mind, and in the spirit of healthy debate, we will now offer a new section of the Advisor entitled Point/CounterPoint.

In this section, we will feature controversial topics such as Hormone Replacement Therapy. Opposing opinions and/or recommendations will be presented and discussed by experts in the field, and readers are encouraged to respond with comments that will be published in future issues.

The Communications Committee of the ASBD believes that providing this forum for candid exchange between professionals will offer its members and other readers interesting and important information. It should be noted, however, that the opinions published in Point/CounterPoint represent those of the individual authors and are not meant to serve as recommendations or guidelines set forth by the Society.

We welcome your comments. Respectfully yours,

Gail S. Lebovic, MA, MD, FACS
 Chair, ASBD Communications Committee
 Associate Director,
 Lee Comprehensive Breast Center
 Associate Professor of Surgery
 USC Keck School of Medicine

Dr. Pollycove is a board-certified obstetrician/gynecologist, practicing gynecology and specializing in breast health, menopause, infertility, women's wellness/disease prevention and integrative medicine for women in San Francisco. She is a member of the ASBD, and serves on its Symposium program committee. She is coauthor with Rick and Jan Hanson of the recently published integrative health book, Mother Nurture: A Mother's Guide to Health in Body, Mind and Intimate Relationships, Penguin Press, 2002. Dr. Pollycove has been a member of the speaker bureaus of the following companies: Aventis, Barr, Lilly, Merck, Pharmacia, Pfizer, Warner-Chilcott, Watson and Wyeth. She has not received any financial support for clinical research.

Point

Hormone Re

POINT / HRT and Breast Cancer: Where Are We Now After the WHI?

Ricki Pollycove, MD, MHS

A firestorm of fear and mistrust erupted following the sensational release of the Women's Health Initiative (WHI) study of the effects of estrogen plus progestin (E+P) (Prempro™) as compared to placebo in menopausal women on July 9, 2002.¹ Unlike most previous publications of data from a large research trial, the WHI results continue to create intense fear and debate in public and professional sectors. Described by one of its investigators as "the end-all-be-all study,"² the Hormone Replacement Therapy (HRT) trial and its results continue to appear in the press, fueling growing public mistrust of doctors and the medical establishment. Dramatic TV, magazine and newspaper stories depict women by the thousands throwing out their HRT prescriptions and questioning their trust in their doctors. How can the results of the WHI be so contrary and terrifying? And what was so enormously powerful about the trial data that it "revolutionized" the approach to HRT?

In angry circles of women activists the WHI study became synonymous with the claim that HRT was the biggest experiment ever foisted upon vulnerable women who mistakenly trusted their doctors. But in actuality, the study did not tell us much that was new. The study confirmed the following: HRT (Prempro) use reduced risks of colon cancer and hip fractures. HRT slightly increased risks of hypercoagulation-related events (stroke, MI, DVT) and breast cancer diagnosis. The WHI showed a 24 percent increased relative risk of being diagnosed with a breast cancer if using HRT, with the actual difference in risk (absolute risk) between women who did and did not use HRT exceedingly small, 8 in 10,000 women per year, equaling 0.08 percent or eight-hundredths of 1 percent.³

We have all seen the scattergram closely hugging 1 of the relative risk data from articles published comparing breast cancer incidence in HRT users vs non-users, with a slight trend towards the positive (approximately +0.3 RR overall increase when taken in aggregate).⁴ But what is generally shared by physicians with patients is at odds with the facts regarding HRT and breast cancer diagnosis and long-term outcomes. For example, not only does pregnancy subsequent to breast cancer diagnosis not shorten life span nor increase risk of recurrence, but the women (or those who are too symptomatic to endure life without HRT) who resume use of estrogen after breast cancer therapy if anything live longer and experience fewer breast cancer recurrences.⁵ Both the pregnancy data and the HRT data may reflect "healthy user" effect, but these are, in fact, the patients for whom we are prescribing

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CounterPoint

placement Therapy

COUNTERPOINT / Menopausal Hormone Therapy and Breast Cancer: Where We Are After the WHI

Rowan T. Chlebowski, MD, PhD

Several issues are raised by Dr. Polycove regarding the interpretation and medical impact of the Women's Health Initiative (WHI) randomized trial of estrogen plus progestin in postmenopausal women.¹ Dr. Polycove suggests that although the WHI study "did not tell us much that was new" it nevertheless receives ongoing and perhaps unbalanced media attention fueling "public mistrust of doctors and the medical establishment."

The major objective of the WHI trial of estrogen plus progestin was to determine whether for most postmenopausal women long-term use of estrogen plus progestin is associated with overall favorable impact on health (as measured by a global index of life-threatening diseases felt to be under potential hormone influence).² However, the WHI study results have implications for shorter duration menopausal hormone use for vasomotor symptom management as well. The WHI included 5522 women between the ages of 50 to 59 and 2046 women with moderate to severe vasomotor symptoms.³

Did the WHI tell us much that was new? Based on the evidence available prior to the WHI trial results, there was an expectation that more benefit than risk for combined estrogen plus progestin would be seen. Menopausal Hormone Therapy was anticipated to improve vasomotor symptoms (if present), improve general quality of life, reduce hip fractures, reduce coronary heart disease (CHD) and perhaps improve cognition and reduce dementia.^{4,5} Anticipated risks included increased vascular events (pulmonary emboli and stroke) and increased breast cancers which develop after more than five years use but which would have favorable characteristics and would represent relatively easy to treat disease.⁶

In fact, the results of the WHI were quite different. The trial was stopped early after about five years when observed risks exceeded benefits including increased, rather than decreased, CHD, increased strokes, pulmonary emboli and invasive breast cancers compared to reduced hip fractures and colon cancers.² In addition, a significantly increased risk of dementia in women 65 years of age or older resulted from estrogen plus progestin use in a WHI ancillary study.⁷ It is especially noteworthy that the breast cancers in the estrogen plus progestin group were diagnosed at a more advanced stage and did not have the expected more favorable histologic characteristics.⁸ Several of these largely unexpected findings can well be considered new information.

Why "unlike most previous publications of data from a large research trial" do WHI results continue to receive media attention? Ongoing attention con-

tinues largely related to reports of new and/or updated information from the WHI in medical journals with practice impact (including JAMA and New England Journal of Medicine). The ongoing media coverage follows and reflects the assessment of the editors and reviewers of these journals that additional information from the first full-scale prospective randomized clinical trial of menopausal hormone use in otherwise healthy women warrant dissemination especially considering the large number of women who are potential candidates for this therapy.

A timeline of some of these reports follows. In July of 2002 the WHI reported that the overall risk of estrogen plus progestin use exceeded benefits.² In March of 2003 the WHI reported that quality of life was not improved with estrogen plus progestin use.³ In May 2003 the WHI reported that women on estrogen plus progestin were at higher risk for developing dementia.⁷ In June 2003 the WHI reported that women on estrogen plus progestin had increased numbers of breast cancers diagnosed at higher stage and a substantially increased frequency of abnormal mammograms seen beginning after only one year, a new side effect of short term hormone use.⁸ Most recently, August of 2003, the WHI reported that the increased risk of CHD was most apparent after one year of estrogen plus progestin use.⁹ As such new information becomes available its integration into clinical practice requires further attention from the medical and lay community.

It is not only medical journals and the media which have considered this information worth disseminating. In response largely to the WHI results, the Federal Drug Administration (FDA) in 2003 revised the consumer labeling for all estrogen plus progestin combinations including a black box warning for heart disease, heart attacks, strokes and breast cancer and a recommendation to use the lowest dose for the shortest duration when using menopausal hormone therapy for any indication.

Additional information confirming and extending many of the major WHI findings regarding breast cancer comes from the Million Women Study.¹⁰ In this large cohort study, menopausal hormone therapy use was associated with increased breast cancers beginning after only one year and a significant increase in breast cancer mortality was seen. In this cohort, oral, transdermal and implanted hormone use were all associated with an increase in breast cancers. The Million Women Study also found that women who used estrogen alone were at some increased breast cancer risk, but this risk was much lower than for combination therapy.

What about "bioidentical" hormone therapies? Currently there is no clinical evidence supporting the safety for coronary heart disease or breast cancer for

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Dr. Chlebowski is a board-certified Medical Oncologist with a PhD in reproductive biology. He is a professor of Medicine at the David Geffen School of Medicine at UCLA, an investigator in the Women's Health Initiative and Chief of Medical Oncology at the Harbor-UCLA Medical Center. Dr. Chlebowski is a consultant to Astra-Zeneca, on the Novartis speaker's bureau, and receives grant support from Abbott International and Taiho.

From the Harbor-UCLA Research and Education Institute. The views expressed in this report represent those of the authors and do not necessarily reflect those of the Women's Health Initiative Investigators or Program.

Some of the work reviewed in this report was funded by the National Heart, Lung, and Blood Institute, National Institutes of Health Department of Health and Human Services.

HRT: Point

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HRT or condoning pregnancy post breast cancer treatment.

The small associated increased rate of breast cancer diagnosis has been documented in many previous HRT studies, but last July was headlined as "Citing Risk US Will Halt Study of Hormones."⁶ The fact that the great majority of retrospective and observational analyses around the globe show that HRT users compared to non-users diagnosed with breast cancer have better outcomes and live longer was not mentioned. The following day "This is a dangerous drug,"⁷ appeared which would lead readers to fear horrible and frequent harm from its use.

Contrary to the expectations of surgeons and frightened patients, O'Meara's review⁸ added reassuring data regarding reduced breast cancer recurrence and lowered mortality in those women who used HRT after diagnosis of breast cancer. Trials such as HERS, ERA^{9,10} and the Nurses Health Study were not previously household terms. Yet the data was available and used responsibly by most physicians who prescribed HRT appropriately to millions of younger symptomatic newly menopausal women as contrasted with the asymptomatic population, average age 63 on entry, studied in the WHI.

Further confusion and problems have been created by the absence of discussions in the media regarding differences between the WHI trial and bio-identical estrogen and progesterone regimens. Focus on a fixed dosage of combination estrogen/progestin reflects outmoded "one size fits all" HRT prescribing patterns, which was the previous standard of care for millions of menopausal women. Large volumes of reassuring data obtained from lower physiologic doses of estrogen and non-oral routes of delivery are also woefully missing from media coverage [author's personal observation]. Women have been robbed of any confidence they might have had in the innate wisdom of their bodies, with their natural hormones viewed as killers, not friends.

Demographic data reveal that the opportunity to experience menopausal hormone changes is a relatively new gift of longevity, mostly brought to us by public health measures (such as clean water, control of sewage, immunizations for high-mortality infectious diseases, treatment for TB, etc.).¹¹ The average life expectancy for women in the U.S. after the Revolutionary War was 32 years and rose slowly to 49 by 1900, and now approaches 80 years of age in 2000.¹²

When women express anger over our lack of good solid data regarding optimal management of menopause they can be assured that this is a relatively new phenomenon in the eons of time for biologic evolution and our understanding of it. For a variety of reasons, some of them not so politically correct, gender-based research trials are a new kid on the block. It has taken many decades to raise concerns about the disenfranchisement of women from traditional Western medical research trials. For the very reasons biology between men and women differ, women were historically excluded from trials so as to not confound the data. This is not current-day consciousness or wisdom and we have to do better.

The reproductive constraints of menstrual cycling are essential to women's physiology and have profound biologic implications. Menopause imitates the endocrine state of postpartum lactation in many essential aspects. The low-estrogen state of menopause (cessation of ovarian hormone production) causes an inexorable mobilization of calcium from bone and fats from fat stores. Evolutionary biology would favor this particular physiology only dur-

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HRT: Counterpoint

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any of these agents. In fact, in the observational Million Women Study, increased breast cancer risk was seen for all hormone preparations including some considered "bioidentical."¹⁰

With respect to estrogen alone use, the question of risks and benefits is still open as the WHI randomized trial comparing estrogen alone to placebo continues under Data Safety Monitoring Board oversight. This trial is scheduled to report results in about two years.

Dr. Polycove makes a range of additional arguments to support a favorable role for hormone therapy largely based on biological inferences and/or observational study results. However, the medical and scientific communities and health regulatory agencies have considered an appropriately powered, randomized prospective clinical trial as representing a higher standard for producing reliable results with randomized clinical trials described recently as "the best basis" for making clinical decisions.¹¹

For over the past twenty years it has been recognized that use of menopausal hormone therapy requires a balanced consideration of the associated benefits and risks in light of a woman's individual values and judgment. That process has not been altered by the results of the WHI trial of estrogen plus progestin. However, what has changed is that we now have more reliable information from a large randomized trial which suggests our prior understanding of the risk versus benefit balance of combined estrogen plus progestin use need to be adjusted.

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This summary of key issues of interest to ASBD members is provided in cooperation with the Susan G. Komen Breast Cancer Foundation.

REFORM OF MEDICARE REIMBURSEMENT FOR CANCER CHEMOTHERAPY DRUGS AND SERVICES UNDER PART B

Medicare Part B currently covers certain oral anti-cancer drugs and anti-nausea drugs that have an IV equivalent. Payment is based on 95% of the Average Wholesale Price (AWP). Medicare pays 80% and the beneficiary pays 20% of the recognized price. In the Medicare reform bills passed by the House and the Senate, reimbursement rates for drugs already covered under Part B of the Medicare program (such as oncology drugs) would be reduced to produce savings to pay for a new Medicare outpatient prescription drug benefit. Both bills include provisions to adjust the physician fee schedule to reflect practice expenses for oncology administration services. However, the reduction in reimbursement to physicians for drugs exceeds the increase in payments for oncology drug administration. According to the House estimates, the provisions remove from \$460-700 million annually from the drug payments, and the Senate bill contains cuts of a similar magnitude. Both bills would increase practice expense payments by no more than \$190 million. The House and Senate bills are currently being reconciled by a Conference Committee.

► **Senate bill** Part B covered drugs would continue to be reimbursed under Part B. Part B reimbursement for existing drugs and biologicals would be reduced from 95% AWP to 85% AWP. Over time, widely available market prices would become the basis for reimbursement.

► **House bill** Physicians would choose between acquiring Part B covered drugs from a contractor or being reimbursed at a percent of Average Sales Price (ASP) (112% through 2006, after which the amount would be set at 100% ASP). Physicians acquiring drugs from contractors would neither pay for the drug nor be reimbursed by Medicare for it.

CMS Proposed Rule

The Centers for Medicare and Medicaid Services (CMS) claim that the agency has the authority to reform reimbursement of Part B covered drugs administratively, without new legislation. On

August 20, CMS issued a proposed rule that set forth four options for reducing payment for Part B covered drugs:

► **Comparability** The reimbursement rate would be set at the cost that Medicare carriers pay for comparable drugs in a comparable setting in their private plans (such as PPOs).

► **Percent of AWP** Models the Senate bill. Drugs would be reimbursed at 85% AWP. Reimbursement of new drugs would be based on the market price.

► **Market Monitoring** Models the Senate bill. In the long-term, the AWP would be redefined as the widely available market price (WAMP) based on price data from manufacturers, physicians, suppliers, etc.

► **Competitive Acquisition/Average Sales Price (ASP)**. Models the House bill. Third parties would negotiate prices with manufacturers and submit a bid to Medicare based on the negotiated price. Awarded contractors would bill Medicare directly for drugs. Physicians would then acquire drugs either from (1) awarded contractors (physician would neither purchase drugs nor be reimbursed for them); or (2) manufacturers or suppliers as in status quo, but would be reimbursed at a percent of ASP (112% ASP until 2006; 100% ASP after 2006).

Quality Cancer Care Preservation Act

On April 8, 2003, Representatives Charles Norwood (R-GA) and Lois Capps (D-CA) announced their sponsorship of legislation to reform the current Medicare system for reimbursing chemotherapy and other cancer care services. H.R. 1622, the "Quality Cancer Care Preservation Act", would significantly increase Medicare reimbursement for practice expenses incurred in administering chemotherapy drugs while decreasing reimbursement to physicians for the drugs. The Act would reimburse drugs at rates based on the manufacturer's Average Sales Price with an additional amount to cover costs associated with handling the drugs. It would also cover the full costs of administering chemotherapy, including specialized equipment and supplies as well as oncology nurse time; and would establish reimbursement for a broad spectrum of patient care services, including patient counseling concerning treatment, side effects, nutrition, end of life issues

and psychosocial services. H.R. 1622 currently has 112 cosponsors. S. 1303, the Senate companion bill, was introduced by Senator Sam Brownback (R-KS) and currently has nine cosponsors.

ACCESS TO NECESSARY CANCER THERAPIES

Representative Deborah Pryce (R-OH) and Senator Olympia Snowe (R-ME) have introduced H.R. 1288 and S. 1037, the "Access to Cancer Therapies Act," to extend Medicare outpatient coverage to include all oral anti-cancer drugs. Medicare currently covers only those oral anti-cancer drugs that also are available in injectable form. Hormonal agents for breast cancer (such as tamoxifen and anastrozole) are not currently covered, and many new oral cancer therapies are expected on the market in the near future. H.R. 1288 currently has 206 cosponsors, while S. 1037 has 30.

REAUTHORIZATION OF AND INCREASED FUNDING FOR THE NATIONAL BREAST AND CERVICAL CANCER EARLY DETECTION PROGRAM (NBCCEDP)

The NBCCEDP provides breast cancer screening, outreach and case management services for women who lack access to health care. Since 1990, this landmark program has screened nearly two million women, and detected approximately 13,000 cases of breast cancer. The NBCCEDP has helped reduce disparities in screening for racial and ethnic minority women, who represent half of all women screened through the program. Yet, the current NBCCEDP funding level allows it to cover only about 18 to 20 percent of the eligible population – which means that four out of five eligible women are not being served. The NBCCEDP is currently up for reauthorization. [Providers and patient groups are urging Members of Congress to reauthorize NBCCEDP this year and to increase FY 2004 funding for the program to at least \$220 million to expand access to these important screening services]. The Senate and House bills would provide almost \$211 million, which is \$11.5 million above the fiscal year 2003 comparable level and equal to the President's budget request. The full House has

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Legislative Update

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passed its appropriations bill, whereas the Senate has not.

FUNDING FOR THE NATIONAL INSTITUTES OF HEALTH (NIH)/NATIONAL CANCER INSTITUTE (NCI)

Over the last five years, the cancer community successfully advocated for doubling the NIH budget to accelerate progress in critical research areas, including breast cancer. The five-year doubling effort is now complete, and there is concern that current proposals for NIH funding are inadequate. The House and Senate bills appropriate \$4.77 billion to the National Cancer Institute (\$178 million above FY 2003 and the same as the President's budget request). The House provides almost \$27.7 billion to the NIH (same as President's request); the Senate provides almost \$28 billion (\$1 million over FY 2003 and \$318 million over President's request).

Senators Dianne Feinstein, Tom Harkin and Arlen Specter recently introduced an amendment to continue on the path set in recent years by increasing the NIH budget to \$29.6 billion in FY 2004 (an 8.5 percent increase), and allocating \$5.9 billion to NCI per the NCI Director's budget request. Given the timing of the amendment, it could only be considered under a waiver of the Congressional Budget Act, which requires a positive vote of 60 Senators. The amendment was defeated on September 10, 2003, by a vote of 52 to 43. Although the amendment did not pass in the Senate, it sets the stage for the FY '05 budget process.

REAUTHORIZATION OF THE MAMMOGRAPHY QUALITY STANDARDS ACT (MQSA)

In 1992, Congress recognized the importance of high quality mammography screening by passing the MQSA, which established national standards of mammography care. The MQSA requires mammography facilities to meet minimum quality standards for equipment and record keeping, and to ensure that all personnel maintain regular continuing education requirements. While the MQSA has set standards that keep mammography a safe and reliable method of early detection, concerns remain regarding poor image interpretation and inadequate collection and evaluation of mammography data. To begin deliberations on reauthorization of the MQSA, the Senate held a hearing on April 8, 2003 with witnesses representing the Susan G. Komen Breast Cancer Foundation, the American College of Radiology, and the Society of Breast Imaging. Topics discussed included: (1) strengthening continuing medical

education requirements, including self-assessment, for radiologists who read and interpret mammography films; (2) promoting improvements in the quality of image interpretation through enhanced outcomes data collection; and (3) providing appropriate incentives, such as reimbursement rate increases, for radiologists and technicians to continue their commitment to mammography screening and interpretation. No further action has been taken to amend the Act.

PREVENTION OF "DRIVE-THROUGH" MASTECTOMIES

A number of states have enacted legislation requiring insurers and health plans to cover an inpatient post-mastectomy hospital stay of at least 48 hours. At the Federal level, Representative Rosa DeLauro (D-CT), and 149 cosponsors, have introduced H.R. 1886, the "Breast Cancer Patient Protection Act of 2003," which would require individual and group insurance coverage and group health plans to cover a minimum hospital stay of at least 48 hours subsequent to mastectomy. Rather than mandating a particular length of stay, Representative Frank LoBiondo (R-NJ) has introduced Federal legislation (H.R. 1448, the "Women's Cancer Recovery Act of 2003") to ensure that decisions concerning the length of hospital stays subsequent to mastectomy are made jointly by physicians and patients. H.R. 1448 currently has 36 cosponsors.

PATIENT NAVIGATOR SERVICES FOR BREAST CANCER PATIENTS

"Patient navigator" programs can increase access to quality care and prevention by shepherding medically underserved women through the complex health care system. Patient navigators help patients make appointments for physician visits, complete insurance paperwork, and provide culturally sensitive services tailored to the community's specific needs. In particular, these programs have been instrumental in ensuring follow-up diagnostic and treatment services for women with suspicious breast cancer screening findings. Senator Kay Bailey Hutchison (R-TX) and Representatives Robert Menendez (D-NJ) and Deborah Pryce (R-OH) have introduced legislation (S. 453, H.R. 918, the "Patient Navigator Outreach, and Chronic Disease Prevention Act of 2003") to provide Federal grant funds for model patient navigator programs providing prevention, early detection, treatment and follow-up care services for medically underserved patients suffering from cancer and chronic diseases. The Senate bill currently has six cosponsors, while the House bill has 51.

BREAST CANCER RESEARCH STAMP

Senator Dianne Feinstein recently introduced an amendment in the Senate Transportation, Treasury and General Government Appropriations bill that would extend the life of the Breast Cancer Research Stamp (BCRS) by two more years. Unless Senator Feinstein's amendment is enacted into law, the BCRS will expire on December 31, 2003.

The BCRS stamp is sold at a surcharge above the price of an ordinary first class stamp. Currently, first-class stamps sell for 37 cents; the BCRS sells for 45 cents. The surplus above the price of the first-class stamp is collected by the Postal Service and allocated to the National Institutes of Health and the Department of Defense for breast cancer research. Since the inception of the BCRS program, the BCRS had generated more than \$32.8 million for breast cancer research through the sale of 464 million stamps. The Feinstein amendment was adopted unanimously by the Senate Appropriations Committee, and the bill is now headed to the Senate Floor.

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HRT: Point

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ing lactation to enrich milk for nursing offspring, enhancing successful survival of the species. There does not appear to be a significant evolutionary biologic pressure to support longevity, with a paucity of mammals ever living past menopause.¹³ Thus the Darwinian view of menopause (with low estrogen levels leading to mobilization of calcium and fat) explains women's dilemma as a biologic constraint of reproduction unique to the female of the species. This may also provide a helpful perspective from which to counsel confused patients, friends and family members.

Men are blessed to maintain a serum estrogen level of 40 pgm/ml from boyhood until they are 70. Girls share this low level of estrogen until they begin menses, with an abrupt fall below 30 after menopause.^{14,15} This small but crucial level serves to slow the loss of bone and leads to a later onset and slower ascent in the curve of acquired dementias. Of interest, women who take estrogen from onset of menopause and continue longest have the lowest rates of dementia, mirroring men, as compared to those who never took it or started HRT late (as in the WHI population).¹⁶ Women have to reconcile ourselves with an adverse biology that may in fact not serve us optimally after menopause. This is not a politically correct thing to say in some circles, but it appears to be the brutal biologic truth.

The baby boomers are truly the first generation of women who have a significant opportunity to prevent disease and enhance their chances for independent living into very old age with a good quality of life. Over the past 50 years a steady and rather consistent picture has emerged: There is no pill that can overcome the negative health impacts of a bad lifestyle. Obesity, inactivity, untreated hypertension, hyperlipidemia and hyperglycemia all lead to significantly higher disease risks, morbidity and earlier mortality.¹⁷

Physicians are faced with the day-to-day office demands of reassuring patients about that which we think is still true about the use of hormones to control symptoms versus the peculiarities of the specific population of women who compose the WHI study group. One wants to ask: "What is really going on with our 'system' of health information across this media-rich country of ours? Where is the professional leadership voice that could make sense out of the discrepancies between our fund of existing data and the results of the WHI? And how do we share this knowledge with our anxious concerned public?"

It is my hope that the members of the ASBD can provide leadership on this issue. If we are to practice evidence-based medicine (drawing upon our published medical literature) then we can offer overall very supportive data as to the safety of allowing individual choices regarding the use of sex hormones to relieve menopausal symptoms and decrease morbidity from such common afflictions as vaginitis, recurrent urinary tract infections, painful intercourse, osteoporosis and sleep disorders.¹⁸ From the WHI we have learned one thing if we have learned anything: The system of dissemination of medical information is broken and needs inspired repair.

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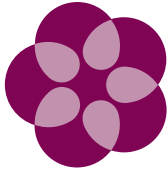
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Fall
Dinner
Lectures

For information on attending the ASBD's fall dinner lectures on neoadjuvant therapy in breast cancer, call 214-368-6836. Programs are currently scheduled for:

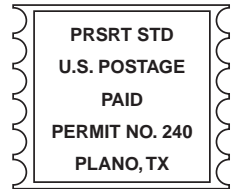
October 6	Dallas	November 4	Short Hills, NJ
October 20	Philadelphia	November 11	Tampa
October 29	Houston	November 12	Orlando
October 29	Boston	November 12	Long Island, New York
November 3	St. Louis	November 13	Miami
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