

Hormone Replacement Grows: Some Experts Worried

By Elaine Blume, Journal of the National Cancer Institute, May 15, 1996

As the vanguard of baby boomers reaches menopause, gynecologists, internists, and family practitioners are prescribing replacement hormones—principally estrogen and progestins—to a growing number of women. This trend worries some experts, and they are sounding the alarm.

Virtually nobody questions use of HRT (hormone replacement therapy) to relieve the acute symptoms of menopause. What concerns the naysayers is that increasingly the hormones are being prescribed on a long-term, even life-long basis, in the unproven hope that they will stave off heart disease and osteoporosis.

Rush to Judgment

"It is disturbing that the medical profession is rushing to judgment," said Jacques Rossouw, M.D., lead project officer of the National Institutes of Health Women's Health Initiative, which

"...after several years of replacement therapy, breast cancer risk gradually begins to increase, and... the increase continues for the duration of HRT."

is recruiting women for a clinical trial designed to establish definitively the value of long-term HRT. "Those who believe in evidence-based medicine should be worried about the current trends," he added.

Speaking at a recent meeting of the National Cancer Institute's advisory board, Rossouw reminded listeners of the swings in popularity that estrogen replacement therapy experienced from the 1960s to the 1990s. ERT use underwent a marked decline after it was observed that women treated with high doses of unopposed estrogens often developed endometrial cancer at a higher than expected rate.

The weight of evidence suggests that hormone replacement might lower overall mortality, chiefly by decreasing the incidence of heart disease, and that it might reduce the incidence of osteoporosis as well.... But

definitive clinical trials have not yet been done. For this reason, Food and Drug administration approval for estrogen only applies to its use for menopausal symptoms and for established osteoporosis; prophylactic use of HRT is entirely off-label.

Estrogens and progestins produce a panoply of effects. And while most of these, including possible influences on mental acuity and incidence of Alzheimer's disease, appear to be positive, others—both known and potential—are adverse.

Doctors have learned that the increase in endometrial cancer incidence prefaced by estrogen can be eliminated by giving the patient progestin along with estrogen. But other hazards cannot be so easily avoided. **The greatest concern of physicians is that administration of HRT on a long-term basis may increase a woman's risk of developing breast cancer.** (Our emphasis)

Considerable indirect evidence links estrogen and breast cancer. For example, several known risk factors for the disease, including early menarche and late menopause, can be explained on the basis of increased exposure to estrogen. Epidemiological studies of HRT have yielded contradictory results, but a reasonable interpretation of the studies

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DES Action Affiliates

Each group was created and nurtured by volunteers. Write them if you want information on their activities or can volunteer.

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letters to the editor

Dear Editor:

I am responding to a letter in the Spring 1996 issue from Debra Carney. I too am a DES daughter and have suffered with recurrent erosion of the cornea for several years. I would appreciate finding out if the eye problem is reported by many DES exposed people. I also was told by ophthalmologists that the structure of the epithelium of the cornea was abnormal and not usual and they could not say what caused it.

MLK, Beaverton, OR.

Dear Editor:

As the mother of a breast cancer survivor and president of MSDBC (Mothers Supporting Daughters with Breast Cancer), we want all other support groups to know about our organization. We can be reached on the Internet by e-mail to: lillie@ix.netcom.com or via U.S. mail to:

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Correction

In our Spring issue 68 article on the new book *Our Stolen Future*, an editing error led to the referral to the New England Journal of Medicine report as "twenty years earlier." It should have read "25 years": the publication date was April 22, 1971.

Published quarterly by
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Notes from Nora

Lawmakers join DES Action against Eli Lilly "Awards"

In response to requests from DES Action, three lawmakers declined their "public policy awards" which were to have been presented at an event co-hosted by Eli Lilly and Company, the most prominent manufacturer of DES.

Eli Lilly joined the Society for the Advancement of Women's Health Research in hosting the "1996 Achievement Awards in Women's Health," which took place June 18 at Washington, D.C.'s Four Seasons Hotel. The Award Dinner was to have honored nine individuals for their contributions to women's health research. However, Sen. Olympia Snowe (R-ME), Rep. Pat Schroeder (D-CO) and Rep. Henry Waxman (D-CA) all declined their awards, denying the Society and Eli Lilly their most prestigious honorees.

In a statement to the Associated Press about her decision to decline the award, Schroeder said: "Until 'the people who were injured by the actions of Eli Lilly are satisfied that that very sad chapter's been closed...to allow them to try and change their image and buy good P.R. by backing these types of events is really wrong.'"

A coalition of DES consumer groups including DES Action, the DES Cancer Network, the DES Sons Network and the DES Third Generation Network protested pharmaceutical giant Eli Lilly and Co.'s hosting of the event. DES Action stated that "It's a travesty that Eli Lilly and Co.—who continues to show complete disrespect and disregard to those

seriously injured by their DES exposure—is now trying to present itself as a proponent of women's health."

Lilly has never acknowledged that DES is anything but beneficial and continues to fight all attempts from injured DES consumers to obtain compensation.

Upon hearing of Lilly's involvement in the awards event DES daughter and DES Action Board member Karen Lang (Seattle) exclaimed: "Eli Lilly's connection to awards for women's health research is like a tobacco company making awards for lung cancer research."

In a letter to sponsors Eli Lilly and Co. and the Society for the Advancement of Women's Health Research, the DES consumer groups asked that Eli Lilly uphold the ethical standards of scientific research which these awards propose to honor. This letter, which was not answered, called upon Lilly "to issue a statement acknowledging that DES caused serious damage, including cancer, reproductive problems, and the possibility of further damages to mothers, daughters and sons exposed to DES during the time that it was manufactured and marketed by Eli Lilly and Co."

The letter also called upon Eli Lilly to offer a public apology to the DES exposed population, and to publish both the statement and apology in the *New York Times*, *The Wall Street Journal* and *The Los Angeles Times*.

Lilly's only response to the incident was this statement to the

Associated Press: "a cause-and-effect relationship has never been proven" between DES and cancer.

DES-exposed individuals, consumer groups including Public Citizen, the National Women's Health Network, and many others wrote letters urging all honorees to decline their awards unless Eli Lilly agreed to the above three requests. They were joined by international organizations such as Health Action International, DES Action The Netherlands, and DES Action Canada. Unfortunately, the remaining six honorees bowed to pressure from the Society and Lilly and accepted their tainted awards.

On June 18 approximately 40 people held an informational picket and handed out flyers explaining our position to those attending the dinner. DES mothers and daughters were joined by friends from Public Citizen, the National Women's Health Network, and the Corporate Crime Reporter.

Lilly's hosting of the Women's Health Awards coincides with their development of new drugs for osteoporosis and breast cancer and appears to be part of a company strategy to portray itself as a company women can trust. Lilly recently established a Women's Health Center at the company. But Lilly's efforts to whitewash its image will not succeed with millions of Americans who remember DES and have learned that Eli Lilly is a company that women cannot trust.

HRT from page 1...

suggests that after several years of replacement therapy, breast cancer risk gradually begins to increase, and that the increase continues for the duration of HRT. This added risk appears to occur regardless of whether estrogen is given alone or with progestin. In some studies, the increased risk did not occur in women who had stopped taking the hormones; in others the risk appeared to be sustained.

Practicing physicians are aware of the evidence that HRT may protect against heart disease and osteoporosis, as well as the studies suggesting that it may increase the risk of breast cancer. Conscious of the fact that heart disease is the number one killer of older women, and that hundreds of thousands sustain hip and other fractures because of osteoporosis, may doctors have weighed the presumptive risks and benefits and concluded that long-term HRT is often appropriate.

William C. Andrews, M.D.,

"The assumption that data collected on estrogen also apply to the combination therapy is largely that—an assumption—and may or may not prove correct."

professor emeritus of obstetrics and gynecology at Eastern Virginia Medical School, Norfolk, Va., and immediate past president of the American College of Obstetricians and Gynecologists, is representative of these physicians. He counts lowering the risk of heart disease as the most important reason for a woman to consider lifelong HRT.

"Almost half the women in the world die of heart disease, so I think this is an enormous reason to give HRT," he said, "For anyone who can objectively look at the data, I think it is so consistent. Almost every study has shown

protection." Andrews contrasted these data with those regarding estrogen and breast cancer, where some studies show a relationship, while others find none.

Some researchers argue, however, that observational studies—essentially the only studies that have been done to date on long-term HRT—are inherently unreliable because of the likely presence of confounding factors.

"(Such studies furnish) the interesting observations that lead one to think that maybe we should do a trial to find out whether this is true or not, but they in themselves can never prove the case," said Rossouw. "What we think isn't enough. We really need to know."

And even though the data on long-term HRT suggest a strongly favorable ratio of benefit to risk, experts note that other factors must be taken into account.

"We have many ways to lower risk of heart disease," Meir Stampfer, M.D., told the National Cancer Advisory Board. Stampfer, an epidemiologist at the Harvard School of Public Health in Boston, heads the Nurses' Health study, which has followed 121,700 female nurses since 1976 and has proved to be an invaluable source of epidemiological data on women. "We have identified many risk factors that are modifiable, and a woman can alter her lifestyle in ways that will very markedly lower her risk of heart disease," Stampfer said. "In contrast, we know very few ways that a woman can lower her risk of breast cancer. So we cannot simply say, well, because many

Mammography Affected by Estrogen Replacement Therapy

In an accompanying story, Elaine Blume reports that added to the debate on HRT is "the fear that estrogen given after menopause may make it more difficult to interpret mammograms properly." She states that ERT in post-menopausal women increases breast density which makes it more difficult to diagnose breast cancer by mammography. Ms Blume summarizes a research article in that same issue of the Journal:

"Compared with former use and never use of ERT, current use was associated with an increased likelihood of both false-positive and false-negative mammographic readings. The relative risk of a false positive for current users versus never users was about 1.33 (33% increase), and that of a false negative was about 5.23 (423% increase).

In an editorial in that issue of the Journal, two physicians urge that these new findings be taken into account by women considering ERT, and by their physicians.

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Plans for Study on Environment and Reproductive Risk

DES is considered an "environmental" estrogen because it is a drug that enters the body from outside, and is not produced by the woman's own endocrine system. As we know, it has a profound effect on body systems that may not show up for years. In this way there are similarities with other estrogen or estrogen-like chemicals that can affect living organisms.

Over recent years studies of birds and fish exposed to pollutants have shown some of the same effects on their reproductive systems that scientists observed years ago on DES daughters and sons. This topic is well covered in the recent book *Our Stolen Future* that we reviewed in the Spring issue of the **Voice**. As the public reads about these studies, or sees television programs on them, they have rising concerns about possible hazards to their own or their children's health.

Dr. Michael Shelby, a geneticist at the National Institute of Environmental Health Sciences (NIEHS), wants to work on improving our knowledge. A recent report in the NIEHS journal *Environmental Health Perspectives* provides details:

"Shelby contends that a major problem behind sensational, if inaccurate, media reports is that the state of the science in reproductive risk is, at best, uncertain. The press and the public may be left to draw their own conclusions about why more than 20% of couples can't conceive a child,

and more than two-thirds of all birth defects are without definable cause. Diane Aronson, director of Resolve, an infertility support organization, echoes the problem: 'Tell me what to say to those men and women who want so desperately to have a healthy child, and who think it is the air they breathe or the water they drink that prevents them.'

"Shelby is calling for the establishment of a scientific clearinghouse of sorts that will produce balanced assessments of the adverse effects of chemical exposure to environmental toxicants on all aspects of reproduction, including genetics, fertility, and development. 'Somewhere there must be a voice of reason, a respected source from which objective, balanced answers to such questions are available,' says Shelby. 'The public supports our research and testing activities and deserves informed answers to their questions. Such answers must be based on what we know, and equally importantly, what we don't know....'

"The Center for the Evaluation of Risks to Human Reproduction would be based somewhat on the model of the International Agency for Research on Cancer (IARC), which uses groups of scientific experts to develop monographs on human carcinogenic risks. The center, which would be funded by a consortium of federal agencies and private industries, would be an independent organization, staffed by toxicologists and

support personnel who would arrange meetings of expert committees, and prepare, publish, and distribute reports. Topics for evaluation would be selected by an oversight committee designated by those contributing support. Unlike the IARC, however, no defined categories of evidence of effects are envisioned for the reproductive risk center, says Shelby....

"Although it will take time to get the center up and running, Shelby insists that the public must have such a resource. 'We have to have fair reporting, so the public isn't continually worried about things that maybe they shouldn't be, or sanguine about what may be real risks,' he says. 'People are more concerned about the health of their children, or even their ability to have a family, than anything else—including cancer.'"

Some centers are now doing research on toxicology and risk, but John Bucher, of the NIEHS Environmental Toxicology Program, believes that Dr. Shelby's plan "is the only way to secure a public trust in the valiant efforts being made in the nation's labs. 'The public should not have to sort through reasonings and regulations,' he says, 'It's time to be clear about what the threats are to human reproductive health and happiness, and to move on to preventing them.'"

DES Action Opposes Bill to Weaken FDA

As the Voice goes to press, two DES Action representatives (Pat Cody, Program Director, and Kari Christianson, Secretary of the Board) are preparing to travel to Capitol Hill for a press conference opposing the "FDA Overhaul Bill." They will join many other consumers injured by defective or dangerous products and visit members of Congress to explain why this bill is so dangerous.

The **Food and Drug Administration Performance and Accountability Act of 1996**, S. 1477, is sponsored by Senator Nancy Kassebaum and backed by major pharmaceutical and other manufacturing companies. These special interests have long sought to weaken FDA approval process so that they can more rapidly develop and promote new drugs and medical devices. This latest attempt is an extremely dangerous effort to undermine the agency that protects consumers from harmful food and drugs.

Here are some of the major provisions of the bill, and why we oppose them:

Would subvert the product approval process by permitting device and drug companies to promote the unapproved uses of a given product.

Physicians may prescribe drugs for any use. Indeed, many products are prescribed for "off-label" uses. However, allowing promotion of off-label use would allow an end-run around the current FDA approval process. If a company can successfully promote its product for unapproved uses, it is unlikely to spend the time or money to seek FDA approval. Allowing promotion of medical products for

unapproved uses would enable companies to substitute preliminary research for the sound science required by the FDA approval process.

Speeds up FDA review time without additional staff, allows for outside reviews.

The Kassebaum bill would force the FDA to reduce the review time for new products by one-third or more, without providing for any additional funding to hire staff. It also allows for private, outside reviewers to take over some of the FDA's review functions. Because of the training and expertise necessary to review drugs, most non-governmental reviewers will inevitably have ties to industry, thus creating a potential conflict-of-interest.

Allows for marketing of drugs and devices based on European Union or U.K. Approval.

Under S.1477, a medical product manufacturer could petition the FDA for default approval of a medical product if that product had been approved in the U.K. or a European Union country and the FDA had missed the deadline for making a final decision on a new product application. Once the manufacturer requested default approval, the FDA would only have 30 days to approve or reject the product.

The FDA remains the "gold standard" for drug approval in the world. From 1970 to 1992, the U.S. was forced to withdraw approval of nine drugs for safety reasons. During the same period the U.K. was forced to withdraw 23, Germany 30, and France 31. Also, most other countries,

including the UK., do not now have or are only just starting to implement medical device laws. Thus disastrous products like the Dalkon Shield are likely to be much more common in Europe. Reduces "Effectiveness" testing requirements for new prescription drugs.

S. 1477 would allow new drug approval after only one clinical trial. Even that trial could be waived. Given the already insufficient attention to women's health in clinical testing, this provision could be especially harmful to women. The DES story should serve as a red flag against this proposal.

If the one clinical trial that is done is only composed of men, then data on dosage, safety, and efficacy for women will not be gathered. Women may be harmed by this careless approach to their specific needs.



DES Action representatives will be in Washington to tell their stories and to urge that lawmakers learn from the DES experience. Certainly DES should teach all of us that, if anything, we need a stronger Food and Drug Administration. We cannot afford to take chances with our health and, indeed, our lives.

We urge all our members to write to your Representative and Senators and express your concerns about S.1477. More information is available from our office (1-800-DES-9288) and your local library can supply the name and address of your representatives in Congress.



book notes

Menopause Naturally, Preparing for the Second Half of Life, by Sadjia Greenwood M.D., Volcano Press, \$14.95. From bookstores or from the publisher with shipping and handling cost of \$4.50. Credit card orders can be called in on 800-879-9636.

This is the 1996 update that includes research on the medical implications of using hormones, as well as alternative methods of symptom relief and health promotion. The latest information on the importance of soy foods is also covered.

Corporate Victimization of Women, E. Szockyj and J. Fox, editors. Northeastern University Press, Boston, \$17.95.

This study looks at how corporations cause harm by exploiting women's employment, reproductive and consumer vulnerability. Chapters focus on exclusionary practices in the workplace, employment discrimination, women in the market place, and the pharmaceutical industry and women's reproductive health. This last-named chapter, by Prof. Lucinda Finley of the SUNY Buffalo Law School, features the story of DES in its first 24 pages. Finley begins:

"Too many of the most tragic and preventable instances of unsafe drugs and medical devices have been products used in women's bodies, often in connection with sexuality and reproduction. The litany includes: Thalidomide; DES; the early high hormone birth control pills...IUDs...super tampons...Parlodel...and silicone breast implants.

"Drug companies have often blamed women themselves for any reported problems, or doctors and manufacturers have ignored complaints."

"These drugs and devices were developed not in response to disease, but for use in healthy women's bodies, to enhance what nature has provided or to control the natural processes of reproduction. Medical science has long sought to control women's reproductive capacity and to surgically manipulate or technologically "improve on" women's bodies. Normal female attributes, such as small breasts or menopause, have been classified as disease conditions requiring treatment. It is women exclusively who have faced the risks of iatrogenic injuries and disease from drugs and devices designed to alter the natural processes or shape of their healthy bodies.

"The desire to control or 'improve' women's bodies reflects a devaluation of women and their health. One manifestation is that pharmaceutical manufacturers have been lax about testing for or heeding signs of danger to women. Drug companies have often blamed women themselves for any reported problems, or doctors and manufacturers have ignored complaints or attributed women's descriptions of adverse

effects to emotional reactions by stereotypically 'hysterical' women. Marketing and profit considerations have proved more important to the pharmaceutical industry than women's health and safety concerns, and the corporate form too readily allows for the evasion of individual legal or social accountability...."

Finley writes that in introducing DES the drug companies "adopted a marketing approach wholly tilted towards emphasizing positive claims for efficacy and safety over critical voices and adverse evidence. A Squibb medical director summed up this attitude as anything that helps sell a drug is valid, even if it is supported by the crudest testimonial, while anything that decreases sales must be suppressed, distorted and rejected because it is not absolutely conclusive proof."

Finley concludes that "warning signs, adverse reports, and troubling animal studies should be diligently pursued, rather than regarded as a marketing problem to be finessed or buried."



HORMONES from page 4... more women die of heart disease, the benefits outweigh the risks."

Similarly, Stampfer and other researchers point out that several safe and effective interventions are available for prevention of osteoporosis; in 1995 the FDA approved two drugs—calcitonin and alendronate—to treat the disease. It is likely that these drugs will be used for prevention as well.

But proponents of long-term HRT are not easily convinced. Andrews, for example, argues that estrogen has effects on blood vessels and bone that go beyond those that can be produced by other means. He and others believe the beneficial effects of estrogen and alternative interventions may be additive and that it may often be best to employ both.

Another concern of experts is that although much of the data physicians are using to make decisions about long-term HRT come from studies on estrogen alone, thousands of patients are taking both estrogen and progestin. The assumption that data collected on estrogen also apply to the combination therapy is largely that—an assumption—and may or may not prove correct.

Tough Decisions

This apparent split between researchers and practitioners is characteristic of medicine at the cutting edge. Researchers, keenly aware of the limitations of their work and the pitfalls in its interpretation, warn against changing practice until final results are in, and some practitioners heed

these warnings.

Others, however, caught between the medical dictum *primum non nocere* (first, do no harm) on the one hand, and reluctance to deprive patients of a promising, if uncertain, new treatment on the other, are prepared to move ahead on the basis of the best available evidence. But members of both groups agree that the patient should take part in the decision.

Sandra Adarnson Fryhofer, M.D., an Atlanta, Ga., internist who serves as chair of the Ad Hoc Committee on Women's Health of the American College of Physicians, stressed this point.

"There's no such thing as an average patient," she said. "You have to treat patients as individuals and make a decision together."

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