THE DES ACTION VOICE
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Breast Cancer and Hormone Treatment

Relationship Between Estrogen Levels, Use of Hormone Replacement Therapy, and Breast Cancer

by Graham A. Colditz, MD, Dr. PH; Harvard Medical School
Journal of the National Cancer Institute, Vol. 90, No. 11, 3 June 1998, pp. 814-823

Reviewed by Cynthia J. Laitman, M.S., University of Wisconsin/Madison. Author, *DES, The Complete Story.*

DURING the past two decades, widescale prescription of long-term hormone replacement therapy (HRT) has become well-established, with hundreds of thousands of women in the United States receiving either estrogen alone or in combination with progesterone. Enthusiasm for HRT has grown not merely because it effectively relieves uncomfortable subjective symptoms such as "hot flashes" and vaginal dryness, but because it significantly reduces the risk of heart disease, and of osteoporosis which is responsible for over one million hip fractures a year in older women.

INSIDE

Despite the benefits of HRT, increasing evidence suggests that long-term HRT may increase a woman's risk of developing breast cancer. The purpose of Graham Colditz's paper is to weigh existing evidence about the relationship between breast cancer and estrogen, with special emphasis on postmenopausal replacement therapy.

He studied all English language papers on hormones and breast cancer in the MEDLINE® database (the National Library of Medicine's computerized database of medical papers, considered to be the most comprehensive single source of such information).

Factors associated with breast cancer risk

In studies of women who do not take hormones, the younger a woman is at menopause, the lower her risk of breast cancer. For every one-year increase in age at onset of menopause, the risk of breast cancer increases by approximately 3%. Other factors affecting a woman's lifetime risk of breast cancer are as follows. The younger she is at first pregnancy, the lower her risk. Breast-feeding has also been shown to reduce breast cancer risk. The older a woman is when she started menstruating, the lower her risk. And, because fat cells metabolize androgens into estrogens, obesity increases a woman's risk of breast cancer and of dying from breast cancer.

These risk factors are associated with greater lifetime exposure to **naturally** produced estrogens. What happens, then, when women take estrogen as hormone replacement? The author concludes that "growing evidence supports a positive relationship between blood levels of estrogens and the risk of breast cancer."

Women who take hormones

Women who are slender at menopause are more likely to report hot flashes and to use HRT. They are also likely to have lower bone density (an indicator of lower natural levels of estrogen) than women who don't take HRT. Women who undergo menopause at a younger age are also more likely than others to take HRT and to take it for a longer period of time. Based on these characteristics, Colditz makes a generalized conclusion about all women who take HRT. He believes overall that these women are actually at lower natural risk of breast cancer, leading to what he believes is an underestimate of the true adverse effects of post-menopausal hormones.

Duration of hormone use

A combined reanalysis conducted at Oxford University of data from 51 epidemiologic studies that included 52,000 women with breast cancer and over 100,000 women without breast cancer, indicated that for each year that a woman uses HRT, her risk of breast cancer

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

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Ohio Decision Against Daughters

DES daughters in Ohio cannot sue the drug companies for compensation unless they name the specific maker of the DES their mothers took, according to a ruling by the Ohio Supreme Court on June 30. In a narrow 4-3 decision, Justice Deborah Cook wrote that "We recognize that the DES plaintiff who, without fault, is unable to identify the manufacturer responsible for her injury...engenders sympathy. It is, however, the role of the court to interpret the law, not to legislate."

The three justices who voted to use the market-share liability principle in DES cases, as is done in a number of states and allows a suit without naming an exact manufacturer, wrote a strong dissent. Justice Andy Douglas stated that "The majority, by today's decision, rings the death knell for most of the DES litigation in Ohio. This prescription by the majority is the functional equivalent of saying: 'Take two aspirin and do not call us in the morning.'"

A second dissenting Justice, Paul Pfeifer, added that "...the majority is more comfortable shielding the defendant drug companies than with applying a theory of discovery that would allow the plaintiffs to go forward with their case. DES-injured women will have to content themselves with knowing that they 'engender sympathy.'"

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Notes from Nora

THANKS to all of you who have responded generously and donated to our new National DES Advocacy Program. We are moving forward with the work for this Program and making progress in our ongoing campaigns for DES research and a national DES education program.

In June I visited Washington, D.C. and met with legislative staff and others regarding the status of DES legislation. We must continue to push our DES bills H.R. 1788 and S. 834. At the same time, much of the language from these bills has been incorporated into a larger women's health omnibus bill sponsored by Senator Bill Frist (R-TN). We are hoping that one of these bills will pass and we can get started with a National DES Education Program. Funds for DES research also need to be reauthorized; the National Cancer Institute does continue in the meantime to fund and conduct DES research.

I also had the opportunity to meet with Dr. Wanda Jones, Director of the Office of Women's Health of the Department of Health and Human Services, and with Dr. Suzanne Haynes from the same office. We had a productive discussion and they pledged to support a DES education program at the Centers for Disease Control. They are in the process of forwarding start-up funds for such a program to the CDC.

In January Pat Cody and I spent a day at the Federal Centers for Disease Control and Prevention (CDC) in Atlanta. We were invited to meet with Dr. Richard Jackson, Director of the CDC's National Center for Environmental Health, and members of his staff. Dr. Jackson, who worked in California for many years, is very familiar with DES and its effects and interested in the possibility of a national DES education campaign.

We brought with us a copy of Judith Helfand's film A Healthy Baby Girl and staff from various CDC departments viewed the film on their lunch break.

While at the CDC we also met with members of the Endocrine Disrupters Group, an interdisclipinary team of scientists studying the recent emergence of endocrine disrupters in the environment. They are very interested in learning more about the effects of DES on humans as they explore potential endocrine disrupters in the environment.

Pat and I were impressed with the work of the CDC and with their welcoming and open atmosphere. We hope to collaborate with the Center for Environmental Health in the future as we develop plans for informing the public about DES.

We frequently hear from DES-exposed individuals who would like to volunteer to join research studies. While we are grateful to everyone who is eager to help us learn more about DES exposure, I would like to explain why this is usually not possible.

A large-scale survey of DES daughters, sons, and mothers has been going on for several years now. DES exposure for the participants of this study has been verified, and they have been matched with non-exposed "controls." The scientists leading the study are unable to add any more people to this survey. In addition, few scientists will consider results from individuals who do not have documented (i.e. with written medical records) DES exposure. However, here at the DES Action office, we welcome reports from DES-exposed people on any unusual health conditions they have that they think could be related to exposure. We forward these accounts (anonymously if you wish) to researchers. Sometimes your accounts are a stimulus to new research.

Do you know what "statute of limitations?"

It refers to the length of time within which an individual is permitted to file suit to recover damages for a DES-related medical problem. The length of time varies by state, but is usually from one to three years. The statute of limitations does not begin when you were exposed to DES but dates either from the date of your injury (cancer, infertility, etc.) and/or from your discovery that it was related to DES exposure.

Sometimes people wait a long time before calling an attorney because they are unsure about proceeding with a lawsuit. Then when they decide to call it may be too late, because their statute of limitations has expired. I urge that anyone even considering a lawsuit place a call to an attorney right away. DES Action maintains a list of attorneys who have handled DES lawsuits.

Book Reviews

by Pat Cody

Beyond Second Opinions: Making Decisions about Fertility Treatment.
University of California Press, 1998. 385 pp. $16.95 paper edition.

DR. TURIEL, whose introduction to fertility problems was brought about by her DES exposure, has written with great care what is surely a very important book. Because of her DES experience she is especially sensitive to the special issues DES daughters have that distinguish them from the usual fertility patient. In her first chapter on "Facing Infertility" she writes that

> "I grew increasingly concerned that today's state-of-the-art fertility treatments, considered the best in medical care, parallel in significant ways the DES mistake of a previous generation."

She tells us that

> "My overwhelming reaction as a layperson who has viewed more extensively than most the world of fertility medicine was that there is a tremendous amount fertility patients are not told about diagnoses and treatments. What they are learning at the doctor's office is not the picture conveyed in medical journals and conferences. If patients could see what I have seen of the disagreements among doctors, the uncertainties, the nonmedical pressures that are shaping our medical care, they might think very differently about their infertility diagnoses and reach different decisions about pursuing medical treatment."

The following chapters cover the diagnoses and treatments offered in the 1990s; several types of fertility problems, including that of growing older; discussion of scientific evidence; how lay people can become informed patients; and how they can be protected from incompetent or unethical treatment.

Dr.Turiel reminds us that

> "The sheer number of doctors hanging out fertility shingles with inadequate training exacerbated an absence of oversight typical of American medicine. No mechanism existed to oversee the explosion of fertility treatments performed in offices and clinics throughout the country, to evaluate whether doctors employ such procedures in appropriate cases and with the necessary skill. Unlike other types of medical laboratories, those handling embryos are subject to no mandatory regulations..."

Whether the patient marches into a doctor's office to demand treatment or somewhat more tentatively asks for information and advice, doctor and patient share a need to be aware that dominant sources of information advocate medical intervention, not caution.

Later, she reverts to this point:

> "...fertility medicine has tended toward jumping in too soon, with too little previously established scientific groundwork, too little regard for potential harm, and too little effort to demonstrate significant benefits. Thousands of articles on highly invasive and technological interventions have filled volume after volume of obstetric-gynecologic journals during the last two decades; among their most notable features is the extent of experimentation, especially on women, despite substantial gaps in knowledge about the biological processes underlying these fertility interventions. These experiments are uncontrolled, in far more than the scientific sense, as individual doctors try out treatments on individual patients on a daily basis, with no evaluation or documentation of outcomes."

In chapter 7 on "How is Consent Informed?" she points out that

> "Whether the patient marches into a doctor's office to demand treatment or somewhat more tentatively asks for information and advice, doctor and patient share a need to be aware that dominant sources of information advocate medical intervention, not caution. Beyond vulnerability to advertisements, anecdotes, and the momentum of treatment, doctors and patients also share a vested interest in the optimistic outlook and a compelling desire to "do something," to be part of a success. For doctors, the desire is rein-

forced by a perceived consumer demand, by a view skewed toward the most tenacious patients, and by the overall thrust and competition of the medical-pharmaceutical industry. For patients, the desire is reinforced by ubiquitous social pressures and by every new hope, endlessly reignited, like trick candles, with each newly announced reproductive therapy."

Chapter 8, on Protecting Patients, describes how the anti-abortion forces have succeeded in stifling research on fertility, and includes these remarks from Congressman. Ted Weiss that "Infertile couples are spending their life savings on treatment that doesn't work because the Federal Government has not been willing to study infertility treatment the way it studies treatment for every other disease. It is outrageous that our national health agency has ignored the repeated pleas of their own scientists, the medical and scientific communities, and millions of infertile Americans who have repeatedly asked them to fund this research and to appoint an EA. (Ethics Advisory Board) to review all controversial medical research."

Dr. Turiel concludes this remarkably thorough and useful book with a chapter on "Finding What You Need," followed by five appendices of resources and reminders. She has written a landmark work on a problem faced by millions of couples.

(Ed. note: If you cannot get this book from your library or bookstore, you can order it from us for $16.95 plus $2.50 shipping).

The Breast Cancer Prevention Program

by Samuel S. Epstein M.D., David Steinman and Suzanne LeVert. Macmillan Publishers, 1633 Broadway, New York NY 10019. 416 pages. Clothbound, $24.95.

THE authors start right off with "What you don't know CAN hurt you.

Breast cancer rates continue to climb, with this disease striking more women every year, and yet information about known risks and prevention strategies is not reaching you. The cancer establishment has a vested interest in keeping you focused on early detection, treatment, and basic genetic research rather than on reducing the risks for developing the disease in the first place."

Breast cancer rates continue to climb, with this disease striking more women every year, and yet information about known risks and prevention strategies is not reaching you.

Documenting every strategy they present, the writers call attention to what they call "The Dirty Dozen," twelve unpublicized risks for breast cancer. As DES exposed people, mothers and daughters have a particular concern with breast cancer; this information is of special interest to us.

- Oral contraceptives
- Estrogen replacement treatment
- Premenopausal mammography
- Drugs used to 'prevent' breast cancer, such as tamoxifen and GnRH, in healthy women
- Silicone gel breast implant
- Alcohol abuse
- Tobacco abuse
- A diet high in animal fat (for example, the authors cite high levels of estrogen and other hormones in beef).
- A sedentary lifestyle
- Exposure to household chemicals and neighborhood pollution from chemical plants and hazardous waste sites.
- Workplace exposures to a wide range of carcinogens. (Some studies have shown that cancer-causing chemicals carried home on the clothes of men working in certain industries may pose significant risks to their wives, mothers, sisters, and daughters).
- Dark hair dyes

Once these risks have been described, the authors tell us what we can do about them.

They have had lengthy experience: Dr. Epstein, professor of occupational and environmental medicine at the University of Illinois School of Public Health, is a leading international expert and author of *The Politics of Cancer, Safe Shoppers' Bible,* and *Hazardous Waste in America.* Investigative journalist David Steinman has written *Diet for a Poisoned Planet* , and science writer Suzanne LeVert has written several books on health, including *The Woman Doctor's Guide to Menopause.*

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increases by 2.3%. In other words this meta-analysis estimates that for every 1000 women who begin to take HRT at age 50 and who take them for 10 years, there are six more cases of breast cancer than would be expected; for 15 years' duration of use, there are 12 excess cases of breast cancer.

Interestingly, Colditz's analysis also found that breast cancer patients who have taken HRT have a higher survival rate than women with breast cancer who have not taken HRT. Colditz speculates that this may be due in part to the HRT patients having a lower initial risk of breast cancer. He also suggests that these women may be more health-conscious; this may contribute to earlier detection, but this remains to be investigated.

Other factors

Colditz emphasizes that most epidemiologic studies linking hormone use and increased breast cancer risk in the United States are based on the use of estrogen alone (so-called unopposed estrogen). The relative risk of a combined regimen of estrogen and progestins (synthetic progesterone) has not been addressed. The use of progestin in combination with estrogen has been found to significantly decrease the risk of endometrial cancer (cancer of the uterine lining). Therefore, the combined therapy is generally given to women with an intact uterus. Women who have undergone a hysterectomy are frequently given only estrogen since progestin is considered irrelevant. And even less is known of a more recent addition to the HRT arsenal, to wit, a small amount of testosterone in combination with estrogen.

Conclusions

Based on his review, the author concludes that postmenopausal use of hormones can increase a woman's risk of breast cancer. Taking into consideration the consistent evidence that HRT reduces the risk of heart disease, osteoporosis and "several other major illnesses," how can women make informed choices?

Dr. Colditz suggests taking into consideration individual risk of diseases affected by HRT with "quality-adjusted" life-years. (Remember here that each individual has to determine what "quality-of-life" means to her.) Thus, he says that some individual women will experience an increased risk of one disease or another—depending on her decision to take or not to take HRT.

He concludes that "further work is needed." Of this there is no doubt; many central questions still remain. The old adage that "you get nothing for nothing" has never been more true than with HRT. This is an issue fraught with difficult choices. They should, insofar as possible, be informed choices.

Note: In the Winter issue of ***The Voice****, we will be reviewing another major article further discussing the effects of hormones and breast cancer, to be published in the November 1998 issue of Annals of Surgery.*

Letters to the Editor

DEAR Editor:

I am 40 years old and have been diagnosed with conductive hearing loss—otosclerosis—in my left ear. My ENT said there is some indication that DES could play a role—his research showed that hearing loss during pregnancy was greater for DES-exposed women than others. However, I am not now pregnant, my youngest child is 5 years old. This is the first year I have noticed the hearing loss, so if it began during pregnancy, the loss was gradual for the last 5 years. The condition is treatable with medication (sodium fluoride — experimental), surgery, or a hearing aid. For now, the doctor suggested yearly audiograms to track the progression. He also said it could occur in my right ear. He said it is quite rare for someone 40 years old to have otosclerosis; the condition usually occurs in the general population at age 50-60 or older.

Are any other DES daughters experiencing premature hearing loss?

Thanks for your response. I'm sure my doctor would welcome talking to other doctors if their experience shows a connection.

Nancy Rudolph
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Environmental Estrogen–Global Problem

by Pat Cody

THE leading center for research on DES effects on mice is the National Institute for Environmental Health Sciences (NIEHS), one of the nine institutes of the National Institutes of Health. We have learned much about effects on humans from the studies on mice, and the NIEHS scientists have learned from us. As they wrote in their journal for June 1993,

"...DES may be viewed as a model compound for other environmental agents with estrogenic potential. The bioaccumulation of these environmental estrogens is recognized as a problem of increasing magnitude. Certain human populations in the United States have been shown to carry amounts of these fat-soluble compounds which, in fish and other wildlife, cause significant endocrine dysfunction and developmental anomalies of the reproductive tract. Insights into the biological effects of DES should therefore provide a foundation upon which future environmental health problems may be effectively addressed."

We are five years down the road from that statement, and scientists world-wide have confirmed the problems of exposures to pollutants that have estrogenic effects:

- **Frogs** and other amphibians are dying out or showing bizarre changes like extra legs or missing eyes. Scientist David Wake of the University of California at Berkeley said that the comparison often made between changes in amphibians and the canaries that once warned coal miners of danger isn't quite right. "If a canary died the miners got out of the mine. We don't have that option. We don't have any place to go."
- **Sperm whales** who live in depths of 1,200-3,600 feet have dangerous chemicals similar to DDT and PCBs in their blubber.
- **Polar bears** near the North Pole have been found with both female and male genitals. They are genetic females and some have had cubs, but they also have small penises in front of their vaginas. Scientists suspect PCBs in the bears' fishy diet, since many pollutants evaporate in the south and fall to earth in cold northern air, where it is not warm enough for them to evaporate again.
- **Fish** consumption advisories have been issued by Delaware, New Jersey and Pennsylvania because of high levels of PCBs in Delaware River fish. Sewage treatment plants and estuary sediments are believed to be the sources. The Minneapolis *Star Tribune* reported in April on male walleye fish from the Mississippi River with such high levels of estrogen and low levels of testosterone that their breeding ability may be impaired. Female walleye taken near sewage treatment plants had five times the normal level of estrogens in their blood, which could prevent ovulation. The *Arizona Daily Star* reported in June that 30 years after DDT was banned, parts of the Gila River near Phoenix still have levels among the highest in the U.S. Fish from the river have 24 parts per million of DDF, a breakdown from DDT. U.S. and Arizona agencies set a hazard level for humans as more than 0.3 parts per million, so again, warnings have been posted about eating fish.
- Florida Game and Fresh Water Fish Commission is studying a puzzling decline in **alligator** hatchings in Lake Griffin, according to an April story in the *Christian Science Monitor*. Alligator farmers told officials that only 4.4% of the 1,033 eggs they had collected were hatching, compared to the normal rate of 50%. They were told that practically none hatched in the lake last season and there have been "unexplained deaths" of turtles, snakes and fish. A similar decline in alligator hatchings, and the birth of abnormal alligators, occurred in Lake Apopka in the 1980s after a pesticide spill. This time, researchers think that pesticide and fertilizer use on farms near Lake Griffin may be responsible.

Turning to reports on humans, much of the news comes from Japan, where scientists and the general public are both becoming more aware of 'endocrine

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disruptors.' In June, the press carried a story that breast-fed babies in Japan were receiving about six times the daily tolerable amount of dioxins. They speculated that because dioxin is produced daily by the incinerators used to destroy mountains of garbage, it reaches the mothers in the environment. In May a press report from Tokyo stated that Japan had the lowest number of children in its population since organized census taking began in 1920. There has been a significant increase in infertile couples and a study from the World Health Organization showed that 33 out of 34 healthy Japanese men between the ages of 20 and 26 had below normal sperm counts. This July, a press report from Bombay stated that 70% of Indian men had fallen sperm counts because of pollution. Less than 30% had normal semen.

Growing world wide concern from both scientists and environmental activists is beginning to be heard. The *Baltimore Sun* reported in June that the Clinton administration has listed endocrine disruption as one of its top five environmental research priorities. Congress ordered the EPA to start a chemical screening program by this August. The Federal Dept. of Health and Human Services stated that many chemicals "have the potential to disrupt the normal functions of the endocrine system, (which) may have a serious impact on reproductive and developmental parameters in wild life and human populations."

Of particular interest to us is news of a World Breast Cancer Conference in Canada in mid July. Michele Landsberg, a columnist for the *Toronto Star*, wrote that the thrust of the conference was to demand action for prevention, rather than continue to concentrate all resources in a possibly vain search for a cure.... "Pollutants are metabolized in our bodies as estrogen," said author and cancer surgeon Dr. Susan Love. And it is lifetime exposure to estrogen that has increased world cancer rates by 26% since 1980.... We live in a toxic soup of chemicals.

What can we do? Some good suggestions are in the book by Dr. Samuel Epstein, reviewed in this issue of the VOICE.

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