# V O I C E

A FOCUS ON DIETHYLSTILBESTROL

Summer 1992

#53

## Research Conference: Ideas and Goals

ong Term Effects of Exposure to Diethylstilbestrol" was the first major national conference of DES researchers and DES-exposed people ever held. Sponsored by four divisions of the National Institutes of Health, the April meetings began with keynote speeches by Arthur Herbst M.D., Howard Bern, Ph.D., Margaret Lee Braun of the DES Cancer Network and Nora Cody, Executive Director of DES Action.

Here are highlights from the two days of presentations and discussions.

Theodore Colton, Sc.D., Boston University School of Public Health. Breast Cancer in DES Mothers.

Several studies have shown an increased risk of 30-45% for breast cancer in DES mothers. According to Dr. Colton, this "confounding factor" does not represent as large a risk as such other factors as family history, age at menarche, etc., but is still a risk factor that DES mothers should know about.

Kenneth Noller M.D., Chair, OB/Gyn Dept., University of Massachusetts Medical School. DESAD Project, DES Daughters.

DES daughters have double the incidence of squamous neoplasia and carcinoma in situ (CIS). He gave a caution: many women are being told that they have an abnormal Pap when they



Louise Slaughter

squamous metaplasia, a non-cancerous cell change that is normal for DES daughters, and that doctors need education

are found with

about DES. He recommends increased follow-up since DES daughters are now entering the ages when invasive cancers are more common.

Arthur Herbst, M.D., Chair, Dept. Ob/Gyn, University of Chicago Medical Center (and the lead author of the 1971 medical report that gave the first alert on the association between in-utero DES exposure and damage to the offspring). Incidence, Survival and Screening for Vaginal Clear-Cell Cancer.

Dr. Herbst presented data based on his registry of 587 clearcell adenocarcinoma cases. The oldest patient was 42 at the time of diagnosis. Of the 526 cases where follow-up was possible, 25% have died and 19% have had recurrences; 56% are "living and well."

Dr. Herbst's recommendations and concerns for the future:

Since most recurrences occur in the chest or lungs, annual chest x-rays for CCA survivors.

Will there be a second age continued on page 4 "It's now twenty years after the association was first noted between in utero exposure to DES and the development of clear cell carcinoma of the vagina. Yet questions remain concerning the long-term effects of DES. Clearly, we must revisit this important issue and discern where further action is required.

"But, we should not proceed on our concern alone. We must frame the scientific questions clearly so that we can consider the most efficacious and expeditious action. We must be clear and decisive on where we must go.

"You who are participants in this workshop, especially those who have known and been committed to this problem for some time, have been invited because you have a particular perspective and expertise that we shall count on to focus our scientific inquiry. We are pledged to good science, for it must drive and define our efforts. We, therefore, welcome your thoughtful discussion and challenges. I can assure you that we will consider your recommendations seriously."

Vivian W. Pinn, M.D. Director, Office of Research on Women's Health National Institute of Health

## **Get Into Action**

DES Action USA could not have originated and grown without the dedicated efforts of volunteers. Today, we proudly boast the activities of over forty DES Action groups across the country and around the world. The foundation of each group was created and nurtured by volunteers. We still need you. Write your group today. Offer your services for a few hours a week. Become a part of the action with DES Action.

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## \* \* \* dear doctor

I have heard that DESexposed women, mothers and daughters, may have a higher risk for ovarian cancer. Is this true? And in any case, what kind of medical exam would test for this? Would it be ultra-sound, a blood test, palpation or all three?

There have been reports of ovarian cancer in DES-exposed mothers and daughters, although the true incidence is not known. As far as testing for ovarian cancer, all three tests are helpful. There are important points to remember about these tests:

1. The blood test, CA 125, is a blood test looking for a tumor marker for ovarian cancer. The test is non-specific and the value can be elevated in the presence of other malignancies or even benign conditions such as endometriosis, pregnancy, etc.

2. The ultrasound test determines the presence or absence of growth in the ovary, which can be benign or malignant.

The most important point to remember is that all these tests should be performed by a reputable laboratory.

Norma Perez Veridiano, M.D. Associate Director Dept. of Ob/Gyn Maimonides Medical Center Brooklyn, N.Y.

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## **Notes From Nora**

urray for Tom Harkin!
On June 11 this Democratic Senator from Iowa introduced S. 2837, the "DES Education and Research Amendments of 1992." S. 2837 is a companion bill to Louise Slaughter's H.R. 4178, and the language in the Senate and House versions are identical.

Here is an excerpt from Senator Harkin's eloquent statement in the June 11 Congressional Record.

"Mr. President, I rise today to introduce legislation that is of vital importance to some 10 million Americans. These 10 million people were inappropriately exposed to a drug, diethylstilbestrol or DES, during pregnancy or in utero. This exposure has been linked to a variety of health problems, including a number of forms of cancer.

"...It is clear that tens of thousands...are not yet aware that their medical problems are caused by exposure to DES many years ago. It is also clear that many doctors and other health professionals are not fully informed about DES-related medical problems. As a result of this widespread concern, a grasroots organization DES Action, has taken the lead in pressing for more research and better professional and public education. Their efforts to promote legislation for this purpose has been strongly supported by a coalition of medical and consumer groups, including the American Fertility Society, the Alliance for Consumer Rights, the American Medical Women's Association, the National Women's Health Network, and the YWCA of the



USA."

Senator
Harkin is the chief sponsor of the ground-breaking
Americans
With Disabili-

ties Act, and has now taken the lead in helping DES-exposed Americans. We commend his actions and look forward to working closely with the Senator and his fine staff.

I also want to thank Kristin Evenson, our Iowa Coordinator, for her hard work in facilitating this legislation, and all of our Iowa members for their very moving letters to Senator Harkin. And once again, thanks to all of you whose letters to your Senators will now help persuade them to sign on to S. 2837.

If you haven't written already,

or if you'd like to write again: please do! Now that we have specific legislation, a letter reminding your senators of your concern about DES and pointing them towards S. 2837 is just what is needed to ensure the passage of this bill.

One more reminder on the DES Health History Survey: it's not too late to send it in to Boston University's Slone Epidemiology Unit! If you've tucked the Survey away with plans to fill it out in the future, please DO IT TODAY! I can't over-emphasize the importance of a large pool of participants so that we can evaluate health risks and pave the way for DES research. Please, send in your survey and give a copy to a DES-exposed friend or relative. (If you have never received the survey, drop us a note and we'll gladly send you

## The politics of DES

one.)

ne of the leading clinical researchers on DES sent an article on ovarian cysts in DES daughters to a leading ob/gyn journal. As is the custom, the journal sent the article out for 'peer review.' This is the 'review' from one of the doctor's peers:

"This is a very dangerous article and should not be published anywhere! One can only envision the future when a patient who has been exposed to DES in utero appears with an ovarian cyst and the lawyers refer to this as probably related to exposure. The lawsuits are too numerous now and they would be even more significant if such an article was published."

The journal decided not to publish the article. Fortunately for the health and proper medical diagnosis of DES daughters, another journal had no trouble with publishing it.

## **DES on TV!**

he series on PBS called "Health Quarterly" is going to have about half of its one-hour presentation on DES. This will be on Monday evening, August 10—mark your calendars. Darci Picoult of our New York chapter has been working with the producers on research and interviews for the show.

## VOI

## Stepping Out Again

It had been a long time since I'd thrown myself into the DES public arena.... Of course, the DES issue never went away. I continued to receive the newsletter, to stay current.... But that public piece—the advocacy, the solidarity, the possiblity of real change—was missing.

Until Washington.

Once again I felt the "high" that comes only from mobilizing oneself in the direction of one's beliefs. The euphoria of speaking in an arena of decision-makers, of bringing a new and very personal perspective to a clinical issue. The warm and immediate bond between DES sisters who have suffered and survived, who will not forget the legacy of this drug...and who wish for something more for themselves and for women everywhere. The light-headed giddiness of being together, and the power of our collective strength.

Stepping into the public area takes an effort-and maybe a little bit of courage but it's worth the risk. Yes, we each need to take care of ourselves. But without concerted action, there can be no real change. It's time to leave behind our reticence and our fears...time to step out from our inner circles into a wider sphere. I am personally going to find more opportunities to take that step-for myself, and

for each of you.

Linda Crociata Rochester, New York

IDEAS & GOALS from page 1... peak for CCA in DES daughters?

What about other mullerian sites (ovaries, tubes, uterus)?

We need studies on: patterns of recurrence and optimal treatment; risks for all DES daughters



Dr. Arthur Herbst

of breast cancer and of squamous cell cancer.

Two unanswered questions from the discussion: Should DESexposed

women avoid entering tamoxifen and other clinical trials? What about risks for DES daughters in estrogen replacement treatment (ERT)?

Michael Luster, Ph.D., National Institute of Environmental Health Sciences. Mechanisms of Immunotoxicology by DES and Related Compounds.

Dr. Luster reported strong suppression of cell-mediated immunity in DES-exposed mice. He found: suppression of natural killer (anti-tumor) cells, decrease in host resistance, alterations in mucus, and earlier onset and increased severity in auto-immune diseases.

Phyllis Blair, PhD., Dept. of Immunology, University of California at Berkeley. Human Studies of the Effect of DES on the Immune System.

Dr. Blair and Dr. Noller conducted a review of the records of 1,711 DES daughters and 922 controls (non-DES-exposed young women). They found that DES daughters had an overall increase of nearly double the incidence of a lifetime prevalence of autoimmune diseases—28.6 per 1,000 DES exposed versus 16.3 per 1,000 for the controls. They also found a five-fold increase in Hashimoto's Thyroiditis.

Deborah Wingard, Ph.D., Community and Family Medicine, University of California at San Diego. Epidemiologic Evidences of Immune Dysfunction and Other Effects.

Dr. Wingard reviewed results from a 1985 DES Action Health



Dr. Howard Bern

History Survey of 520 DES mothers, 1,079 daughters, and 94 sons. She found higher incidences of automimmune diseases such

as asthma, arthritis, lupus, and diabetes than those found in the general population, and an increased incidence of respiratory tract conditions. Her recommendations for future research:

Mothers: Immune system, breast and other cancers.

📽 Sons: Immune system, testicular and prostate cancers, other cancers, infertility.

Daughters: Immune system, lumbar vertebrae malformations, eating disorders, breast, ovarian, pituitary and other cancers; menopause, impact of ERT and oral contraceptives.

Third Generation: should be followed for possible effects.

In general: More research, contact with major cohorts (groups of exposed) should be maintained, and there should be multi-disciplinary collaboration.

Kenneth Noller M.D. Other

Health Outcomes Found in the DESAD Project:

Over 1,400 diseases were recorded in the entire DESAD project. Of these, seven conditions showed significant differences between DES daughters and non-exposed women:

Candida infections	More common in exposed	
Middle ear infections	More common in exposed	
Mitral valve disorders dis	ers More common, but difference disappeared over time	
Breast disease N	Negligible difference	
Infertility	Three-fold increase in exposed	
Auto-immune disease	2.8% in exposed, 1.6% in controls	
Eating disorders	Three-fold increase in exposed	

Arthur Haney M.D., Director, Reproductive Endocrinology, Duke University Medical Center. Reproductive Consequences of Prenatal DES Exposure.

Dr. Haney presented interesting data on in-vitro fertilization outcomes in DES daughters as compared with non-exposed controls:

DE	S-exposed	Controls
Implantation	7%	32.2%
Clinical pregnancies	16%	22%
Ongoing pregnancies	8.8%	15.9%
Miscarriages	44.4%	28.1%

## Research Recommendations

In addition to the ideas for future research already presented, here are some of the conferees' suggestions:

#### **Immune System**

- Studies on existing cohorts extended and with closer followup.
- Coordinate different cohorts with one questionnaire.
- New cohorts, with DES sons and third generation children, should be initiated.

- "Questions should attempt to quantify frequency of mild and severe diseases. An illness diary can be used.
- There should be a serum and leukocyte bank, based on existing DES cohorts, to develop "biomarkers" for disease.
- \*Earlier animal studies can be reviewed and improved, including male and female animals, different strains (of mice), short and long term, and molecular levels.
- <sup>™</sup> Need for multi-institutional support for multi-disciplinary problems.

Weed to study prolactin levels in humans.

### Developmental and Reproductive Effects of Exposure

- Ways to improve pregnancy maintenance and delivery should be studied.
- Study of male genital tract tissues, and of mullerian epithelium in males.
- Study onset in timing of menopause, and possible toxic effects of DES on ovaries.
- Third generation outcomes; endocrine dysfunctions; masculinizing/feminizing effects, and risk for osteoporosis in early menopause.
- W Hormonal effects on embryonic tissue; evaluate clinical treatments for ectopic pregnancies and premature labor.
- Weurobehavioral effects, e.g. depression, should be studied.

#### **Education and Outreach**

- Updated national physician referral list.
  - Current and accurate continued on page 6

"At times DES Action has sent up "red flags" pointing to key areas of concern. Our 1985 health survey brought forth the evidence, later confirmed by the DESAD study, of impairment of the immune system.

"What are today's warning flags? We hear every day from people around the country who are desperate for answers. We spent the last several months holding a series of public meetings and soliciting questions from our members through the mail. I bring their concerns and their hope to you today.

"We hope through our work to give all women a sense of greater control through information about health consequences and options. We do not want to, nor do we believe we can, go it alone. We want to be active partners in the research and the medical care which affects our lives.

"The NIH will fund new areas of DES research. Others here will help carry out that research and provide breakthroughs in understanding. The clinicians will incorporate new knowledge into their care for DES-exposed people. And DES Action and the DES Cancer Network will continue to bridge the gap between the scientific community and the public, reporting new findings to the affected populations."

Nora Cody
Executive Director,
DES Action

IDEAS & GOALS from page 5... information must be distributed to the public and to health care providers.

\* Expand outreach and research to include long-term emotional effects.

Cerclage experience—need case reports and double-blind trials.

### Ideas from DES Action

DES Action's Board of Directors held their semi-annual meeding directly after the NIH conference. Here are additional recommendations from their meeting:

- 1. Existing cohorts should be expanded for a large epidemiologic study with at least 20,000 DES mothers, daughters and sons. Additionally, sibling controls should be used for comparison studies of hormone levels, immune and endocrine system function, cancers, and other health effects. In addition to the areas already identified in the NIH workshop, the study should include:
  - Effects of estrogen replacement treatment on DES mothers and DES daughters, that is, does additional exogenous estrogen have an effect on cancer rates in these women?
  - Effects of long term expo sure to oral contraceptives on DES daughters and mothers.
- 2. Retrospective (looking at past experience) case control study of treatments for pregnancy complications, including cervical cerclage and bed rest.

- 3. Methodological study to investigate ways to document and identify exposure to DES in the absence of (often unavailable) maternal medical records. Investigators could analyze sales, prescriptions, demographics, percentage of pregnancy "vitamins" that included DES.
- 4. Retrospective case control study of breast cancer in DES mothers.
- 5. Conference should be convened by some group such as the Gynecologic Oncology Group to share information and treatment methods for primary and recurrent clear-cell adenocarcinoma. Specifically, that treatment teams of gynecologic-oncologists and radiologists be brought together for this purpose.
- 6. Studies using blood and tissue samples toward an understanding of the mechanisms involved in the development of clear-cell cancer. There should be efforts to find DES-exposed cohorts and controls for participation in such studies.
- 7. Animal studies to provide more information on the effects of DES on the neuro-endocrine system, the skeletal system, metabolism, the immune system, and the urinary tract.
- 8. The DES 'working group" that convened the DES research conference should be expanded to include representatives of the exposed (DES Action and the DES Cancer Network) to facilitate the most thorough follow-up from the conference.

"We may find as we proceed that we must create new models for how to respond scientifically to a population injured by medical action.

"Research-driven investigation and reporting are critical to improving the quality of life and saving the lives of the DES-exposed. Because without data all we have are anecdotes. And anecdotes are inadequate to our survival.

"Two decades after the alarm on DES we need a new phase of DES research. One that follows the DES-exposed throughout their life span. One that benefits DES-exposed people by giving information back to them. One that looks at other research models that investigate latent disease. One that stretches the boundaries of traditional methods of recruitment, using, perhaps, concepts of community consultationinvolving patient groups. And, so importantly, one that provides for communication and collaboration among specialists and between disciplines.

"Much has been said lately about the obligation science has to provide research that includes and benefits women. What about the responsibility science has to victims of medical catastrophe? Is there a unique obligation to provide information and care?

"I think there is. I think we will see, more and more, in those of us who design and implement research, an orientation towards ethical considerations."

Margaret Lee Braun Director, DES Cancer Network

## (a) letters to the editor

Dear Editor:

Not sure if related to DES or not, but a brilliant gyn finally diagnosed my chronic vulvar skin problem as Lichen Sclerosis at Atrophicus. My whole life I have suffered with severe burning to unbearable itchiness to the point where I would scratch myself until I would bleed as a young child. From skin specialist to skin specialist I would go, only to be given mycalog or kenalog cream. Absolutely nothing soothed or helped. In April 1990, a vaginal infection sent me to Dr. Bert Schonkerman in Thousand Oaks, California (who by the way was recommended to me through DES Action whom I called when I moved to California). The infection was no big deal but the intense vulvar burning from the discharge had me in the emergency room and then at home in ice baths.

For the first time in my life, someone knew what was wrong with me! Now diagnosed with LSA, Dr. S. had me on a 2% Testosterone/hydrocortisone cream. What a miracle! After about 1-1/2 years, the condition was under control. My skin doctor here in Boston is so very impressed with Dr. S's ability to diagnose this—he now has me down to a very mild hydro cream.

In addition, a related skin abnormality is described as a fusion of the labia majora and minora bilaterally in addition to some midline fusion below the clitoris. In other words, the skin fusion that I have covers my clitoris. The clitoris peeks through a small opening in the skin and is fused together down to my urethra.

It is not known if these conditions are related to DES. Yet it seems that the Voice is such an effective way to reach other DES daughters like myself who may have these two problems and don't know what to do. Hope this helps!

Reader, Boston.

Dear Editor:

After reading "A Reminder on Estrogen" in the Spring 1992 Voice I feel I need to respond. In 1976 I was diagnosed with clear cell adenocarcinoma of the vagina. Treatment included removing my ovaries. I have taken ERT for 15 years and for a long time have felt very frightened and confused about my choice to take it. I always wondered if I was subjecting myself to further risk of getting cancer again.

But without ERT I am a different person. I have incapacitating hot flashes and mood swings I don't wish to cope with. And I now know that without this therapy, I am subjecting myself to different health problems. The risks of not taking estrogen replacement therapy are clearly defined. Evidence is widely found in the medical literature that ERT does protect us from osteoporosis and heart disease. Deaths due to these diseases are more prevalent than women's cancer.

The effects of ERT on DESexposed women are unknown. But because some cancers are known to be sensitive to estrogen, the issue of taking ERT or not should be carefully considered between you and your physician.

Both sides of this issue need to

be given equal time so as not to put unnecessary fear in women who are already living in fear of their health.

Vickie Dandridge Encinitas, CA.

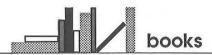
Dear Editor:

In her essay titled "Viewpoint," in DES Action Voice, Spring 1992, Ms Esposito speaks bitterly of "the male-dominanted medical and legal systems designed to...oppress those considered weaker in our society..." Speaking of "DES moms and DES daughters," she says "We are and have been intimately connected to DES in a way that no man has, even DES sons." Affter exhorting women to "...be public and demand...what we need," she continues, "We must not exclude anyone. Yes, even men."

I am a DES father. Does that make me any less sensitive to the pain and suffering of my DES daughter? I am a DES husband. Does my maleness make me any less apprehensive about what the future may hold for my DES wife? Has my gender made me less supportive of DES Action and all that it stands for? No, no, and no!

Sure. I know that women have been, and are being, wronged by men. My consciousness began rising over forty years ago, and I understand full well Ms Esposito's anger. Her remarks may be appropriate in a different forum. I just wonder if it benefits the DES Action cause to divide its supporters.

Walter A. Benjamin Brooklyn



DES Update, ed. Kenneth L. Noller M.D., Elsevier Science Publishing Co., 655 Ave. of the Americas, New York, N.Y. 10010, \$36 prepaid.

his 140-page book is one of a series on "Clinical Practice of Gynecology" and is edited by Kenneth Noller, known to our readers as one of the directors of the DESAD research project. There are nine chapters in this basic book:

1. Medical and surgical diseases associated with in utero exposure to diethylstilbestrol, Noller et al.

2. Evaluation of the female exposed in utero to diethylstilbestrol, Louis Burke.

3. Reproductive consequences of prenatal exposure to diethylstilbestrol in women, A.F. Haney.

4. Upper genital tract changes and pregnancy outcome in the diethylstilbestrol-exposed woman, Raymond H. Kaufman.

5. Cytology of the female lower genital tract in diethylstilbestrol-exposed women, D.A. Antonioli and B.S. Ducatman.

6. Pathology of prenatal exposure to diethylstilbestrol in women, Stanley J. Robboy et al.

7. Immunologic consequences of early exposure of mice to diethylstilbestrol, Phyllis B. Blair.

8. Selection bias in observational studies: An example from the Diethylstilbestrol Project—a study of diethylstilbestrol and its relationship to vaginal epithelial changes, Peter O'Brien et al.

9. Social impact of diethylstilbestrol exposure on women in the United States, Judith S. Turiel.

We refer any DES daughter wanting more detailed information about health effects to this study. It is gratifying that the editor concludes the book with the monograph by DES daughter Judith Turiel. She has contributed much to our work with her reports for the Voice on medical journal articles. Here, she writes for the medical community to let them know about the broader aspects of DES exposure and its impact on our lives.

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