V O I C E

A FOCUS ON DIETHYLSTILBESTROL

Summer 1995

#65

medical report

Fertility in DES Sons

Review by Cynthia Laitman (formerly Cynthia Laitman Orenberg), author of DES: The Complete Story

Fertility in men exposed prenatally to diethylstilbestrol Allen J. Wilcox, MD, PhD; Donna D. Baird, PhD; Clarice R. Weinberg, PhD; Paige P. Hornsby, PhD; and Arthur L. Herbst, MD. New England Journal of Medicine, Vol. 332, No. 21, pp 1411-1416, May 25, 1995.

o men exposed to DES before birth have more fertility problems than other men? This question has been hanging in the academic air ever since William Gill and his colleagues at the University of Chicago first described urogenital abnormalities in the DES sons of the Dieckmann study, conducted in the early 1950s.

The Dieckmann Study

Dr. William Dieckmann, chief of the University of Chicago's Lying-In Hospital in the 1950s, was troubled by the large-scale

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use of DES during pregnancy despite a lack of scientific proof that it was effective in preventing miscarriage. Dieckmann and his colleagues decided to study 2,000 consecutively registered women in their prenatal clinic, in the first controlled, randomized, doubleblind study of the effectiveness of DES as an anti-miscarriage agent. (It should be noted here that Dieckmann did not know that DES could cause harm.)

Women enrolled in the study were assigned at random to receive either DES or placebo. The study was termed "doubleblind" because neither the physicians nor the patients knew who was receiving DES and who was receiving placebo (only the pharmacists dispensing the pills knew). The results of the Dieckmann study revealed that DES given according to the commonly recommended regimen (the Smith & Smith regimen, named for the Harvard doctors who first proposed the use of DES during pregnancy) did not reduce the number of miscarriages, premature or postmature births, or pregnancy complications such as toxemia or eclampsia.

Dieckmann published his results in 1953 and thereafter the use of DES gradually declined. However, the children whose

mothers took part in the Dieckmann study have since become known as the Dieckmann cohort. These people, now in their early forties, are the objects of keen ongoing medical interest because they are, in effect, a long-term experiment in the prenatal effects of DES. The full results of this unintentional human experiment will not be known until these "children" have completed their lives.

25 year follow-up on Dieckmann cohort

In the 1970's, after DES's harmful effects on daughters became know, Dr. William Gill, a professor of urology at the University of Chicago, followed up on the sons of the Dieckmann study. He was able to find and examine 301 men from the DESexposed group and 307 men whose mothers had been given placebo. These men were in their mid to late twenties at that time. Dr. Gill found that 40% of the DES sons compared to only 14% of men from the control group had pathologic sperm as judged by motility, shape, and density. Although these laboratory measures hinted at lowered fertility, the men were still relatively young and most had not yet tried fathering children,

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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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ES (diethylstilbestrol) is a synthetic form of the female hormone estrogen. From 1938 to 1971, several million pregnant women in the U.S. were prescribed DES, especially if they had a history of previous miscarriage or slight bleeding or had diabetes. DES was given in pills, injections and suppositories and sold by over 200 drug companies under their own brand names.

DES exposure can lead to health problems:

DES mothers have a slightly increased risk for breast cancer

DES daughters have a 1 in 1,000 risk for a rare vaginal/ cervical cancer, clear-cell adenocarcinoma. This is the reason all daughters need regular gyn exams. They also are at risk for reproductive difficulties: infertility, ectopic pregnancy, miscarriage and premature delivery, and should always receive high-risk pregnancy care.

DES sons have an increased risk for undescended testicles, cysts on the epididymus, and possibly for infertility.

DES Action, the major consumer group working on this issue since 1974, has special publications, physician referral lists, attorney referral lists, this quarterly newsletter, and a hotline: 1-800-DES-9288.



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V O I C E

DES in Developing Countries

by Ellen 't Hoen, DES Aktiegroep The Netherlands

ES use is disappearing in most western industrialized countries. For instance, in the Netherlands and Canada, DES is exclusively allowed for the treatment of prostate cancer. All other indications, most of which were aimed at women, have officially been eliminated.

The United Nations Consolidated List of Products whose Consumption and/or Sale have been Banned, Withdrawn, Severely Restricted or Not Approved by Governments lists some of the regulatory measures taken by different countries concerning DES use. In Italy, DES was withdrawn completely from the market in 1983. In Germany and Greece, indications for use are limited to the treatment of prostate cancer. The French prescribing guide Vidal clearly states that DES is contra-indicated for use in women.

The second edition of *The Consolidated List* published in 1986, quoted the World Health Organization (WHO):

"...Diethylstilbestrol and other stilbenes retain a place in the treatment of carcinoma of the prostate and postmenopausal breast cancer." The fourth edition (1991) states the diethylstilbestrol and other stilbenes still remain available in many countries for these indications.

But in countries with less strict pharmaceutical regulatory systems, as is the case with most developing countries, DES exists for a range of indications that have been abandoned or were never allowed in many Western countries. These indications "A general practitioner needs only about 140 drugs to treat most illnesses."

include menstrual irregularities, delayed menstruation, menstrual complaints, ovarian disturbances, suppression of milk production after childbirth, vaginal or cervical infections, infertility problems and others. Although DES is no longer promoted as a remedy for miscarriage, chances are that some women could still get DES during pregnancy.

At the 1994 7th International Women and Health Conference held in Uganda, DES Aktiegroep The Netherlands collected evidence of DES use by women in developing countries. Women from Uganda, Nigeria, Ghana, South Africa, Mexico and Colombia testified that DES is still used in their countries to suppress lactation and/or to prevent miscarriage.

Two indications for DES most often found in developing countries are for the treatment of menstrual irregularities and the suppression of lactation (breast milk). The indication 'menstrual irregularities' is vague, including for example delayed menstruation. Delayed menstruation is often due to malnutrition which should not be treated with medication. Pregnancy is another common cause for delayed menstruation, which means that a woman could receive DES to induce menstruation while she is

unknowingly pregnant.

In some cases, DES is used to stop milk production when another child is desired, the rationale being that fertility will return once milk production has stopped. Once again, using DES this way makes it possible for a woman to receive the drug while she is pregnant....

In 1975 the WHO developed the essential drugs concept. Its goal is to give everyone access to safe, effective, good quality drugs that they can afford. Central to this concept is a list of about 270 essential drugs needed by a particular country to treat a majority of its health problems. An essential drugs list enables countries to rationally use their limited resources available for health care.

Norway, for example, has 2,200 drugs on the market (about 1,200 active ingredients) and is known for its high quality health care. The Netherlands has about 3,000 products compared to India which has about 30,000 drugs. A general practitioner needs only about 140 drugs to treat most illnesses....

...all information distributed with pharmaceuticals should be of the same quality as the information available in the exporting country. A lack of information about the hazards of DES has harmed women all over the world. It is sad to conclude that among the many irrational and/or harmful drugs, DES can still be found in countries where people are the most vulnerable.

—Excerpted from DES Action Canada Newsletter, Winter 1995

letters to the editor

Dear Editor,

I received a copy of your newsletter (Fall 1994—editor) through the Southwest DES Center (Texas) where I have been a participant in research since 1973. I admire your efforts at educating doctors and the rest of the public about DES exposure. I do, however, find it a bit disturbing that your newsletter seems to focus on the sensational rather than a more balanced picture. The articles are heavily biased toward presenting horror stories about bad treatment by physicians, and crowing about litigation. While these are certainly important, I think it is just as important to balance each issue with reassurances that the great majority of DES exposed men and women suffer no ill effects, most pregnancies are unproblematic, and many doctors are sympathetic and wellinformed. Instead, you fill people's minds with all the worst possible fears without giving them the essential knowledge to make rational decisions.

For instance, a friend of mine had received information from you for a number of years. She was so frightened that she and her husband had decided against trying to have children at all. Luckily, I talked to her and gave her the number of the Southwest DES Center who were very informative and helpful. The couple, after an uneventful pregnancy, have a perfectly healthy, normal 6-year-old girl.

Even the information you give, which is quite sketchy, makes it impossible to draw any real conclusions. For instance, you say that "DES daughters

have a 1 in 1,000 risk for...clear-cell adenocarcinoma." But you fail to say what the incidence is in the population at large. Nor do you mention that the number of reported DES-related cases of clear cell adenocarcinoma has steadily declined....

As to whether DES was effective at preventing miscarriages or not, the evidence was mixed. The National Cancer Institute report concluded that it might not be effective and decided to withdraw it. However, I firmly believe that were it not for DES, neither my brother nor I would be here. My mother had three miscarriages, had my brother while taking DES, had two more miscarriages, and then had me while taking DES. While this is only anecdotal evidence, it is not an isolated occurrence.

Finally, the doctor-bashing is quite unfortunate also. How about publishing stories about doctors who are helpful and informed? The three ob/gyns that I went to in Texas were all very informed and encouraged me to read and ask questions. One of your readers says that the doctor said that her premature birth might not have been related to her DES exposure. This is quite possibly true. Not all premature births are caused by DES. The same writer says, "I never knew to ask DES questions." Perhaps a vital role which you can play is to publish such questions, some answers, and some sources of further information in each issue.

I don't mean to sound so churlish and I really do think that you are providing a very important service. I do think, though, that another of your roles should be to give people a balanced picture and to offer reassurance that the large majority of DES exposed people experience no serious problems at all. Mental well-being is just as important as being well-informed.

Dr. Jean McKendree Physiological Psychologist University of Heslington, England

Reply from Nora Cody, Executive Director, DES Action

Thank you for writing to share your concerns regarding our newsletter.

All of the medical information we present in our newsletter has passed the approval of our medical review board, composed of obstetricians, gynecologists and other physicians who are nationally recognized experts in the care of DES-exposed individuals. We always strive the present information in a balanced, reasonable manner.

We also strive to serve as a voice for DES-exposed people who feel ignored or dismissed by their doctors or others, and so from time to time we publish personal stories which may include what you call "doctor bashing." We are confident that our readers recognize that these stories reflect one person's experience. We are proud to feature and honor caring physicians, as we did recently (Winter 1995 issue) in highlighting a plaque we presented to Dr. Kenneth Noller in appreciation for his services to DES daughters.

As to the information we present, you suggest that we overstate the risk for clear cell adenocarcinoma. We always state that this is a rare disease among DES daughters. However, we do feel a need to counteract the mistaken impression among some physicians and the general public that the risk for clear cell cancer disappears after the age of 30. This could be a fatal assumption. We are not only seeing (fortunately few) cases of clear cell in recent years in women in their late 30s and early 40s, we are also mindful that DES experts like Dr. Noller warn that we may see a second "wave" of clear cell cases as we age. It is our job to make sure DES daughters realize that this small but real danger has not gone away.

I was surprised and sorry to hear your anecdote about your friend's fear of having children, since I spend much of my time on the phone reassuring DES daughters and encouraging them to attempt to have children. I find that this is necessary because often DES daughters call with the impression (left by their doctors) that their T-shaped uterus or even simply DES exposure renders them automatically infertile.

In regard to your discussion of the effectiveness of DES: perhaps you are not aware of the Dieckmann study at the University of Chicago in 1952. Considered one of the best DES studies (in fact, the best, according to the National Cancer Institute) this controlled, randomized, doubleblind study of 2,000 pregnant women concluded that DES was not effective in preventing miscarriage. In fact, the women who received DES were more likely to miscarry than those receiving a placebo. And in the 1970's, DES was widely used in the U.S. as a morning-after pill to help women lose a pregnancy.

Lastly, we do publish questions and answers in almost every issue of the newsletter. The answers are always provided by physicians well-trained in care for DES daughters (including Dr. Kaufman from the Southwest DES Center).

Please keep in mind that mental well-being includes being validated in one's legitimate concerns about health risks and care, and not in being consistently dismissed, as has too often happened for too many DES daughters.

Dear Editor,

I was extremely distressed to read the medical report in your Spring 1995 issue, stating that only one documented case of early menopause was reported in the study of DES-exposed daughters, and thereby concluding that "there appears to be no relationship between prenatal DES exposure and diagnosis or symptoms of early menopause." The doctors involved should be more cautious in coming to this conclusion. To me it sounds as if their sample was limited, or they just didn't include the right people. I, for one, can personally refute this conclusion—with my first "hot flashes" coming at the age of 32, my last period at the age of 36. Other than the DES exposure, there were no other "risk" factors in my history (my mother had periods until she

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Some Lilly History

The Wall St. Journal last year had a news account of a warning by the Food and Drug Administration to Eli Lilly to 'stop engaging in false and misleading' promotion of its \$400 million-a-year ulcer drug, Axid.... The FDA said Lilly recommended dosages 50% to 100% greater than the doses recommended in approved product labeling...and made 'highly misleading' statements about...the competing ulcer drug Tagamet.'

Eli Lilly, as many of our readers know, was and remains the leading producer of DES, and its trade name Stilbestrol became almost a generic name for the drug. This latest censure reveals a pattern of indifference to the health effects of their products that is only too familiar to us. Disclosures made in Lilly company documents during the law suits against them, for example, show that

☑ In 1940 tests of stilbestrol on rats showed hydropic degeneration
of the liver in five of seven animals examined. Lilly researchers
agreed not to submit this data to the FDA.

In 1972, in a company report on the 'Status of warning statements in package literature' (this was a year after the Herbst report on clear-cell cancer in DES daughters) a company official wrote that

'Material shipped to Peru and the Dominican Republic is labeled in Spanish, and the contraindication presently incorporated in United States labeling is not included therein...

'Our diethylstilbestrol...is supplied to Mexico and Guatemala in bulk for tableting. Products marketed in these countries do not contain any package literature.'

VOICE

Notes from Nora

he last issue of this newsletter featured a cover story on the new DES booklets that are now available to the public. Some of you followed our advice and called the Cancer Information Service to request copies of the booklets. Unfortunately, we were mistaken and the CIS will not be distributing any of these booklets. Please call us at 1-800-DES-9288 if you wish us to send you any booklets. Or drop us a note, and please include \$2 to help cover the postage. That is, \$2 for the order, NOT per booklet.

DES Action and the DES Cancer Network

Recently some members of DES Action have contacted us because they received mail from the DES Cancer Network and were unclear about the relationship between these two organizations. We thought it might be helpful to provide some clarification.

The DES Cancer Network formed in 1982 as a network of women who had survived clear cell adenocarcinoma, and operated as an affiliate of DES Action until 1992. At that time the DCN became a fully separate organization, with separate operations, funding, and mailing lists. Contributions to DCN will go to fund their activities, and contributions to DES Action fund the work of DES Action.

New booklets on hormone treatment

The National Women's Health Network has revised and expanded its booklet on *Taking* Hormones and Women's Health: Choices, Risks and Benefits, and created a new information packet on Alternative/Complementary Medicine and Menopause.

The new version of the first booklet has a section on natural progesterone and a section dealing with claims that estrogen will prevent memory loss, depression, and wrinkles. The osteoporosis section has been expanded to include a section on the pros and cons of bone density screening. The hysterectomy section now covers both medically and surgically induced menopause.

The packet on alternatives to HRT is a collection of articles on alternative/complementary medicine in general and its conceptions of menopause; ways to build good health; and the use of herbs, nutritional supplements, acupressure, yoga, massage and acupuncture in dealing with menopause.

Each of these publications costs \$7.50 and is available from the National Women's Health Network, Suite 400, 514—10th St. N.W., Washington DC 20004.

...and a reference book
The People's Medical Society is

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As a courtesy to our members, it is our policy that we never sell or rent your names and addresses to any other organization.

a national consumer group whose goals are to empower consumers to improve their health and take charge of their medical care. They have a number of publications and now a new one: *The Consumer's Medical Desk Reference*.

Written by Charles B. Inlander, President of the Society and a faculty lecturer at the College of Medicine at Yale, the description of the book states that it is "straightforward, sensibly organized and free of medical jargon. It delivers a wealth of practical information, from descriptions of diseases and medical terms to how to deal effectively with doctors and hospitals. Where and when to seek the right specialist; where to file a complaint, important factors about fitness, diet and vitamins, and much more make this the most comprehensive handbook ever published for managing your own healthcare efficiently and intelligently." The book costs \$21.95 plus \$3 shipping and can be ordered from the People's Medical Society at 462 Walnut St., Allentown PA 18102. There is a toll-free order line at 1-800-624-8773.

Next time you decide to honor someone with a gift or memorial tribute, think of DES Action. Our

Tribute Gift

program allows you to donate in someone's honor or memory. V O I C E

LETTERS *from page 5...* was well into her sixties!).

I would greatly appreciate it if you could forward this letter to the doctors involved. The last thing we DES daughters need (as we grapple with extremely difficult decisions regarding hormone replacement therapy, infertility drugs, etc.) is one more faulty study.

Reader, New York City

Dr. Allen Wilcox replies:

No study by itself gives the final answer. This fact is frustrating for scientists as well as for lay people. The whole picture often does not emerge until many studies have been pieced together.

The correspondent's description of her own premature menopause is a compelling reason to be concerned about DES effects on menopause. Our study was the first one ever to look at this problem. We interviewed over 500 women, half of whom had been exposed to high doses of DES prenatally, and half who had no DES. There was no difference between the two groups in hot flashes or other symptoms of menopause, and no difference in cessation of menses. When we reported these findings, we emphasized that the results were preliminary. Women were only 38 years old at the time they were interviewed, and there could be differences in age at menopause between DES daughters and other women that won't show up until later.

The correspondent raises good questions about the effects of hormone replacement therapy and other treatments on DES daughters. Unfortunately, our study doesn't allow us to answer these questions. We hope that the

DES Action elects four new members to Board of Directors

t our Spring Board of Directors meeting DES Action bid a very fond "so long" to Pat Cody and Andrea Goldstein, who left the Board after each serving two three-year terms. (According to DES Action bylaws, Directors must resign after six years, but are eligible to run for election again after a one-year absence.) Both Andrea and Pat remain very active in the organization, and Pat continues on staff as Program Director.

The Directors also elected four new Board members and a new vice president and secretary. Karen Lang, our DES Action Washington Coordinator and a DES daughter, was elected for the first time, as was Stephanie Kanarek, also a DES daughter and active in the New York affiliate and in the national battle against product liability "reform." Both women bring enthusiasm, savvy and a fighting spirit to the Board.

Returning to the Board after being away for a few years are Libby Saks, DES mother and longtime New York activist, and Candy Tedeschi, RN, an expert in care for DES daughters and nurse at the DES Screening Clinic at Long Island Jewish Hospital. Libby was elected secretary and Amanda Sherman is DES Action's new vice president. Karen Fernandes remains president and our treasurer is Kari Christianson.

renewed interest in DES-related research will lead to findings that can help guide DES daughters in those decisions.

Dear Editor,

This is in answer to the letter in the Spring 1995 issue from LOVCATS on taking the birth control pill....

As a DES daughter my own experiences in having used estrogen-containing products i.e. birth control pills has resulted in deleterious effects. Within six months of taking this medication I was found to have an atypical Pap smear result. My symptoms included a continuous, copious quantity of mucosal discharge from cervical glands. After a pelvic examination it was determined that the surrounding cells were hypertrophied, but not cancerous. After approximately one year of discontinuing the pill, my symptoms

completely subsided. As a result of this experience I will refuse all forms of ERTs.

Although dietary calcium supplementation is not sufficient to prevent osteoporosis, women are not being notified of a product that may prevent it. This is a hormone known as Calcitonin. Presently it can only be absorbed by injection since the intestinal tract breaks down this hormone. An attempt is being made whereby a nasal inhaler can be used as a simple route of delivery. It should be noted that pharmaceutical companies will continue to do research wherever they believe the greatest profits are to be found. At this time it is in ERT.

Further detailed information can be obtained on request.

Laura Scholler 1 S. Pine Island Rd., #1-316 Plantation FL 33324 (305) 452-7970 V O I C F

SONS *con't from pg* 1... the ultimate test of fertility.

The Wilcox study

Fertility in men exposed prenatally to diethylstilbestrol is the first significant study of the actual fertility status of DES sons—in other words, of their ability to father children. The Wilcox study is especially important since it further follows the sons from the excellently designed Dieckmann study.

In a telephone questionnaire, Dr. Wilcox and his colleagues were able to contact 253 DES-exposed men and 241 men from the control group of the original Dieckmann study. A total of 848 male babies were born in the Dieckmann cohort, 425 in the DES-exposed group and 423 in the control group. At the time of

the Wilcox survey the cohort was about 40 years old.

Although the DES-exposed men reported urogenital malformations three times as often as the men whose mothers were in the placebo group, there was no significant difference between the exposed and non-exposed men with respect to their ever having impregnated a women, their age at birth of their first child, average number of children, medical diagnosis of a fertility problem, or length of time to conception in the most recent pregnancy of the female partner.

Practically speaking, this is wonderful news for DES-exposed men. What it means is that although DES sons were indeed damaged by their exposure (hence, the significantly higher incidence of urogenital abnormalities), the damage was not enough to prevent them from fathering children.

The academic debate continues, however, as male fertility specialists are now suggesting a medical re-examination of this cohort, including a semen analysis, to determine how laboratory findings correlate with fatherhood status.

In spite of their very significant findings, Dr. Wilcox and his colleagues end their paper with a cautionary note, saying, "However, our data do not address any health effects of diethylstilbestrol that might emerge at older ages."

And so, active inquiry must continue since substantial questions still remain about other long-term health effects of DES exposure.

DES Action USA

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