THE DES ACTION
VOICE
A FOCUS ON DIETHYLSTILBESTROL
Fall 1997 #74

DES Research Update

Report from the National Cancer Institute on the DES Follow-up Study

The current DES Follow-up Study is a nation–wide research study following a large group of both DES-exposed and unexposed people, in order to learn as much as possible about the health effects of exposure to DES. Beginning in 1994, all participants from previous studies, as well as newly identified individuals in New England, were mailed a questionnaire. The following is an excerpt from their latest newsletter:

Questionnaires were mailed to over 6,900 mothers, 6,500 daughters, and 3,600 sons over a two-year period. The first phase of data collection is complete, and we are now analyzing the data and hope to have answers to many remaining questions about DES exposure by early next year.

Mothers

Some previous research has shown that mothers who took DES... have a slightly higher risk of breast cancer (approximately 30 percent higher) than a similar group of women who were not exposed to DES during pregnancy. This risk has been stable over time, and does not seem to be increasing as the mothers become older. During the current DES Follow-up Study, we have received questionnaires from nearly 6,000 mothers. This is the largest study of DES-exposed mothers to date and we expect to provide further insight into whether the risk of breast cancer remains elevated. In addition, we will also determine whether DES-exposed mothers are at higher risk for any other types of cancer.

Daughters

We have received questionnaires from nearly 6,000 exposed and unexposed daughters that will enable us to provide answers to many health questions.

Cancer risk

No new cases of clear cell cancer of the vagina or cervix were reported during this phase of the DES Follow-up Study among the 4,883 DES-exposed daughters being followed, and the incidence is estimated to be less than one case for every 1,000 daughters who were exposed.

It is important for DES daughters to continue regular screening for cervical and vaginal abnormalities, since some doctors are concerned about the risk of clear cell cancer during the menopausal years. This is the usual age at which this disease occurs without DES exposure, and there have been cases of clear cell cancer among DES-exposed women in their 40s.

We have conducted preliminary analyses of the risks of other types of cancer, including breast cancer in DES daughters, and find no evidence of any major excess risks at this time. We expect to publish our findings on cancer in 1998, and will continue to update you as more specific information becomes available. Because of the relatively young age of the daughters being followed, there have not been many cancers to date. More definitive analyses will not be possible until after a few more years of follow-up.

Pregnancy

Most DES-exposed women have no trouble becoming pregnant and carrying their pregnancies to terms, yet there continues to be an increased risk of miscarriage, ectopic pregnancy, infertility, and premature birth. We are currently analyzing the information that respondents provided us on pregnancy outcomes, and we will publish updates as more specific results become available.

Other diseases

A previous study reported a slightly higher risk of thyroid disorders in DES-exposed daughters. We are planning a more detailed study of thyroid and other related diseases among those who reported these disorders in our last questionnaire.

Effects on the Third Generation

A small study which looked at effects of DES in mice suggested

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RESEARCH *from page 1...*
that there may be some increased risks of reproductive tract abnormalities among the offspring of mice who were themselves exposed to DES in utero. Many scientists consider this unlikely, but since it is a concern on the part of the DES-exposed population, and can be addressed by this study, we are planning a questionnaire study of third-generation daughters (DES granddaughters) who are 18 years or older. We are also examining third generation daughters to see whether reproductive abnormalities are present. To date, all examinations have been normal.

Sons

We have received over 2,500 questionnaires from both exposed and unexposed sons. Because of the relatively young age of this study population, there were few adverse health effects reported overall. Nevertheless, we plan to analyze the overall risk of cancer as well as any other conditions that have occurred frequently enough to be evaluated.... A recent study, published in the *New England Journal of Medicine*, found no overall increased risk of infertility among DES-exposed men, although there were increased frequencies of some minor genital abnormalities. Whether these abnormalities indicate that more serious conditions may develop in the future can only be determined by further systematic follow-up. It is important to follow DES-exposed males for the long-term risk of prostate and other cancers.

VOICE

The Story of a DES Father

By Geert van der Holst, translated by Dietske van der Brugge, DES Action/Netherlands

I am the father of a DES daughter who has known a lot of sorrow and grief over his child. I am often surprised that most of the time fathers stay out of the picture in DES cases. In our family, DES is certainly not exclusively a women's affair. I have always been very much involved, during my wife Ida's pregnancy, as well as during our daughter Gemma's illness, when we went through the most difficult period of our lives.

We already had two boys, and a third child was really welcome. I come from a family of eleven children, and Ida and I also wanted a big family of our own. However, Ida's third pregnancy ended in a miscarriage. When she got pregnant again in 1959, the drug Stilbestrol was on the market. It seemed it would help safeguard Ida's pregnancy and the child we desired so much. I talked it over with the family doctor myself, and was comforted in the knowledge that there existed such a drug that could reinforce Ida's pregnancy.

I went to the pharmacy to get the pills. I remember walking there, and saying over in my mind the name Stilbestrol and "still being strong" on it. Ida took those pills all through her pregnancy, and in September our daughter Gemma was born. We were overjoyed, Gemma was a healthy and pretty child. Until 1983, we never had the faintest idea that DES could cause damage to her health. After Gemma, we had another three boys. The eight of us formed a nice, tight family. It is still the case.

"I am often surprised that fathers stay out of the picture..."

In 1983, Ida and I were watching a television program on medicine. It was about the harmful consequences of DES. On hearing the brand name Stilbestrol, we knew immediately that this program related to us, especially to Gemma, who we felt should know what we learned right away. She had already been to our family doctor several times because she had complaints of discharge and blood loss. The doctor didn't think it alarming in a young girl, and saw no reason to refer her to a gynecologist.

Thinking this new information on DES could possibly shed another light on Gemma's symptoms, she consulted the doctor again. It still didn't result in her getting a referral to a gynecologist. In fact, she only got one a few months later after more or less insisting on it. Ida called me at my office the day after Gemma had her gynecological exam. We were asked by the specialist to go over the results. Naturally, this was an unusual request. Gemma had already been living on her own for several years. I knew something was terribly wrong.

The gynecologist didn't beat around the bush. He said Gemma had cancer, but added that "Something can be done about it, and in nine out of ten cases things turn out fine." At the time, the relationship to DES exposure was not mentioned. It didn't occur to us to make the connection then, as the reality of cancer hit us first, and took precedence over everything else. It wasn't discussed until later, when an exact diagnosis of the kind of cancer was made.

Gemma was hospitalized for further examination. We were with her when she got the results. The gynecologist explained what the treatment would be like, which organs would have to be removed, and that there were doubts that she would be able to keep her bladder. When she heard what would have to be done, Gemma's reaction was, "Well, there won't be much left over." Never in my life will I forget her reaction. In addition, she was convinced she wouldn't be willing to undergo every treatment.

That frightened me. I am of a different mind, more like, "Do everything possible and necessary to save her." And I knew Gemma: if she has her mind set on something, you can forget her changing her mind. It wasn't at issue at the time, but again, I was frightened. Of course, I understood that she, as a grown woman, had to make her own decisions, but it added to my immense feeling of powerlessness. Adult or not, Gemma was my child, and her life was seriously threatened. As her father, I wanted to do everything in my power for her, and yet I could do

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DES FATHER *from page 3...*
nothing. The feeling of powerlessness consumed me. I found it to be a heavy burden.

Gemma's treatment was taken over by a gynecologist in the University hospital. The first time a friend of Gemma's went with her. Gemma wanted it that way, but I had trouble accepting it. I wanted to go with her myself. I understood though, and respected her choice. What was difficult to cope with was that she was trying to spare us as parents. For this reason, she didn't tell us much about her treatment. I didn't want to be on the sidelines, already feeling powerless anyway.

This really applied more to me than to Ida. Sometimes I discover that there are certain things Ida knows about that I don't. For example, not long ago I had read an article about some kind of recovery operation. When I asked Ida whether or not Gemma had ever considered having it done, I found out they had spoken about it, but the idea hadn't appealed to Gemma. That was one of those moments when I realized how different my position is to Ida's, even though my involvement is no less than hers.

Neither Ida nor I have guilt feelings concerning our role in Gemma's DES case. But that's not the same thing as having 'no part' in it. Our eyes aren't closed. As parents we made the best choice we thought we could make for our child. That it had subsequently had terrible consequences doesn't alter the fact that we chose with care and good intentions at the time.

The evening we took Gemma to the hospital for her operation, she underwent a preliminary examination... She came back to her room with two ball-point circles on her abdomen. The circles marked places where stomas might be inserted. Only during the operation would it prove necessary. These marks made such an awful impression on me. I was completely devastated by them. If anyone were to ask me about the most beautiful day in my life, I wouldn't exactly know. But this was undoubtedly the blackest day I'd ever known. I had never felt as low as I felt then.

More than ten years have passed since then, but I can still feel that oppression. I don't mind admitting that during that whole period, Ida was much stronger than me. The next day, Gemma was operated on early in the morning. We were at home. Late morning we were told we could come to the hospital. Gemma was in intensive care, she had barely come out of anesthesia. The surgeon told us the operation had gone well, that he was able to use a new technique and therefore the stomas weren't necessary.

It wasn't exactly a day to be happy, but nevertheless we were immensely relieved. We knew there was still a lot of sorrow and insecurity ahead of us, but at the moment we were grateful everything had gone well. At night we were together with our boys. I have good memories of our being together, and the solidarity with one another.

The first weeks after her discharge, Gemma stayed with us. She showed such mental resilience that I was truly impressed. I already knew she had a strong personality, but nonetheless it was very special to see how her character remained intact after such a crisis. I didn't work after Gemma's operation. I had problems concentrating, and I began suffering from a heart rhythm disorder. I haven't become a patient with all kinds of restrictions, but I am affected by this whole experience with illness.

It is very typical of Gemma to turn her experience into action. Through the DES Center she found support with other women who had similar experiences. She has also given support to others, even a woman who couldn't be cured. It was our son Jan who first got in touch with the DES Center. Such a network of women who have had the same illness is very important.

In 1986, a number of these women took the pharmaceutical companies that put DES on the market to court. We knew beforehand that the legal battle would be a long and difficult one, for the Dutch liability law doesn't leave much leeway. The claimants have been involved in this lawsuit for more than ten years, and their case still hasn't been resolved. I think it very important that the pharmaceutical companies take responsibility. I also think Gemma deserves compensation for all that she has lost, and is still losing, for example, the opportunity to have children.

Gemma has always been special. After all, she's our only daughter. But since her illness, her position in relation to our other children has changed. It's not that we see her as a patient, but because she has gone through such an existential crisis,

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The Menopausal Transition: A Different View

An international symposium held in Leiden, the Netherlands, on June 18 and 19, 1997. Report from Barbara Mintzes of Health Action International.

This symposium, held under the auspices of Leiden's Boerhaave Foundation, examined the social, cultural, and economic factors contributing to the definition of menopause as a medical event. It assessed the current state of knowledge on health risks in menopausal and post-menopausal women and their need for long-term hormone treatment.

It was indeed a different view as compared to most medical conferences on menopause. There were no glossy stands selling the latest patch or pill. No company-sponsored speakers, and a range of critical, comparative information both from a medical and epidemiological perspective and from disciplines as far-ranging as anthropology, law, sociology, and philosophy.

The menopause, or the cessation of women's menstrual periods, marks the end of her reproductive life and is in many ways the mirror image of the menarche, the beginning of menstruation. As conference organizer Eylard van Hall, retiring this year as Leiden's Professor of Obstetrics and Gynecology, points out: "Just as the transition period around the first menstruation sometimes is accompanied by temporary physical and psychic imbalance, the same can hold true for the transition period around the last menstruation."

In most industrialized countries, however–and increasingly globally–the similarity ends there. Whereas the menarche is seen as a social event marking a young girl's passage into adulthood and the mood swings and other changes associated with it are accepted as part of an adolescent's normal life, menopause has come to be defined as a medical event requiring drug treatment. Hormonal drugs are frequently prescribed for symptoms of menopause and are increasingly recommended for long-term use in order to prevent diseases such as osteoporosis and cardiovascular disease which have come to be associated with menopause in the popular consciousness. There is a growing tendency towards viewing all menopausal women as 'at risk' or potentially ill, and to offer long-term prophylactic drug therapy....

"It was indeed a different view as compared to most medical conferences."

Osteoporosis, a disease in which bones become brittle and fracture easily, has come to be associated with menopause because women begin to lose bone density more quickly after menopause. Estrogen causes bone density to be lost more slowly during current use but effects generally disappear by five years after discontinuation. However, most fractures occur after age 70....

Is osteoporosis mainly a female post-menopausal disease? A comparison of incidence rates for five-year age groups shows that men tend to develop the disease later. Men, 70-75 years old have similar fracture rates to 65-69 year old women; 75-80 year-old-men similar rates to 70-75 year-old-women, and so on. Sixty percent of fractures occur in women with normal bone density and normal risk of falling. Poor eyesight, dementia, and use of tranquillizers have all been shown to increase the risk of fractures.

Dr. Sips, a general practitioner, concluded that bone density screening and hormone therapy were likely to prevent at most five percent of all fractures in women. This raises questions about the cost effectiveness of screening and also the usefulness of bone density measurements for individual case finding.

Rates of cardiovascular disease gradually increase with age in both men and women. Women remain at lower risk than men throughout their lives and the hormonal changes at menopause do not cause any sudden acceleration in heart disease or shift in women's risk in comparison to men. Nevertheless, increasingly hormone therapies are being recommended to prevent heart disease in women. Two observations contribute to this view. One is that women's blood cholesterol levels change after menopause as a result of hormone changes; the second is that a number of observational studies have shown a protective effect for estrogen use.

These studies are of self-selected groups and have been

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criticized on the basis that women at high risk for heart disease are less likely to be prescribed hormones, a "healthy drug taker bias" similar to the healthy worker effect seen in occupational health studies. As Yvonne van der Graaf from Utrecht pointed out, "Most of the evidence comes from major studies conducted during the years that estrogens were withheld from women with cardiovascular risk factors." Two large-scale randomized trials in the U.S. and the U.K. should provide answers to whether the protective effect of estrogens is real or an artifact of healthier women's higher likelihood to use hormones.

Van Hall commented that the large reductions in relative risk observed thus far translate to very few cases of cardiovascular disease prevented, because the populations studied were at low risk. He argued for the use of estimates of absolute risk reduction, not relative risk, so women and doctors have a more realistic idea of how much benefit to expect from hormones. For example, studies of aspirin and heart disease showed a fifty percent relative risk reduction, that is, half the risk in aspirin users, but the observed absolute risk reduction was from a two percent risk to a one percent rate of heart disease. As he pointed out, the same information can be presented in more than one way. The question is how to present it so it best answers women's questions about their own health.

Can estrogen be used to prevent Alzheimer's? Van Duijn, also from the Netherlands, reviewed the evidence to date on use of estrogen both to prevent and treat Alzheimer's, evidence which is contradictory and based mainly on small uncontrolled studies. She argued that longer-term trials currently underway will provide some answers on its effectiveness as a treatment and that double-blind trials of prevention should be carried out in women identified as being genetically susceptible and at high risk for Alzheimer's.

Thus questions remain about the major claimed health benefits of long-term hormone use. What of the risks? The California researcher Dr. Shanna Swan reviewed the evidence on risks of reproductive cancers. "There is little question that unopposed estrogen conveys a duration-dependent, increased risk of endometrial cancer," she noted. Adding progestin for at least ten days per cycle reduces this risk but may not entirely eliminate it. Studies of ovarian cancer and estrogen use shown no increase in risk, although the effects of combined estrogen/progestin products have not been evaluated.

The link between long-term hormone use and breast cancer remains controversial. Many studies have been carried out, but most are on estrogen use alone. On the whole, there appears to be a small increase in relative risk of breast cancer for long-term current users, estimated to be a twenty to thirty percent increase in the likelihood that a woman is diagnosed with breast cancer. One recent large follow-up study, part of the Nurses' Health Study in the U.S., showed a greater increase in risk among women who had used hormones for over five years, including women who had discontinued use within the last two years. Among women 60-64 years old who were current users, there was a seventy percent increase in the likelihood of being diagnosed with breast cancer.

Breast cancer and heart disease are the two conditions associated with hormone use with the greatest impact on life expectancy. In many ways the evidence for the greatest harm, more breast cancer, and the greatest benefit, less heart disease, remains equivocal. Women may seem to have less heart disease on hormone therapy because healthier women tend to take these drugs. Women may also seem to have more breast cancer because middle and upper class women, a group at higher risk for breast cancer, tend to take these drugs.

At the heart of this dilemma is a broader question raised by Dr. Hemminki: "Is it good public policy to prevent one disease with a method causing another?" Not only are randomized controlled trials needed on the health effects of postmenopausal therapy, doctors and women need to be aware of the insufficiency of the current evidence and the commercial interests behind how it is often presented.

What was the commercial incentive for pharmaceutical firms to produce and heavily promote menopausal hormone therapies? The success of the contraceptive pill in the 1960s, as Dr. Graham Dukes from Oslo

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MENOPAUSAL *from page 6...* pointed out in a final paper to the symposium, "had demonstrated the commercial attractiveness of developing products for an essentially healthy population." Small firms specializing in hormones grew enormously in size within a few years and it soon became apparent that in order to maintain their competitive advantage new products were needed. "It was not very long before the choice fell upon the menopausal woman," noted Dukes. Although in the early 1970s specialized peer-reviewed journals carried a balance of papers by investigators in favor or against menopausal treatments, one side of this information was vigorously propagated whereas the other was not: "The pro-estrogen papers found their way, emphatically and repeatedly, into the secondary literature. They were propagated through reprints. They were echoed at hundreds of meetings...."

The symposium was reminded of the issue of *Time* magazine for June 26, 1995, which carried a cover story with the headline: "Menopause is unnecessary. Thanks to hormone therapy (women) may look forward to prolonged well-being and extended youth." As in the glowing vibrant women portrayed in 1990s advertisements for hormones, the underside being presented–menopause without hormones–is one of poor health, misery, and decrepit old age.

As van Hall pointed out, individual menopausal and postmenopausal women are no more potentially ill than members of any other population group of a specific age and gender. This symposium was one step towards relegating this medical and commercial myth to the wastebasket of time. Let us hope that it is followed by many more independent assessments of both the social and medical consequences of long-term preventative drug treatment of menopausal women.

Editor's note: The full conference proceedings are in the Journal of Psychosomatic Obstetrics and Gynecology *1997, vol. 18, issue 2. Our report was condensed from an article appearing in the* International Journal of Risk and Safety in Medicine.

Research on Eye Problems

Over the years since 1991, we have had letters to the editor about eye problems. Now we have been contacted by an eye specialist who theorizes that alterations in maternal estrogen may affect eye development in the fetus. Philip Lempert M.D. has written us as follows:

"I have been working on the physical status of eyes in people with amblyopia (lazy eye). The conventional thinking about amblyopia is that it is a developmental aberration that occurs in people whose eyes cross (esotropia) or have a difference in the focusing power of the two eyes (anisometropia). It is assumed that the brain develops in response to stimulation and that if the brain is presented with dissimilar images that the part of the brain dealing with one of those images does not develop properly."

The data I have accumulated clearly demonstrates that people with amblyopia actually have:

1. eyes that are shorter than normal;
2. the eye with poorer vision is shorter than the fellow eye;
3. the opic nerves are smaller than in the normal population and have fewer nerve fibers;
4. forty percent of people with amblyopia have deformed optic nerves with abnormal entrance of blood vessels.

There is some indication that these findings might be related to alterations in maternal estrogen or other corticosteroid levels during either the first or third trimester. I am in the midst of setting up animal studies to explore the effects of these hormones on optic nerve and eye development.

It would be very interesting if optic nerve or ocular deformities were present in the population of people who were exposed to DES during fetal development. I was particularly interested in the reports of low tension glaucoma since that may be indicative of optic nerve damage. Although corneal erosions and contact lens intol-

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EYES PROBLEMS *from page 7...*
erance may be real problems for some individuals, they really don't fit within the spectrum of disorders I am interested in.

If this study is to be useful then it must be based on hard numeric data. I would appreciate it if I can be contacted by mail, fax or e-mail by any DES daughter or son:

- with amblyopia–poor vision in one eye that cannot be corrected with lenses;
- strabismus–inward or outward deviation of the eyes;
- optic nerve abnormalities–low tension glaucoma, colobomas, hypoplasia.

I will need accurate information from their opthalmologist or optometrist. The study requires hard data for validity. The minimum measurements needed are visual acuity, refractive error (strength of eyeglass lenses), age at the time of the examination, and a statement about ocular alignment (crossing, straight or turning out.) Other very important pieces of information, if they are available, are the axial length of the eyes, usually determined with ultrasonography, corneal curvatures (K readings) and photographs of the optic nerve. If photos are available then it would be very helpful to have the camera model and the field setting.

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we keep feeling a need to be extra careful with her. This is the way I see her. I also still have bouts of waking in a fearful state. DES has left its mark on both of us. It's a comfort to have the whole family gathered, especially to see how great Gemma is with her nieces and nephews. I don't know if Gemma would have had children, if she had been given the choice, but it hurts that she was deprived of that choice.

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