

## Educating DES Sons and Their Physicians

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

One of the doctors I spoke with when I was writing my book said he wasn't interested in DES because it was, in his words, "A self-limited women's problem."

Today, we know that the DES story is neither self-limited nor for women only. In fact, because of its effects on men, and after more than a decade of relative scientific neglect, DES is being rediscovered in the 1990s. A model for a much broader societal concern—the effects of environmental chemicals on male fertility.

The lead science story in the 23 August issue of the *New York Times* was titled "Pesticides May Leave Legacy of Hormonal Chaos." A local paper in my home city published a story this summer with the title, "Why Johnny Can't Breed." Two of the three major television networks in the United States have devoted

major efforts to covering the story of environmental chemicals and their effects on males. The BBC's production on the subject, titled "Assault on the Male", aired in the U.S. just a few weeks ago. All of these stories have featured DES.

Our best information about the consequences of DES exposure in men comes from a study done at the University of Chicago in the early 1950s by Dr. William Dieckmann. You may already be familiar with this study, the purpose of which was to find out if DES was effective as an anti-miscarriage drug. Although DES had already been in large-scale use for at least four years (from 1948, when it was widely promoted in the medical literature), no scientific evaluation of the drug's effectiveness to prevent miscarriages had ever been conducted.

The two Harvard scientists who originally promoted the use of DES during pregnancy, Drs. Olive and George Smith, had based their enthusiasm entirely on their theoretical expectations and on the subjective observations of 117 physicians who gave DES to a total of 632 women. There were no standardized criteria of care for these women nor was there, for comparison, a matched group of pregnant

women who did not receive DES.

Noting the shortcomings of the Smith study, Dr. Dieckmann designed a controlled, randomized, double-blind study, enrolling 2,000 pregnant women, half of whom were given DES and the other half of whom were given a placebo. Although it was not Dr. Dieckmann's intent to do so, he established a situation whereby it became possible to evaluate the effects of DES as the children of this study have grown to adulthood and at this time, as they enter middle age.

When these Dieckmann study children were about 25 years old, a urologist at the University of Chicago, Dr. William Gill, conducted a follow-up study of the sons. He was able to examine 308 DES sons and 301 young men whose mothers had been given the placebo. While much scientific attention was already being given to daughters as a result of the link with clear-cell cancer, no one had systematically looked at the sons.

What Dr. Gill found was that about 30% of the DES-exposed men had some kind of urogenital abnormality ranging from harmless and painless to malfunctioning or malformed. The DES-exposed men had a significantly higher incidence of cysts inside the

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**D**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, including careful visual inspection and pap smear from the vagina. 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 are at higher risk for undescended testicles, epididymal cysts, and may be at higher risk 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 hot-line: 1-800-DES-9288.

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# Award for Senator Tom Harkin

**S**enator Tom Harkin, sponsor of our DES legislation in the Senate, has been a long-time leader on health issues (he was the principal author of the Americans with Disabilities Act.) This year, he led the campaign in the Senate against the attempt to pass a product liability law that would greatly restrict consumer access to the courts for compensation for injuries. And he will be very active next year if this issue is again introduced. The Board of DES Action, represented by Pat Cody (left) and Amanda Sherman (right) are seen here representing him with a plaque with this inscription:



*DES Action USA*

*Presents Our Advocate of  
the Year Award to*

**Senator  
Tom Harkin**

*whose vision and  
commitment have brought  
hope to the ten million  
Americans exposed  
to DES  
September 1994*

## First French Law Suit

**A**fter more than two years of legal process, a decision in the first DES lawsuit in France was issued in September by the Tribunal de Grande Instance in Nanterre, the location for UCB, manufacturer of DES. Two DES cancer daughters, one 20 years old and the second one 26, are suing UCB.

The Tribunal has ordered that before proceeding to trial, four experts from the fields of gynecology, epidemiology, embryology and pharmacology be consulted

♥ To investigate the medical history of the two plaintiffs and their mothers

♥ To establish the state of medical knowledge about DES in 1967, before the birth of the two women.

This is an important case—France is only the third country, after the U.S. and the Netherlands, in which DES daughters have sued the manufacturers. The French plaintiffs said they hope their case will help make information about DES more widely available. DES was prescribed in France from 1948 to 1977, and it was the most frequently prescribed drug during pregnancy between 1963 and 1973.





## Notes From Nora:

## DES Researchers Meet at National Cancer Institute

The National Cancer Institute has revived and expanded DES research in several areas. The largest single research project is called "Continuation of Follow-up of DES-exposed Cohorts" which, as its name suggests, is a long-term study surveying DES mothers, daughters and sons. This study is the only effort to gather information on a broad range of DES health effects on all affected cohorts (groups). This new research effort, begun in 1993, came about as a direct result of pressure from DES-exposed people and specifically DES legislation passed by Congress in 1992.

Board member Amanda Sherman had the opportunity to attend a meeting of investigators leading the five-site collaborative study on October 6. Here is a summary of the meeting.

The study involves the following numbers:

	Exposed	Unexposed (controls)	Total
DES Mothers	3410	2956	6366
DES Daughters	4240	1421	5661
DES Sons	1439	1335	2774

Participants in the study have been sent lengthy health questionnaires. Investigators responsible for compiling accurate lists of individuals and their medical conditions discussed various problems involved in locating people and, down the road, verifying their reports of their medical problems. In some cases, such as for cancers, investigators plan to compare reported problems with actual medical records and pathology reports/slides.

This will provide the most reliable evidence of medical conditions related to DES.

The current emphasis of this research project is to assemble a stable group of each affected cohort (mothers, daughters, and sons) and to collect as many completed questionnaires as possible. The next phase, yet to be funded, is the analysis of the data. National Cancer Institute officials do not expect funding for the analysis of the data to be a problem.

The collection of data is proceeding well and there remains strong support for DES research within the National Cancer Institute. Additionally, the 1994 Congress has directed the NCI to expand support for DES research and, in particular, to devote resources to investigating possible "third generation" DES effects.

We continue to be encouraged by the progress in this very important follow-up study. DES-exposed people and members of the scientific community are eager to learn as much as we can about the health effects resulting from DES exposure. In addition, the thousands of DES-exposed people who have been identified and are being studied provide a resource for future, more specific studies. Researchers can delve further into areas of concern such as auto-immune disease, infertility and pregnancy problems, and effects on men and on the "third generation."

Some preliminary data may be published before final results of the complete project are avail-

able. You can be certain that any news about DES research will be reported promptly in the Voice.



The Network News, newsletter of the excellent group National Women's Health Network (of which DES Action is a member) featured an article about Frances Oldham Kelsey in its Fall issue. Dr. Kelsey, now 80 years old, was honored by the FDA recently for her pivotal role in stopping the introduction of thalidomide to the United States. Here is an excerpt from the Network News article:

"In September, 1960, Frances Oldham Kelsey received an application for approval of thalidomide, a mild sedative that the manufacturer claimed was safe even for pregnant women. At that time, Dr. Kelsey, who had both an MD and a PhD in pharmacology, was a new medical officer with the FDA. Thalidomide was the first application for a new drug that she handled....

At that time, FDA regulations were much weaker than now, and many drugs received only the most cursory testing in animals. So-called "clinical experiments" in humans were often marketing tactics to make physicians familiar with new drugs. In this atmosphere, Dr. Kelsey's reluctance to approval thalidomide as a matter of routine infuriated the American manufacturer (Merrell Company). Over the next year and a half, Merrell contacted Kelsey dozens of times. At one point, Dr. Kelsey was even forced to consult an attorney when Merrell

# Personal Story

by Sandy Prantl, Cincinnati, Ohio

**A**s a DES daughter, I have experienced almost all of the commonly identified problems associated with DES exposure. The most painful one of late was infertility. After three years of trying and five or six early miscarriages, I was beginning to think that becoming a mother was an impossibility. Without belaboring the details, I am thrilled to announce that my husband and I now have a beautiful, term, healthy girl who was born 9/9/94 (Melissa Christine, 7 lb. 14 oz.!).

Once I had some structural problems repaired and still could not sustain a pregnancy, some research into 'alternative' medicine revealed that I was hypothyroid. I had suspected hypothyroidism for years, but every

*"There are many other signs and symptoms that indicate hypo-thyroidism, but MDs are trained to only look at the blood work."*

time I spoke to a doctor about it, my blood was drawn, the results came back low normal, and my concerns dismissed (never mind that I had felt like hell my whole life). There are many other signs and symptoms that indicate hypothyroidism, but MDs are trained to only look at the blood work.

If I understand it correctly, thyroid hormones affect all hormone balances in the body. If

there is insufficient thyroid hormone, then (at least in my case) there is insufficient progesterone. Consequently, even though I knew I was conceiving, the uterine lining was already breaking down before the implantation could occur, creating a miscarriage around six weeks.

The problem I had is described as subclinical hypothyroidism—which means that the dysfunction is not severe enough to be detected in the blood work. I'm sure that many infertile women have had their thyroid evaluated by standard measures and were told that they were fine.

I am treated by a chiropractor who supplies a nutritional supplement made from bovine thyroid. Standard Process labs make these products and they are available only through licensed practitioners (I'm sure that there are other, similar products available).

I'd like to take this opportunity to stress this. My ob/gyn did not think that I was hypothyroid (of course, all he looked at was blood work). He was aware that I was taking the nutritional supplement, but I am certain that he has no respect for the product.

In any case, I wish to pass on this information in hopes that someone else may benefit. My heart goes out to the families who have been trying so desperately to have a child, spending thousands of dollars and months of their lives, only to be fruitless in their attempts. The point being, all the wonderful technology in the world won't help if you don't have the proper endocrinological support within your own body.

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complained to her superiors that she had made statements that were "somewhat libelous."

However, Dr. Kelsey managed to withstand the pressure brought to bear on her and, eventually, the evidence bore out her concerns. By April, 1961, German pediatricians were reporting dozens of cases of children born with missing limbs. By November, it was clear that thalidomide was responsible and it was taken off the market in Germany and England and its application for approval in the U.S. was withdrawn.

The lasting impact of Dr. Kelsey's refusal to approve thalidomide was the strengthening of the Food, Drug, and

Cosmetics Act to require the more stringent tests of drugs before approval. In late 1962, Congress approved, by a unanimous vote, the Kefauver-Harris Amendments, which required that a new drug could not be approved by the FDA unless it was proven to be both safe and effective."

Unfortunately, drugs already on the market were not subjected to the new, more stringent set of tests to continue receiving FDA approval. However Congress did hold hearings on the efficacy of drugs already on the market. During those hearings, DES was reviewed and was determined to be only *possibly* efficacious, yet no action against the manufacturers of DES was taken.

**DES SONS** *from page 1...*

scrotal sacs, known as epididymal cysts; more cases of smaller than normal genitalia; and more cases of undescended testicles which are themselves a well-established risk factor for testicular cancer.

Upon analyzing semen samples from the DES-exposed men and comparing them to samples from the non-exposed men, Dr. Gill found that 40% of the DES sons had abnormal sperm compared to 14% of the non-exposed men. And 25% of DES sons had severely abnormal sperm compared to only 3% of non-exposed men.

In terms of testicular cancer, no direct link with pre-natal DES exposure has been demonstrated, although a number of inconclusive studies have been done and the suspicion remains that there might be a link. If DES-related cancer does occur in men and is as rare an occurrence as clear-cell adenocarcinoma is in DES daughters, then a definitive study would need to include several thousand men.

Prostate cancer is also a concern. However, an increased risk for prostate cancer is much more problematic to demonstrate than testicular cancer. Since the prostate gland arises from the same embryonic tissue as does the vagina, will DES sons have a higher incidence of prostate cancer as they grow older, when the incidence of prostate cancer in all men increases? We don't know. If there is an association, what we think might happen is that DES sons could develop more cases of prostate cancer and at an earlier age. And these cancers might be more aggressive than prostate cancer in non-DES-

exposed men.

Across the board, in the medical community as well as among the general public, there has been ignorance and frequently outright resistance to acknowledging that DES sons might be affected.

There are at least several reasons for this. First, although there are as many DES sons as there are daughters, only a very few studies have been done on sons. And those that have been done have not revealed anything as dramatic as the clear-cell adenocarcinoma found in daughters.

Second, the fewer the studies done on a problem, the less worthy of study many people believe the problem to be. So there is a kind of self-fulfilling prophecy effect. The less worthy of study a subject is thought to be, the less likely scientists are to study it, resulting in few in any effects found.

Further, far fewer sons than daughters seem to have DES-related problems. And finally, in contrast to dialogue about female reproductive problems, there is a societal reluctance to talk about any problems relating to male sexual organs. As one DES son put it, "In our society, the stigma attached to genital problems totally threatens the male identity. If a man is impotent or sterile, he is made to feel less of a man."

Traditionally, the medical establishment has been as vulnerable to this bias as the general public. Generally, it has been acceptable to talk about a woman being infertile, but it has not been okay to discuss a man's infertility. The likely scenario is that the woman in an apparently infertile couple is subjected to an extensive, expensive, and frequently

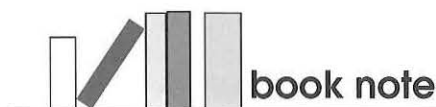
uncomfortable fertility examination before her husband is simply asked for a sperm sample. And when a man has been infertile, more often than not, the family leads people to believe that it is the woman who can't have a child.

During the first year of our national cooperative DES education grant the disparity between knowledge and beliefs concerning DES sons in contrast with DES daughters became apparent almost immediately. Our first national task was to establish medical screening recommendations for DES mothers, daughters and sons. While the committees dealing with daughters' and mothers' health issues had clearly defined information and issues of concern, the only information our sons' committee could present was the findings of the Gill studies. It soon became clear that our education effort about DES sons had to begin with the recruitment of a few key urologists since there wasn't a single practicing urologist involved with DES research.

We accomplished this by making personal presentations to two nationally prominent urologists. We also recruited several other experts, including a prominent animal researcher, two DES sons, a representative of the National Cancer Institute, and a physician consultant who is an expert in physician education. We have drafted provisional medical screening recommendations for DES sons in relation to concerns on fertility, testicular cancer, and prostate cancer. Once the National Cancer Institute and our fellow investigators and consultants accept these guide-

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**K**aren Hicks, *Surviving the Dalkon Shield IUD, Women v. the Pharmaceutical Industry*. Teachers College Press, New York, \$17.95.

Twenty years have passed since the major revelation that the Dalkon Shield IUD, used by over 2 million women in the U.S. between 1970 and 1974, was responsible for infection, permanent infertility, and in some cases death. It is eight years since over 300,000 claims were filed against the manufacturer in a class action suit, and five years since the allocation of \$2.38 billion to the Dalkon Shield Claimants Trust.

Karen Hicks, a Dalkon Shield recipient and founder of the Dalkon Shield Information Network (DSIN), tells the story of the struggle to get corporate responsibility for corporate malfeasance. Members of DES Action will find many similarities to our story:

"Our use of the term *survivor* was also a conscious attempt to

create the sense of activism and power necessary to effect change. DSIN leaders using the term *survivor* met with philosophical challenge from other groups and DSIN allies, who insisted that the term *victim* would garner more sympathy and support for the cause. Many DSIN members, however, expressed gratitude at the use of the term *survivor* as a more positive term that imparted a sense of personal power."

Hicks' comments on the medical world, and on our need to look after ourselves, also sound a familiar note:

"Physicians and the health care system, in general, have not supported the resolution of this social injustice to women.... Some women reported that their doctors would not even cooperate with their attempts to gather their medical records. Several factors compounded this situation. First, the original injuries had happened so long ago that records were now missing, incomplete, or purged....

"An analysis of the range of problems associated with acquir-

ing medical documentation would be a valuable contribution to the literature on the magnitude of medical abuse of women.... People should amass their own personal medical histories *at the time* they receive any form of medical attention, and they should keep a complete file of all their medical records in their own safekeeping. I also believe people should keep records of every pharmaceutical medication they ever consumed. Reconstructing medical histories many years after treatment is virtually impossible. The current system clearly benefits doctors over patients. In many instances, our health care system deliberately refuses people the right to their medical records. The lack of medical records was the chief reason so many Dalkon Shield claims were disqualified by the court and the Trust."

Hicks concludes with guidelines for strategies any grassroots group can use in organizing to inform, educate and empower others within their community.



## Join DES Action!



**Yes** - I want to get the answers about DES. Enclosed is my membership.

- ☐ Benefactor: \$1000 and above    ☐ Supporter: \$100  
☐ Sustainer: \$500    ☐ Friend: \$75  
☐ Associate: \$200    ☐ Subscriber: \$60-\$30 (sliding scale)  
☐ Low income: \$10

All members receive **The DES Action Voice** quarterly. Those at the \$100 level and above receive additional annual reports on DES Action's work and progress.

- ☐ I am enclosing my annual payment of \$ \_\_\_\_\_.  
☐ I would like to donate through the **Pledge Program** with ☐ quarterly or ☐ semi-annual payments totalling \$ \_\_\_\_\_.  
☐ Check enclosed (please make payable to: **DES Action**).

I am a: ☐ DES Daughter    ☐ DES Son    ☐ DES Mother of a ☐ Daughter ☐ Son    ☐ Other

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## letters to the editor

*(Editor's Note: These letters show the importance of learning early whether or not your doctor is knowledgeable about DES.)*

Dear Editor:

I am so glad DES Action exists! I should have been this happy about it all along, of course, but am all the more appreciative now that I have had an experience with cancer—I had a radical hysterectomy last March for adenocarcinoma of the cervix. I was not sure I was being taken seriously by my gynecologist, and so took a name from your doctor list, who came up with the diagnosis very quickly, even though I had been being seen every six months by my previous

doctor for some years! Your list was truly vital to me. I seem to be recovering well now and am back to work and to life in general.


Reader,  
Richmond, California

*Another letter from a reader in New Jersey thanking us for our physician referral told us,*

"Even though my son was born eight weeks early with an emergency C-section, my doctor said it was "God's will" and not because I was a DES daughter. When I got pregnant neither he nor his partner recommended bed rest, cervical cerclage, or any special treatment until I was 27 weeks. I never knew to ask DES questions. I trusted him when he said nothing special had to be done."

**DES SONS** *continued from pg 5...* lines we will be ready to launch our official physician education effort. Our two urologist consultants, leaders in their medical specialties, will then be in position to educate other urologists and then primary care physicians about DES sons.

In addition, just a few weeks ago I was invited to write a chapter on DES sons for a new medical textbook on male infertility. This will be the first time ever that a medical textbook will devote an entire chapter to the effects of DES on sons. Yet another step in the legitimization of the subject!

Progress is almost always made in small unglamorous steps. This past year for DES sons has been a series of small steps forward. 

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