DES Action VOICE

Inside

A Focus On Diethylstilbestrol

WINTER 2011 #127

No Link Found Between DES and Autoimmune Disorders

With The Exception of Rheumatoid Arthritis

"Autoimmune Disease Incidence Among Women Prenatally Exposed to Diethylstilbestrol," William C. Strohsnitter, et al., *The Journal of Rheumatology*, 37(10), October 2010.

Reviewed by Kari Christianson and Fran Howell

Despite the generally held belief that DES exposure causes an increased risk for autoimmune disorders, a new study failed to prove that.

DES research on mice is usually a good predictor of what will happen in humans. So, when DES-exposed animals showed an increase in autoimmune problems caused by altered immune system development and function, it was suspected DES Daughters and DES Sons would, too. But researchers have been exploring that possibility for years and keep coming up nearly empty-handed.

In this latest effort, William Strohsnitter, D.Sc., of Tufts Medical Center, and the team of researchers from the National Cancer Institute (NCI) DES Follow-up Study examined data gathered from study participants. What they found, he says, is that overall, the "data provide little support for an association between prenatal DES exposure and development of autoimmune disease."

The only exception is an increased incidence of rheumatoid arthritis (RA) in DES Daughters under 45 years of age. Strohsnitter is trying to understand this positive association between prenatal DES exposure and RA development in younger women.

Strohsnitter suggests that possibly some participants mistakenly reported that they were diagnosed with RA. He says, "Historically, verification of autoimmune disease has been difficult." While some records were obtained for verification of a RA diagnosis, the review also relied on participants' self-reports.

As DES Action members have reported, for many individuals, the process of diagnosing an autoimmune disease is long and complicated — and sometimes frustrating. Younger women may have reported an RA diagnosis only to learn a few years later their initial diagnosis was in error.

Interestingly, for women over 45, the DES- exposed had a lower RA rate compared with unexposed women. Strohsnitter was surprised by that and says, "Possibly, DES-exposed women develop the disease earlier in their lifetime than unexposed women."

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Recognizing An Important Anniversary

Forty Years Ago Doctors Linked DES To Cancer

By Fran Howell

For many of us in the DES community April 1971 holds significance. The healthy babies that mothers so dearly wanted, in some cases, had turned out not to be so healthy after all.

Why anyone would be surprised is a mystery. Pat Cody, in her book *DES Voices: From Anger to Action* wrote, "Researchers in the 1930s injected estrogen into a variety of animals: cats, capon, guinea pigs, monkeys, rabbits, and especially what came to be the favored mammals, mice and rats. They reported reproductive tract malformations and cancer."

It was cancer that made the world sit up and take notice. According to Cynthia Laitman Orenberg in *DES: The Complete Story*, there were seven patients seen at Massachusetts General Hospital between 1966 and 1969 with a rare form of vaginal cancer known as clear-cell adenocarcinoma. Previously this cancer was seen only in older women, yet here it was being diagnosed in young women between the ages of 14 and 24 years old. "Dr. Howard Ulfelder and fellow obstetrician Dr. Arthur Herbst… began searching for a common denominator, in the process ruling out such factors as

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Join OnLine Support Group for DES Daughters

Want to be in touch, via e-mail, with other DES Daughters? As a benefit of being a DES Action member you can join the DES Action Daughters On Line Support Group. That way you can ask questions and share experiences common only to those of us who are DES exposed.

To join the DES Action On Line Support Group simply send a blank e-mail to: DESactionDaughters-subscribe@yahoogroups.com

You'll receive an e-mail back from Yahoo! Groups confirming your request to join. It offers two registration options and the easiest is Option 2. Click "Reply" so the note is sent back.

Once we've checked to be sure you are a current DES Action member, you'll receive a welcome to the group letter explaining how to send messages. Then you can participate in the e-mail conversations, or just quietly read and enjoy the learning experience.

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MISSION STATEMENT

The mission of DES Action USA is to identify, educate, support and advocate for DES-exposed individuals as well as educate health care professionals.

DES Action VOICE

Published quarterly by:

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P.O. Box 7296
Jupiter, FL 33468
ISSN 1522-0389
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No Link Found *from page 1*

A DES complication may actually lower the risk for rheumatoid arthritis for some DES Daughters. According to Strohsnitter, the incidence of RA is greater after childbirth. But because infertility is linked to DES exposure, those DES Daughters who do not give birth may be at reduced risk for developing RA.

On the other hand, Strohsnitter wonders whether the increase in RA diagnosis immediately after childbirth, "might be more pronounced among DES-exposed women." He raises that possibility to potentially explain the higher rate of RA among DES Daughters younger than 45. There were, however, too few cases in this age group to explore this speculation further.

This study used DES Follow-up Study questionnaire responses from 1994, 1997, and 2001. But these surveys did not gather information on such things as occupational exposures, breast-feeding history, and nutrition. So those factors, which are known to affect RA, could not be evaluated. However, since this information is missing from both the DES- exposed and the unexposed study participants, Strohsnitter is not overly concerned, "There is no reason to suspect that these factors are differentially distributed between the two exposure groups."

Researchers with the DES Follow-up Study have been investigating many health outcomes for individuals exposed to DES, and a report on DES exposure and autoimmune diseases was released in 1988. At that time DES Daughters reported a number of autoimmune diseases, e.g., Graves' disease, Hashimoto's disease, pernicious anemia, lupus, and optic neuritis. In this new study none of those autoimmune diseases was found to be more prevalent in DES-exposed women.

Questions and anecdotal reports about prenatal DES exposure and an increased incidence of autoimmune diseases have been circulating for years. This research study may not put those questions to rest, but it does provide an interesting look into how DES could be linked to at least one of them, rheumatoid arthritis.

Because DES Daughters are now aging into the period when RA is more commonly diagnosed, Strohsnitter stresses the need for further examination of this issue. Questions about RA and other autoimmune disorders will be included on the next NCI DES Follow-up Study survey.

Results from this study will undoubtedly be disconcerting for many DES-exposed individuals who believe their autoimmune problems are a direct result of DES. There is much we don't know. Perhaps DES in combination with other endocrine disruptors in our environment does increase the risk. Or perhaps this study was not large enough to give a broader picture of diseases other than RA. Given what we know about how DES alters the immune system in mice, this vexing issue will come under continued research scrutiny. DES VOICE

An Important Anniversary *from page 1*

vaginal douches, medications taken by the patients, and sex habits. It finally remained for the mother of one of the patients to suggest the DES she had taken during pregnancy as the possible culprit. She was chillingly correct."

Once DES harm was identified 40 years ago, we landed in a group no one wanted to be in. The world became a different place.

Fear spread quickly with the message handled in various ways. Hushed conversations were conducted around dining tables and in bedrooms, as families considered how to respond. Some DES Mothers acted out of (unfounded) guilt and hid information from their children. Others blurted out the horrible story. My parents called me at college and I'd never heard them so upset. They, like many, thought all DES Daughters would get cancer and die. Around the country groups of concerned individuals shook off their fears and paralysis to confront the government and doctors for help.

Unfortunately, for the most part, the medical community responded badly. Here is Cody's assessment: "When the reports started to emerge about the effects of DES exposure, too many physicians compounded the injury they had done in prescribing it by denying that they had done so, by dismissing concern as 'hysteria,' and even by destroying their records."

When DES Daughters went looking for medical care starting in 1971, most of their doctors told them DES was not a problem. (Sounds familiar even today). DES Action USA Program Director Kari Christianson tells of calling doctors, hospitals and clinics in Kansas City looking for someone, anyone, who could properly treat her as a DES Daughter. Eventually she ended up traveling all the way to the Mayo Clinic in Minnesota, where luckily they were taking DES concerns seriously.

The DES story may be 40 years old, but it is **not** an old story. Laitman perhaps says it best. "In spite of the fact that we have been made tragically aware that *any* drug a pregnant woman takes can potentially harm her unborn child, many physicians, as well as many patients, are still seduced by the prepackaged, pre-measured, sterilized, laboratory-tested promises of pills and injections purporting to alleviate pregnancy problems."

Editor's note: In the next issue of the VOICE we will have an interview with Dr. Arthur Herbst, a doctor who always took DES and DES-exposed individuals seriously, about his decades-long work and research into the health effects of DES exposure. Dr. Herbst is a Principal Investigator with the NCI DES Follow-up Study and Director of the DES Cancer Registry. DES VOICE

The DES Experience: Unfortunately Lessons Go Unlearned

By Barbara Mintzes, Ph.D., DES Action Canada and Associate Professor at the University of British Columbia

This is from a paper presented at the Reseau D.E.S. France Congress on Nov. 19, 2010, in Paris. Her presentation was so fascinating that we look forward to sharing additional segments of it in upcoming VOICE issues.

There are several ways in which DES is far from a tragedy of the past: it continues to affect the health of the women who were exposed in pregnancy, and the women and men who were exposed in utero — with possible effects extending into subsequent generations.

As this conference highlights, continuing research is needed on the health effects of DES as the exposed population ages. This research is important both for the health and appropriate medical care of people who are exposed to DES, and for what it can tell us about the effects of other estrogen exposures. It also serves as a more general warning for a precautionary approach to the use of medicines, especially but not only in pregnancy, and to the use of endocrine disrupters in the environment.

DES is also a story of successful consumer activism, especially by mothers and daughters, and a cautionary tale about the need to respect the rights of those who have been harmed by a marketed product.

In many countries, health authorities took the decision "not to alarm the public." This had important health and human rights consequences. The DES Action movement has played a crucial role in reversing this situation, in providing support and information to those who are exposed, working with physicians to ensure access to appropriate medical follow-up and care.

DES Action groups have also played a broader role: assistance with legal action, advocacy for research funding and work with researchers to ensure that the questions of importance to those who are DES-exposed are investigated, international support to ensure that new DES Action groups in another country have access to existing resources and expertise, and broader advocacy for consumer rights in pharmaceutical policy.

The DES regulatory history includes the U.S. FDA decision to allow use of the drug in humans despite animal evidence of harm. After approval for use in pregnancy, there were no regulatory actions taken to effectively limit use.

When regulatory agencies were given the power to require evidence of effectiveness of medicines in the early 1960's throughout the industrialized world, DES was 'grandfathered' in along with other medicines that were already on the market. There was no reassessment of whether DES met requirements for randomized controlled trial evidence of efficacy versus placebo. No attempt was made to prevent promotional messages from reaching doctors that highlighted poorer quality evidence. DES also continued to be prescribed in pregnancy in several European countries until the mid to late 1970's, despite the evidence of carcinogenicity since 1971.

The lessons of DES continue to have resonance today both in terms of the role of regulation of pharmaceuticals in protecting public health, and the need for caution with medicine use in pregnancy.

When researchers, doctors, lawyers and DES-exposed individuals gathered in Paris last November, they looked back on lessons learned - and forward toward issues facing the DES community.

Reseau D.E.S. France organized the D.E.S. Congress: 3 Generations: Realities — Prospects.

The event was dedicated in memory of DES Action USA Co-founder Pat Cody. Like Pat, Reseau D.E.S. France President Anne Levadou is a DES Mother who would not take "no" for an answer when French authorities downplayed the significance of DES exposure.

Barbara Mintzes, from DES Action Canada, discussed the international DES experience as to how countries grappled with DES within their borders, or didn't. Read an excerpt of her fascinating presentation on page 4.

Attendees learned of current research results into DES health concerns, they discussed legal matters and even took up the topic of mandating specific DES maternity leave. DES was prescribed in France well into the late 1970s, so a large number of DES Daughters are in their reproductive years and experiencing pregnancy problems.

DES shows the importance of solid evidence of efficacy of medicines as a criterion for approval. Without a known benefit, any potential for harm is not worth risking. As we know from DES, harmful effects may be devastating and may not be known for many years. Have we learned this lesson when it comes to use of medicines in pregnancy?

In North America, 5 to 10% of pregnant women are exposed to antidepressants during pregnancy, despite the existence of non-drug alternatives to treat depression with equivalent effectiveness. With SSRI use in pregnancy, there is evidence of higher rates of spontaneous abortion and cardiac malformations with first trimester exposure, and persistent pulmonary hypertension of the newborn, and a neonatal syndrome with late pregnancy exposures. This rate of exposure is very similar to the highest rates of DES exposure in the US in the 1950's.

In France, a study of medicine use in pregnancy in 1996 found that 59% of women were exposed to medicines that are generally not recommended in pregnancy, unless no alternatives exist, because of human evidence of fetal risk. These included for example high doses of non-steroidal anti-inflammatory drugs in the third trimester and use of benzodiazepines for sleep and anxiety. In both cases, less risky alternatives exist. There will always be some exposure to risky medicines in pregnancy, as some women face serious conditions that need treatment, and less risky alternatives are unavailable. However, many women continue to be exposed to unnecessarily risky treatments.

How can the experience with DES inform the future of drug regulation, and what can we jointly do to ensure that history is not repeated? Current approaches to the regulation of medicines and to the oversight of pharmaceutical promotion are in many ways inadequate. Solid research evidence of an increased risk of heart attack and stroke with rofecoxib (Vioxx) existed one year into the drug's five years on the market, yet neither information on these risks nor the drug's lack of efficacy advantages effectively reached the physicians who prescribed rofecoxib.

Evidence released in recent court cases documents widespread use of 'key opinion leaders' and 'ghostwritten' articles in the medical literature to sell medicines for unapproved uses, and to dispute evidence of harm.

The growth of direct-to-consumer advertising of prescription medicines in the U.S. and New Zealand — and of disguised 'disease-oriented' advertising elsewhere — has expanded markets, in some cases well beyond health needs. Although the advertisements that recommended use of DES for routine prophylaxis of all pregnancies were aimed at physicians, the parallel is hard to miss.

The experience with DES is a potent reminder of the need for caution when medicines are approved for sale, promoted and used.

It is a reminder that animal studies can be predictive of harm in humans, and of the need for rigorous regulatory standards for effectiveness and safety both before and after a drug is approved for marketing. The DES experience is a reminder that if harm occurs, industry, governments and the medical profession have a responsibility to those who are injured. And finally, it is a reminder of the power of consumer activism. DES VOICE

FDA Concedes DES Is A Tragedy

Does Not Apologize

DES Daughter Caitlin McCarthy, author of the screenplay WONDER DRUG (*Voice* issues 115 and 124), asked her Senators to request an apology from the FDA. In a Feb. 22, 2011 letter to Senators John Kerry and Scott Brown the FDA states that, "The adverse effects on pregnant women and their children caused by the use of DES are a tragedy."

The letter goes on to say, "FDA is charged by Congress with the responsibility of ensuring that drugs on the U.S. market are both safe and effective. Unfortunately, all drug products pose risks as well as benefits, and, even today, all the risks of a drug may not be known at the time of approval."

According to the FDA letter the agency now has "many more tools for identifying, monitoring, and mitigating drug risks than it did 70 years ago when DES was approved." The MedWatch program, created in 1993, encourages voluntary reports from consumers and health professionals. "We carefully evaluate and analyze all reports that are available to us and make recommendations for possible actions, if the science-based evaluation warrants the actions," says the letter.

The FDA is also developing "methods to obtain access to disparate data sources and to establish a post-market risk identification and analysis system to link and analyze health care data from multiple sources." The Sentinel Initiative is described as a "long term national, integrated, electronic system for monitoring the safety of FDA-approved drugs and other medical products… and is a "significant step forward from our current, primarily passive safety surveillance systems."

The FDA letter says it hopes the Agency's "newer tools for identifying, monitoring and mitigating drug risks will prevent other tragedies like those brought about by the widespread use of DES. We are committed to providing the public with timely and accurate drug safety information and we recognize the critical responsibility that FDA has to protect the safety of the public's health."

Of note is that this FDA acknowledgement has not affected the policy for approval of at least one drug for use during pregnancy. (See our story about Makena on page 7). DES VOICE

Bioidentical Hormones: A Caution

PUBLICCITIZEN Your expert, independent second opinion for prescription drug information

Worst Pills, Best Pills

This is going to be controversial. As well it should be, because there are no easy answers. We get frequent questions about the safety of bioidentical (sometimes called natural) hormones. Some of our members swear by them. But we here at DES Action USA have a nagging concern about them - if for no other reason than our bodies treat them as another estrogen, whether natural or synthetic. The use of bioidentical drugs is a very personal decision that should be made with all the facts, and in consultation with your health care provider.

This article, from the September 2010 newsletter, ***Worst Pills Best Pills****, is reprinted with permission from* ***Public Citizen****.*

It is now widely accepted that prescription estrogens such as conjugated estrogens (PREMARIN) and conjugated estrogens with medroxyprogesterone (PREEMPHASE, PREMPRO) cause breast cancer, heart disease and many other serious health problems.

Therefore, exploitative dietary supplement makers — often compounding pharmacists not regulated by the Food and Drug Administration (FDA) — have introduced and heavily marketed so-called bioidentical, "natural" hormone preparations that contain plant-based estrogens derived from soy or yams. These supplement makers attempt to fool the public into thinking these hormones are better and safer than prescription estrogens.

None of these supplements have been approved by the FDA, and according to the widely respected journal *Medical Letter on Drugs and Therapeutics*, these products are "chemically modified to be structurally identical to endogenous [naturally occurring] hormones. Most FDA-approved single-entity hormones are also [natural] derivatives of soy or plants extracts and are structurally identical to hormones produced by the ovary."

According to the May 31, 2010 issue of *Medical Letter*, "The FDA has reported sub-potency, super-potency and contamination of pharmacy-compounded drugs. In one 2006 survey, their potency ranged from 67.5 percent to 268.4 percent of the amount specified on the labeling, and both sub- and super-potent active ingredients were found within the same sample."

It goes on to say that: Bioidentical products that contain progesterone, testosterone and estrogen can be expected to have the same adverse effects that conventional preparations have. Most bioidentical hormone preparations contain estriol. … No drug product containing estriol has been approved by the FDA and the safety and effectiveness of supplemental estriol is unclear. Endometrial cancer associated with bioidentical hormone therapy has been reported.

The appropriately strong conclusion of this matter is that "there is no acceptable evidence that 'bioidentical' hormones are safe or effective. Patients should be discouraged from taking them." We (Public Citizen) strongly agree.

What You Can Do

Aside from avoiding bioidentical hormones for reasons stated above, even FDA-approved prescription estrogens should be used at the lowest effective dose and for the shortest duration consistent with treatment goals. This is because these products increase the risk of breast cancer, cardiovascular disease and dementia.

There is no question that an epidemic of breast cancer in women, now abating somewhat, was caused by several decades of massive use of estrogen-containing products (that has now decreased significantly). DES VOICE

FDA Approves Synthetic Hormone To Prevent Premature Births

DES Action USA Raises Concerns

By Fran Howell

Many of us were left wondering, "How could they?" when the FDA, in February 2011, approved the drug Makena for use by pregnant women. DES Action USA contacted FDA Commissioner Margaret Hamburg asking her agency to reconsider.

Makena, an old drug (previously known as Delalutin and then Gestiva) was technically approved under the priority accelerated approval process. But it still took FDA regulators five years and requests for additional studies before giving their authorization. Even that comes with a stipulation for post-approval clinical trials. Clearly, safety questions remain.

The DES-exposed are the poster population for prenatal drug exposures and epigenetic health and reproductive consequences of fetal exposures to hormones. Makena is a progestin product, rather than a non-steroidal estrogen like DES, but we are not convinced of its long-term safety for pregnant women and their children. If we are right, the next big drug tragedy could be brewing.

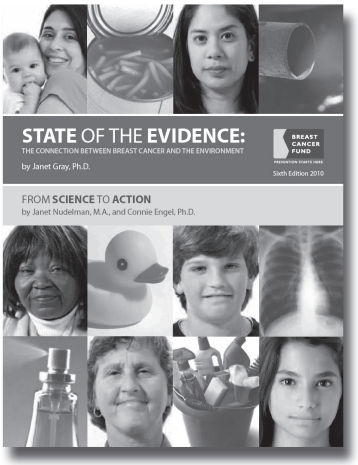
The FDA was wrong in approving DES for use in pregnancy and for letting it stay on the market long past the time when published studies showed it did not work. We asked Commissioner Hamburg to stop Makena's use until further valid and convincing research proves not only its effectiveness, but also its safety.

Barring that, DES Action USA wants the FDA to put explicit warning labels on Makena packaging, so pregnant women can make informed choices when weighing the risks versus benefits of prenatal exposure to a synthetic hormone. DES VOICE

Breast Cancer And The Environment—2010 Update

The Latest On How To Protect Ourselves From Additional Exposures

Reviewed by Kari Christianson



State of the Evidence: The Connection Between Breast Cancer and the Environment, Sixth edition 2010, by Janet Gray, Ph.D., includes an all-new advocacy section, From Science to Action, by Janet Nudelman, M.A., and Connie Engel, Ph.D.

The 2010 edition of *State of the Evidence* by the Breast Cancer Fund is now available. This edition, just as each previous one, presents information about the link between exposure to DES and breast cancer. The report also has a complete bibliography listing many human and animal research studies about breast cancer and DES.

Information about DES exposure and other estrogenic products appears in a section about hormones in pharmaceutical and personal care products. It states, "the clearest evidence that a synthetic hormone can increase risk for cancer decades later comes from the tragic experience with the pharmaceutical drug diethylstilbestrol (DES). Women who were exposed to DES during their pregnancies and their daughters who were exposed prenatally have increased rates of breast cancer."

The Breast Cancer Fund states that they "use *State of the Evidence* as a roadmap that shapes our public education and policy work. You and your family can use the report as a guide for making practical, everyday changes that can reduce your chemical exposures."

This thorough report gives timely information about the links between all kinds of exposures and the development of breast cancer. For everyone, including those of us who have been exposed to DES, it offers important suggestions about how to reduce exposures to other chemicals to prevent additional harm to our health. And, as consumers, we must demand that the products we use every day — cleaning products, cosmetics, paint, pesticides, clothing, paper — have been tested and are known to be safe for humans and the environment.

State of the Evidence is a "must read" for everyone concerned about human health, cleaning up the environment, stopping pharmaceutical disasters and preventing additional harm to humans and our environment.

Go to www.breastcancerfund.org for a free download of the *2010 State of the Evidence* or to order a printed copy.

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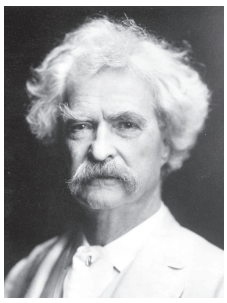
From the interesting website: "Letters of Note." http://www.lettersofnote.com/2010/01/youre-idiot-of-33rd-degree.html



In November 1905, an enraged Mark Twain sent this letter to J. H. Todd, a patent medicine salesman who had attempted to sell bogus medicine by way of a letter and leaflet. According to the literature Twain received, the 'medicine' in question — The Elixir of Life — could cure such ailments as meningitis (which had killed Twain's daughter) and diphtheria (which had killed his 19-month-old son). Twain, himself of ill health at the time and very recently widowed, was understandably furious.

Dear Sir,

Your letter is an insoluble puzzle to me. The handwriting is good and exhibits considerable character, and there are even traces of intelligence in what you say, yet the letter and the accompanying advertisements profess to be the work of the same hand. The person who wrote the advertisements is without doubt the most ignorant person now alive on the planet; also without doubt he is an idiot, an idiot of the 33rd degree, and scion of an ancestral procession of idiots stretching back to the Missing Link. It puzzles me to make out how the same hand could have constructed your letter and your advertisements. Puzzles fret me, puzzles annoy me, puzzles exasperate me; and always, for a moment, they arouse in me an unkind state of mind toward the person who has puzzled me. A few moments from now my resentment will have faded and passed and I shall probably even be praying for you; but while there is yet time I hasten to wish that you may take a dose of your own poison by mistake, and enter swiftly into the damnation which you and all other patent medicine assassins have so remorselessly earned and do so richly deserve.

Adieu, adieu, adieu!
Mark Twain