DES Action VOICE

Inside

A Focus On Diethylstilbestrol

WINTER 2013 #135

DES Breast Cancer Case Ends Well

But Settlement Leaves Some Wishing For More

By Fran Howell

Eli Lilly and Company's settlement offer to the four Melnick sisters who'd filed suit in Boston Federal Court put a sudden end to the first DES Breast Cancer trial. It came abruptly on day two of proceedings and you could almost hear a sigh of relief from the DES community when the agreement was announced.

> "This is a victory for DES Daughters. Sadly, Eli Lilly did not have to admit fault but in our society a settlement is as much an admission of guilt as anything else."

Strings attached stipulate that the DES Daughters who accepted the settlement cannot disclose the amount, and Eli Lilly does not have to admit guilt for making and promoting DES as an anti-miscarriage drug that causes breast cancer. It's that last stipulation that draws the ire of many, even though standard in such settlements.

While unsatisfying to many, the agreement was more than a year in the making. After 53 DES Daughters filed their breast cancer lawsuits, the attorneys for 14 drug makers tried to squelch them by calling for a Daubert Hearing. At stake was whether the cases could even go to trial. The drug makers claimed scientific evidence linking DES to breast cancer was flawed. But Attorney Aaron Levine vigorously disputed that by presenting experts who showed their evidence connecting DES to breast cancer is scientifically rigorous enough to withstand courtroom scrutiny.

U.S. Magistrate Judge Marianne Bowler ruled for the DES Daughters after the hearing and ordered drug company lawyers, including those representing Lilly, Merck and Bristol-Meyers Squibb, to negotiate settlements with the plaintiffs. Mediation talks took place in April 2012, but dollar amounts offered did not rise to the level of acceptability. When talks stalled, Judge Bowler set a trial date for early January 2013.

The litigation was filed as individual DES breast cancer cases that were bundled together, so it was not a class-action lawsuit. The first to go before a jury was the case filed by four DES Daughter sisters who all developed breast cancer in their forties. Attorney Levine felt it best to zero in specifically on Eli Lilly, so other drug makers were not included when this first DES breast cancer product liability case went to trial.

During opening arguments, Levine told the jury that Lilly failed to test DES's effect on fetuses before promoting it to prevent miscarriage. He also pointed out that the Melnick sister's mother was not prescribed DES while pregnant with a fifth sister, who has remained breast cancer free. "What are the odds of that happening in nature, if DES wasn't the culprit?" Levine asked. He told jurors that Lilly urged doctors to prescribe DES without proof that it was safe.

Attorney James Dillon, representing Eli Lilly, acknowledged that it is "terribly unfair" the four sisters got breast cancer but pointed out that its a common disease and doctors still don't understand what causes it. He then conceded that it "wouldn't be unreasonable" for the jury to be sympathetic to the sisters, so he asked that they keep an "open mind to the facts."

But jurors didn't get the chance to deliberate because Lilly came through

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DES Action USA Has Been Empowering the DES Community for 35 Years. *So we thought you'd enjoy seeing some of the items that have helped us define ourselves over time. Because our members are the most loyal that any nonprofit could hope to have, we suspect many of you will remember these—and may even have some of them tucked away at home as treasures!*

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DES Action USA
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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 Online 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 Online 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.

Have You Considered Planned Giving?

Think about including DES Action USA in your estate planning, trusts and wills. Speak with your estate planning attorney to ensure your wishes are correctly put in place.

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Contacts

United States

DES Action USA Headquarters
P.O. Box 7296
Jupiter, FL 33468
info@desaction.org
www.desaction.org
800-337-9288

DES Action Related Organizations

Australia
DES Action Australia, Inc.
PO Box 282
Camberwell 3124 Vic. Australia
info@desaction.org.au
www.desaction.org.au

DES Action Australia - NSW
14 Edmundson Close
Thornleigh NSW, 2120
Australia
C_devine@bigpond.net.au
www.desnsw.blogspot.com

France
Reseau DES France
12 rue Martinon
40000 Mont de Marsan
France
reseaudesfrance@wanadoo.fr

The Netherlands
DES Centrum
Wilhilminapark 25
3581 NE Utrecht
The Netherlands
des@descentrum.nl
www.descentrum.nl

MISSION STATEMENT

The mission of DES Action USA is to identify, educate, empower and advocate for DES-exposed individuals.

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1- (800) DES-9288 (800) 337-9288
info@desaction.org
www.desaction.org

Executive Director
Fran Howell

Program Director
Kari Christianson

Board of Directors
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Linda Marks
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Jackie White

VOICE Design and Layout
Solunar Graphics, Columbus
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DES Breast Cancer Case

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with a settlement offer that suited the Melnick sisters, who then agreed to it. While the amount cannot be disclosed, it clearly was a higher number than Lilly was willing to discuss during last year's negotiations.

Why right then? Attorney Levine believes negative news media coverage of the trial was one reason. Another was that in his estimation the jury seemed inclined to rule in favor of the DES Daughters who'd suffered so much as a result of their DES-caused breast cancers. While Levine might have preferred to press on with the trial, his clients felt the settlement offer was significant enough to take, and he's happy for them. Levine is also pleased about the timing because the settlement didn't come until after opening arguments were presented. That allowed the DES Daughter's stories to be told and written into the court record.

Eli Lilly, for its part, couldn't even bring itself to use the words DES or breast cancer in its official comment after the trial. "While we continue to believe that Lilly's medication did not cause the conditions alleged in this lawsuit, we believe the settlement is in the best interest of the Company."

With one case now concluded there are still about 70 other DES breast cancer lawsuits already filed and waiting in the wings. Judge Bowler told Lilly to be ready to attend an Alternative Dispute Resolution Hearing, or mediation, on March 11, 2013.

Even though there was no actual guilty verdict against Eli Lilly, there is still a feeling of satisfaction in the DES community. Here's what DES Action USA told Los Angeles Times reporter Rosie Mestel, who used a portion of the quote in her story:

"This is a victory for DES Daughters. Sadly, Eli Lilly did not have to admit fault, but in our society a settlement is as much an admission of guilt as anything else. The trial was closely watched by those who were exposed to DES and the outcome provides a feeling of vindication, of holding the drug maker accountable for the harm that was caused." DES VOICE

Reaction To The Settlement Was Swift and Positive

This first DES Breast Cancer trial captured the attention of the DES community, which has followed it closely from the beginning. Without question the mood was upbeat when news got out. Here's a sampling of what was heard, and shared via social media after Eli Lilly suddenly settled:

- Congrats to the Plaintiffs and to Aaron Levine! Lilly so rarely even offers to settle—they must have been concerned about losing the case. All the press must have helped too.
- Way to Go!
- Hooray!! Victory for the Sisters, which equates to another victory for all of us.
- In the DES community we have a sense of pride in the women who stood up to Eli Lilly and came away successful. We hope it contributes to their happiness and well-being. But of course, no amount of money can ever make up for the harm caused by DES.
- Will Lilly's settling of the DES breast cancer case reform the way they work? Naw, it's just the cost of doing business for Big Pharma.
- Wooooo Hoooooo! ;o)
- What a wonderful outcome! I would like to take this time to thank those ladies who put themselves out there front and center to bring the link between DES and their breast cancer to the forefront.
- OMGoodness! This is WONDERFUL NEWS! I am so very happy about this.
- As I watched a magnificent sunrise, I heard the news of the courtroom victory in Boston, and wept. I wept tears of joy for the legal settlement, tears of sadness for all the pain and suffering, and tears of gratitude for the DES-exposed's bravery and resolve. It's a new day!
- All together now: air fist pumps and a resounding "YES"!!! Aaron Levine rocks.
- Two days of trial and Eli Lilly caved! Must have seen the writing on the wall. Wonderful victory for DES Daughters and their families.
- Lilly is really eating some much-deserved crow with this settlement.
- I pray there will be many more settlements to follow!

Editor's Note: On page 7 you'll find a moving explanation from a DES Daughter plaintiff, who describes her feelings upon learning that Lilly settled without admitting guilt for the DES tragedy. She speaks for so many!

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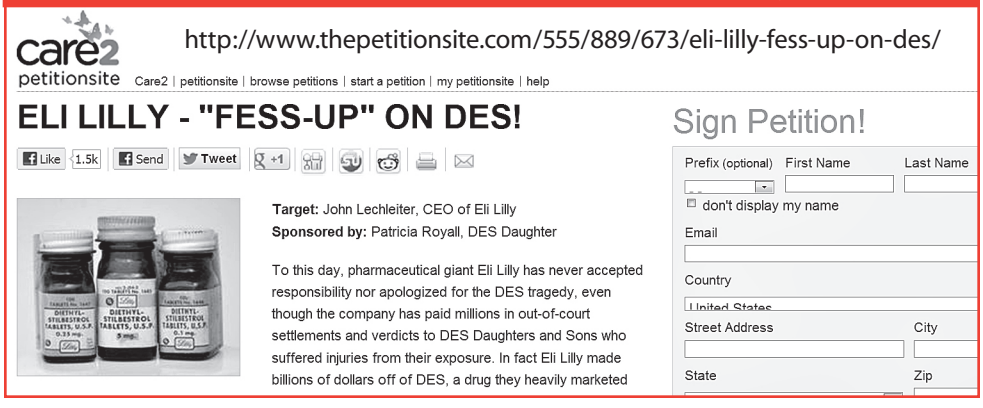
You can sign an online petition started by a DES Daughter who wants to send a message to Eli Lilly



DES Lessons Not Learned

Concerns Raised About Another Drug Being Given To Pregnant Women

A constant thought running through the DES community is: "What happened to us should never happen again. Don't let the confluence of drug company greed, lax government regulation and dissemination of faulty research to doctors come together again in another tragedy."

So an article published online in The Atlantic on 1/16/2013 is disturbing. DES and the drug, dexamethasone (dex) are different drugs. DES is a nonsteroidal synthetic hormone, whereas dexamethasone is a synthetic steroid. But that's where the differences end and the similarities begin. We have permission to share the article here.

the Atlantic

IVF on Steroids:

The Dangerous Off-Label Use of 'Dex' During Pregnancy

By Alice Dreger, professor of clinical medical humanities and bioethics at Northwestern University's Feinberg School of Medicine.

Fertility clinics across the U.S. are prescribing a medication with a seriously concerning safety profile and no proven benefits.

When Susan Manning, a 39-year old woman just a few weeks into her first pregnancy, wrote to tell me she had been put on the steroid dexamethasone (Dex) to prevent a miscarriage – and to ask whether she should be worried about taking this drug – at first I could not even process what she was saying. Dexamethasone is known to cross the placental barrier and impact fetal development, so the very idea of first trimester exposure sets off warning bells. Besides, dexamethasone is not known to help in preventing miscarriage. Susan's story sounded too crazy to be true.

It also sounded too close to the history of DES (diethylstilbestrol). From the 1940s through the 1970s, some doctors gave pregnant women DES, a synthetic estrogen, to try to prevent miscarriage. In spite of clinical evidence that it didn't work as intended, millions of fetuses were exposed in utero before doctors discovered that prenatal DES exposure could lead to deadly cancers and infertility.

But it turns out, Susan (a pseudonym) had it right. Women, like her, pregnant by virtue of in vitro fertilization (IVF), are today routinely put on dexamethasone for miscarriage prevention at some IVF clinics. Susan is being treated abroad at a high-profile clinic, but some American infertility clinics also advertise this off-label use of dexamethasone as if it is the standard of care.

I inquired about this with Dr. Geoffrey Sher, Executive Medical Director of the Sher Institutes for Reproductive Medicine, a high-profile infertility practice with offices across the country. He confirmed in an email that, "We recommend 0.5 mg – 1.0 mg [of dexamethasone] orally daily (dosage varies based upon individual patient needs) from the time of initiating the [IVF] cycle through to the tenth week of pregnancy." He could not point to studies showing that dexamethasone helps prevent miscarriage, but argued, "Since there are so many other variables that are involved" in IVF pregnancies, studies "would virtually be impossible to do."

In essence, doctors using dexamethasone for miscarriage prevention are working from a physiological hunch. The hunch is that some women who seek out IVF have immune problems that cause their bodies to reject pregnancies. If dexamethasone suppresses a woman's immune system, maybe it will help her maintain a pregnancy. But, again, there's no scientific evidence that dexamethasone prevents miscarriage, and no evidence that this drug—a drug known from animal and human studies to have the potential to change fetal development—is safe to use in this way.

Surprisingly, it appears that even women like Susan, with no diagnosable immune disorder and no history of recurrent miscarriage, are being put on dexamethasone for miscarriage prevention by some IVF specialists.

I asked Dr. Ralph Kazer, Chief of the Division of Reproductive Endocrinology and Infertility at Northwestern University's Feinberg School of Medicine, to give me his thoughts on this use of dexamethasone. (We work at the same medical school, although Dr. Kazer and I have never communicated before this). Dr. Kazer expressed concern, saying, "The extent to which early [pregnancy] losses are due to immunological problems is controversial, but it is almost certainly a relatively rare problem."

I asked Dr. Kazer if he knew of

studies of efficacy or safety of this off-label (non-FDA-approved) use. The answer was no. "This is not complicated," Dr. Kazer wrote. "In the absence of good evidence for efficacy or a very specific medical condition, a drug like dexamethasone should not be given to pregnant women in the first trimester."

He explained why: "Dexamethasone is a Category C drug, which means that there are concerning animal data [about safety] but no good data in humans regarding teratogenicity [i.e., birth defects caused by a drug]. Such drugs should only be used when potential benefits outweigh potential risks. Dexamethasone does cross the placenta, so at the very least, it reaches the fetus."

At Brown University's Alpert Medical School, Dr. Philip Gruppuso is a pediatric endocrinologist with research interests in the fetal origins of adult health and disease. When I told Dr. Gruppuso about this use of dexamethasone, a steroid in the class of drugs called glucocorticoids, he responded, "Regardless of the rationale, the first trimester use of glucocorticoids should be viewed as an experimental treatment that could have long-lasting untoward effects. Evidence from animal studies raises the possibility that glucocorticoids can alter the fetal epigenome." In other words, prenatal synthetic glucocorticoid exposure could permanently change the way a person's genetics will operate over his or her lifetime.

It is worth remembering that the terrible effects of DES were found almost by accident, when doctors became aware of a cluster of young women with a very rare form of vaginal cancer. A mother of a girl with the cancer pushed doctors to consider the possibility that the cancer came from her daughter's prenatal exposure to DES, and that mother turned out to be right.

What about Dr. Sher's claim that IVF treatment is just too complicated to allow a study of dexamethasone for miscarriage prevention? The infertility specialist Dr. Kazer replies, "Such a study could certainly be designed, although it might be difficult to convince an IRB [i.e., ethics board] to approve it, given the lack of biological plausibility regarding potential efficacy."

What did Susan's doctor tell her about efficacy and safety when he put her on dexamethasone? Nothing until she pressed him, several weeks into the "treatment." At that point, she says, "The doctor had the nerve to tell me that they think the benefits outweighed the risks, but maybe I don't! I've never been party to the discussion. How dare they make that decision on my behalf."

She wrote to me, "I can't understand why nobody is even questioning the use of this drug; in some respects I wonder whether women who go through IVF end up having such low self-esteem that they don't have the confidence to question what the doctors say. They are 'grateful' that they are being treated and therefore don't dare put a foot out of line. I know for a fact that is the situation in my clinic; you never question [the doctor] and if you do create a fuss, then he won't treat you again." She added, "It's a very disempowering relationship."

Kari Christianson, Program Director of DES Action USA, was astounded when I wrote to tell her that dexamethasone is being used for miscarriage prevention. She wrote, "What strikes me most about the horror of dex use is the vulnerability of not only a developing fetus in pregnancy, but also of a mother (and a father) wanting to make the best decisions about a hoped-for child. But again and again, unproven and unsafe drugs are available, offered and given to pregnant women without fully informed consent or understanding at a most vulnerable time. It is unconscionable. To think that we have learned little or nothing in the over 40 years since DES health harm was brought to light is frightening beyond all reason."

I asked Dr. Sher what he tells women he is putting on dexamethasone. He answered, "We tell our IVF patients that in our opinion it is by and large safe to take as prescribed, that there are no proven developmental risks to the baby [and] that side effects to the woman are infrequent, temporary in nature and reversible on proper withdrawal."" He went on, "We do not go into detail describing everything in the literature on what we consider to be safe treatments. That would be overly time consuming, impossible to accomplish thoroughly and comprehensively and in my opinion [would] create unnecessary patient consternation."

This article is available online at: http://www.theatlantic.com/health/archive/2013/01/ivf-on-steroids-the-dangerous-off-label-use-of-dex-during-pregnancy/267187/

Valuable Information Shared As Researchers and Advocacy Groups Meet

By Kari Christianson

Researchers work primarily in their laboratories and offices without much contact with individuals living daily with health problems under scrutiny by the scientists.

In a forward thinking move more than ten years ago the National Institute of Environmental Health Sciences (NIEHS) created an important collaboration between researchers and grassroots organizations to bring interested parties to the table. DES Action USA is proud to have been a member of the NIEHS Partners group from the start.

To say this is a collegial group is an understatement! The NIEHS Partners enjoy a unique working relationship with Institute Director Linda Birnbaum and the scientists. The meetings are informal, meaning no dimmed lights and PowerPoint presentations. Researchers and organization representatives all sit around the table and really talk with one another.

It's an opportunity for consumer representatives to express concerns and experiences that might otherwise go unnoticed by researchers. Shared experiences among various advocacy groups can point the way to perhaps new perspectives on the NIEHS research agenda.

On the flip side, while scientists listen carefully to the Partner groups, these consumer representatives also ask questions of the researchers for up-to-the minute updates on their studies.

The focus during this latest meeting was on endocrine disruption, something the DES community knows much about. Forty years ago concern about harmful effects of diethylstilbestrol exposure to humans, animals and the environment was what actually initiated the field of science that studies endocrine disruptors. Three scientists who work specifically on this type of research at NIEHS and the National Toxicology Program (NTP) were in attendance to help lead discussions.

NIEHS Director Linda Birnbaum is seated in the front row, third from the left. DES Action USA's Program Director Kari Christianson is standing right behind Dr. Birnbaum.

The collegial learning atmosphere between organizations and researchers fosters important dialogue. Information shared this way highlights a growing understanding of the necessity to look at the big picture, with an eye to examining relationships between health issues of all types and how they are connected one to one another, as well as to the environment. DES VOICE

Delayed Sunshine Act Now Back On Track

Have you ever suspected a drug you were prescribed was given because the doctor benefited from the largess of the drug maker? The answer may be easier to discern next year. September 2014 is the new date for long-delayed implementation of the Physician Payment Sunshine Act (PPSA). Passed in 2010, rules for the program were finally issued this month, more than a year behind schedule.

DES Action USA joined with the National Coalition for Appropriate Prescribing to advocate for the legislation because consumers want and need transparency into drug company influence on physicians.

Drug companies and medical device makers will be required to report financial transactions involving doctors that include speaking fees, gifts, food, entertainment, honoraria, etc. You will be able to visit a website where this information will be posted and easily searchable. Some pharmaceutical firms have already begun reporting such payments, but the data is presented in a variety of ways making it difficult to compare. The PPSA will standardize the reporting process.

In announcing the rules and updated timeline, Peter Budetti from the Centers for Medicare and Medicaid Services (CMS), which is in charge of the Sunshine Act, said, "You should know when your doctor has a financial relationship with the companies that manufacture or supply the medicines or medical devices you may need. Disclosure of these relationships allows patients to have more informed discussions with their doctors."

Why should patients care about this? Because studies have consistently shown that drug company influence can bias a doctor's prescribing habits. Case in point: DES.

By 1953 published research showed DES didn't work to prevent miscarriage. As history tells us, drug makers then ramped up their DES promotional efforts to doctors. It worked and for many years thereafter DES continued to be the standard of care for treating problem pregnancies. Of course now we can only speculate, but it's possible that had the Sunshine Act been around back then, enough questions might have focused a spotlight on the huge marketing push around DES. It's the kind of thing we hope never goes unnoticed again. DES VOICE

A Mixed Bag in Two French Court of Appeals Rulings

After a nine-year legal struggle involving hearings in several courts, two French DES Daughters received different judgments from the Paris Court of Appeals.

Marie-Elise Perenti developed vaginal clear cell adenocarcinoma (CCA) when she was twenty-one. Even though she did not have medical record proof of exposure, research has conclusively linked that disease to DES.

In her case, the justices confirmed the joint responsibility of two pharmaceutical companies marketing DES in France until 1977: Distilbene by UCB Pharma and Stilboestrol by Novartis, formerly Borne. The two companies will divide the damage award payment to her of $273,500.

The French DES organization DES Reseau calls this ruling "an important victory for DES victims against pharmaceutical companies. Now, when DES responsibility is pronounced in court, each drug maker must prove that it is not the one that caused harm, otherwise their legal liability will be considered jointly as 50/50."

On the other hand, Sophie Meyer's infertility case did not end well. Like Perenti, she had no proof of exposure. But the justices found that her medical history was not sufficient enough evidence that prenatal DES exposure was the unique cause of her infertility. Her case was rejected.

"The court confirmed still-prevailing legal attitudes that DES Daughters must produce irrefutable proof of prenatal DES exposure—within a 10 year statute of limitations, except in CCA cases. When will such exhausting individual legal struggles cease? We need a decision to accept the principle of class action status for DES victims," says the French advocacy group, DES Reseau.

DES VOICE

A Mother's Guilt: DES, a Tragedy of Three Generations

DES Action USA member ***Hannah Klein Connolly*** *is one of the DES Daughters who filed suit in the breast cancer litigation. She's awaiting settlement negotiations and gives her perspective in a Breast Cancer Action blog that we have permission to share here.*

More than 3,000 miles away, my fate and that of many women diagnosed with breast cancer resided in Boston in the hands of a judge, a jury, and 42 lawyers, 40 of whom worked for pharmaceuticals. Perhaps I am being a bit overly dramatic; it's how I felt. The case, Fecho v. Eli Lilly, was as much about emotion as it was about physical injury, corporate accountability and ultimately, about vindication.

My pregnant mother was prescribed DES. Confined to complete bed-rest she diligently took her medication as prescribed, in spite of the fact that nine years earlier a study in the American Journal of Obstetrics and Gynecology revealed women taking DES suffered a higher number of miscarriages.

What kind of a company does this? What kind of a company creates a drug, heavily markets it to doctors, ignores evidence of serious side effects, and continues day in and day out to manufacture it regardless of the devastating impact research suggests it may have on the health of generations of women?

I have lost both my breasts and my ovaries. I've given birth to two preemies and have autoimmune issues too numerous to count. As this case progressed, I've felt angry, stunned, anti-climactic, and now sad. And, I realized that when I first met with the lawyer a few years ago my goal in being involved was to make sure this never happened to anyone again.

Cases, including mine, are still pending because these drug makers refuse to admit fault and fail to assume liability for peddling a drug that caused so much emotional and physical devastation. The drug companies made huge, fat profits. Of course, financial compensation will help DES Daughters and will reimburse a fraction of the pain and suffering. But I want more. I want acknowledgment of accountability and a commitment to change.

DRUG COMPANIES MUST RIGOROUSLY TEST PRODUCTS. DRUGS NEED TO BE PROVEN SAFE BEFORE THEY REACH CONSUMERS BECAUSE IT'S NOT MY JOB TO DEMONSTRATE THEY ARE HARMFUL TO MY HEALTH.

This is an opportunity to move forward and commit to good science practiced with integrity. I want Lilly to be held accountable for mistakes of the past (and possibly future – with my daughter). I want an apology. And most of all I want change so this never happens again.

If this case ends up being the handslap that warns all others, so be it. I certainly hope it is. Even so, cost to women should never have been so great—all from an "untested" product that has cost too many of us our breasts, our dignity, and our humanity.

Until these companies take responsibility for their actions, I will continue to fight for accountability. I will fight for justice—not merely financial vindication—in the name of all our mothers, ourselves, and our daughters.

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BOOK REVIEW

New DES Novel Hits Close To Home—Gets It Right

SILENT TRAUMA
by Judith Barrow
Available in paperback through
http://www.amazon.com

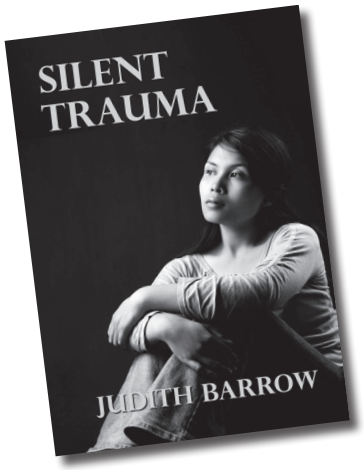
Reviewed by Fran Howell

I finished reading *Silent Trauma* and sat back to marvel at how author Judith Barrow got it so right. This meticulously researched novel pulls the curtain back on wrenching emotional consequences of exposure. Guilt, sadness, depression, and tortured relationships are heartbreakingly familiar to many who live with DES as part of their health histories. And then comes the strength to do something about it.

Intertwined lives of four women show the DES-exposed they are not alone. And reading this novel will be eye opening to their family and friends who wonder what it means to be a DES Mother or DES Daughter.

Scientific studies continue adding to a growing list of serious medical problems caused by exposure before birth to DES. An increased risk for infertility, vaginal/cervical cancer and breast cancer are but the start. Doctors prescribing DES told mothers it was safe and these women had no reason to doubt. Later they learned the horrible truth that DES harmed their children.

Millions around the world were exposed to DES, but this tragedy flies under the radar of general consciousness. You can't look at individuals and see they were exposed. This compelling novel will help spread much needed awareness of DES. The hope is that current and future drugs will be more carefully tested, and



regulators will do their jobs by better regulating these drugs to protect the public, which has every right to believe that drugs being prescribed are safe.

Author Barrow is donating a portion of sales of her compelling novel to DES Action USA!

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