

New Drug Poses Risk of Ovarian Cancer

Reprinted with permission from the Chicago Tribune, April 19, 1998

[E] Lilly's current full page color ads for Evista, a synthetic hormone with both estrogenic and anti-estrogenic effects, in major national and regional newspapers claim that it offers "a new way to prevent osteoporosis" while admitting that "its effect on fractures is not yet known." The ads also claim that "women taking Evista had no increased risks of breast and uterine cancers" in contrast to hormone replacement therapy, and that it reduces LDL or bad cholesterol blood levels. This should be welcome news to women worldwide, particularly as osteoporosis has now reached epidemic proportions, affecting fifteen to twenty million American women each year; osteoporosis causes over a million fractures including 250,000 hip fractures, and killing some 50,000 elderly women from complications of their fractures.

While warning of some possible side effects, such as blood clots or hot flashes, Lilly fails to warn of the more serious risks of ovarian cancer. A company-sponsored publication in the December 4, 1997 issue of

Lilly fails to warn of the more serious risks of ovarian cancer.

The New England Journal of Medicine also ignores this risk. However, Lilly's pre-market clearance study clearly shows that Evista induces ovarian cancer in both mice and rats. Furthermore, carcinogenic effects were noted at dosages extending well below the recommended therapeutic level. However, the study concluded: "The clinical relevance of these tumor findings is not known." Lilly reached this conclusion despite the strong scientific consensus that the induction of cancer in well-designed tests in two rodent species creates the strong presumption of human risk. Nevertheless, Lilly fails to disclose this critical information in its ads and in its "Warning" to patients.

Responding to such criticisms by Dr. Samuel Epstein on the January 12, 1998 "Jim Lehrer News Hour" program, a Lilly spokesman claimed that the carcinogenic effects of Evista in the ovaries of sexually mature rodents are irrelevant to such risks in post-menopausal women as their ovaries are inactive, and that no warning is therefore necessary. However, apart from the fact that the rodent studies were specifically designed to evaluate Evista's safety, ovarian cancer is a scientifically docu-

mented complication of long-term estrogen replacement therapy in the post-menopausal. Also disturbing is the claim that Evista poses no risks of breast and uterine cancers as this is based on clinical trials over only some 40 months, a period totally inadequate to possibly manifest any such risks.

Ovarian cancer strikes about 24,000 U.S. women every year, accounting for 4% of all their cancers. About 15,000 women die from ovarian cancer annually, making it the most lethal of all female reproductive cancers. Lilly's suppression of its own evidence of ovarian cancer risks from Evista is reckless and threatening to women's health and life. Equally reckless is FDA's December, 1997, marketing clearance, especially in the absence of any requirement for warning. Such conduct clearly merits urgent Congressional investigation. This drug should be withdrawn from the world market immediately. As importantly, a "Cancer Alert" should be sent to the over 12,000 women who have participated in U.S. and international clinical trials in the absence of fully informed consent. The doctrine of informed consent is ethically and legally protective only when all facts relevant to benefits and risks are affirmatively disclosed. This is clearly not the case with women who have been involved in the Evista trials. These women

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Each group was created and nurtured by volunteers. Write them if you want information on their activities or can volunteer.

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DES (diethylstilbestrol) is a synthetic form of the female hormone estrogen.

From 1938 to 1971, several million pregnant women in the U.S. were prescribed DES, especially if they had a history of previous miscarriage or slight

bleeding or had diabetes. DES was given in pills, injections and suppositories and sold by over 200 drug companies under their own brand names.

DES exposure can lead to health problems:

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

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



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Update on Legislation: Keep your letters coming!

YOUR stories are making a difference, and we are seeing more lawmakers sign on to sponsor the DES bill in Congress. Here are a few excerpts from letters to Senators and Representatives:

"Dear Senator Murkowski,
I was exposed to DES in 1953 before I was born... I lost my first child, a son, due to his premature birth at around 25 weeks gestation. My second child, a daughter, was born at 30 weeks gestation in spite of all medical attempts to maintain my pregnancy until term. She has numerous..... effects from her prematurity, such as hearing loss, mild cerebral palsy, Attention Deficit Disorder, Retinopathy of Prematurity, balance problems, and small stature."

"Dear Representative
Sensenbrenner,

Being a DES daughter has caused me a great deal of both mental and physical pain... As a teenager and adult I have been riddled with severe pain every month, with every cycle. After many years of fertility tests, it was discovered my fallopian tubes developed abnormally and never opened, due to the DES... To this day, I must go every 3-6 months for a pap smear or colposcopy to make sure that the pre-cancerous tissue I have inside of me (thanks to DES) does not change."

"Dear Senator Hutchison,
Support of this bill will mean so much to so many people. I

hope we can count on you!"

These letters represent just a few of the hundreds we have received in response to our request for help in passing the "DES Education and Research Amendments" currently before Congress. We are so grateful to each of you who has taken the time to write to your Representative and two Senators.

To date I have received copies of letters written to Senators and Representatives in just 22 states. I again urge that every member write to your own Senators and Representative, and ask them to sponsor and support H.R. 1788.

There are several key lawmakers who need to hear from all DES-exposed individuals. These lawmakers are important because of their leadership positions in the House and Senate and in various committees which will handle the DES bill. *I would like*

to issue a strong plea for members to write to the following key Representatives and Senators:

In the House of Representatives:

(Address: Hon. _____
U.S. House of Representatives
Washington, D.C. 20510)
House Speaker Newt Gingrich
(R-GA)
House Majority Leader Dick
Armey (R-TX)
Commerce Committee Chairman
Tom Bliley (R-VA)
Commerce Subcommittee on
Health Chairman Michael
Bilirakis (R-FL)

In the Senate:

(Address: Hon. _____
U.S. Senate
Washington, D.C. 20515)
Senator Bill Frist (R-TN)
Senator Jim Jeffords (R-VT)
Senator Arlen Specter (R-PA)

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PILLS & POTIONS:

Reproductive Technologies, Menopause, & Our Future

Burton Krumholz, M.D.
Treating the DES-Exposed Patient
Judith Turiel, Ed.D.
New Reproductive Technologies

Janine O'Leary Cobb
Alternatives to HRT
Dianne Dumanoski
DES: Lessons for Society

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Book Reviews

My Year of Meats

by Ruth L. Ozeki

Reviewed by Nora Cody

MY YEAR OF MEATS is a wonderful, strong, disturbing, funny novel. It is at times hilarious and absurd, at times shocking and heart wrenching. It's the best book I've read in a long time.

Set in the early 1990's, the novel tells the story of two women, Jane and Akiko. Jane is a young Japanese-American independent filmmaker who is hired to produce a series of documentaries for Japanese television. Funded entirely by the American meat export industry and designed to sell meat to the Japanese market, the series is called "My American Wife." Each show presents a "wholesome, normal" American family at home, with the centerpiece being the preparation of a recipe featuring meat, preferably beef. Or as the producer reminds Jane: "Pork and other meats is second class meats, so please remember this easy motto: 'Pork is possible, but Beef is best!'"

In the beginning Jane complies and produces shows with such recipes as "Coca-Cola Roast" and other delicacies. On the other side of the globe, Akiko, the wife of the Japanese producer, watches and prepares the recipes for her abusive husband. He encourages her to eat large amounts of meat in the hope that it will add weight to her thin body and improve her fertility.

As she travels around the

United States, scouting families for the program, Jane begins to stretch the boundaries of what her producers consider "normal, wholesome" wives and families. Her attempt to film a poor African-American family proves unsuccessful, but she manages to slip in a show about a large interracial family with many adopted children. Eventually her subversive impulses take over and she presents a show featuring a lesbian, inter-racial, vegetarian couple. This is not well-received by her producer.

Watching in Japan, Akiko becomes inspired by the shows and increasingly radicalized as she quietly plots her escape from the life-threatening abuse she endures. There is irony and

After years of coping with gynecological problems, she stumbles upon the knowledge that she is a DES daughter.

brilliance in the bond between Akiko and Jane that is forged through the unlikely medium of "My American Wife."

Jane begins to research American beef and learns about the use of DES to fatten cattle and chickens. After years of coping with gynecological problems, she stumbles upon the knowledge that she is a DES daughter. The health effects of DES, through prenatal exposure, via meat consumption, and through exposure to cattle feed, become interwoven into the story. Descriptions of a livestock feedlot and slaughterhouse are truly harrowing. Ozeki has clearly done her research and

manages to make the complex subject of hormone exposure both clear and compelling.

At the same time, I must point out a misstatement in the final pages of the book. Summing up, Jane cites that she is lucky to have so far escaped "fatal adenocarcinoma." As readers of this newsletter know, DES-related adenocarcinoma is not fatal and in fact has a high survival rate if detected early. I worry that DES daughters reading these words may panic unnecessarily.

There is so much more to this novel. Japanese culture, American culture, race, love, sex, fertility and its destroyers. All DES daughters will relate to her fears and anger about DES, and many will recognize themselves in Jane's struggles with fertility. Beyond that, this is a very good read and one I highly recommend.

Note: Ozeki has included information on how to contact DES Action at the back of her book. This must be a first—a novel with resources listed. We are grateful for the listing.

Unspeakable Losses: Understanding the Experience of pregnancy Loss, Miscarriage, and Abortion

by Kim Kluger-Bell, W.W. Norton, 171. Clothbound. \$23.95.

Reviewed by Judith Turiel

UNSPEAKABLE LOSSES by California psychotherapist Kim Kluger-Bell focuses on an experience far too familiar for too many DES daughters—the loss of

a pregnancy through miscarriage, ectopic implantation, stillbirth, preterm delivery of a baby who does not survive. As Kluger-Bell points out, these reproductive losses are often followed by silence and avoidance from family and friends, rather than by needed recognition and emotional support. In discussing these difficult life experiences, the author draws upon her own history of ectopic pregnancies and failed IVF treatments (an additional form of loss), as well as upon her work with therapy clients and Resolve support groups. This wellspring of material is both a positive contribution to the book and a source of my major hesitation.

On the positive side, Kluger-Bell brings compassion, empathy and personal experience to the topic she has clearly given much thought to. Her very readable book provides examples of women speaking about their losses and ways of coping, along with Kluger-Bell's interpretation of their reactions. In addition, this book includes an often-neglected party: men who live through a partner's miscarriage, elective abortion, stillbirth or other pregnancy loss. Kluger-Bell describes rituals and ceremonies that some people have found comforting, herself included: ways of acknowledging and grieving for what might have been one's child. Beyond the actual cases presented are useful Appendices:

- Common Experiences
Shared by Those Coping with a Reproductive Crisis
- For Family and Friends
Whose Loved Ones Are Dealing with a Reproductive Crisis
- Special Notes for Mental Health and Medical professionals

This very readable book provides examples of women speaking about their losses and ways of coping, along with the author's interpretation of their reactions.

The book lists organizations, readings, and Internet websites in its Resource section.

As to my hesitation: Kim Kluger-Bell is a psychotherapist, and so her book is very psychological. Her particular orientation, moreover, emphasizes unconscious motivations and conflicts traced back to childhood, especially unconscious feelings about relationships with one's own parents. In her view, "Understanding the experience of pregnancy loss, miscarriage, and abortion" (the book's subtitle) entails bringing unconscious feelings into conscious awareness, through such techniques as dream analysis and free association during psychotherapy, in order to uncover, for instance, repressed feelings of abandonment and unresolved conflicts about attachment.

The result, for me, was a heaviness of interpretation as she explained individuals' reactions and suggested ways people can better handle reproductive loss. While her approach may be helpful for some women and men, it is only one, fairly narrow, way of understanding and coping with an emotionally painful loss, and emerging with one's psychological well-being intact. As the author does note, individuals differ: psychoanalytic methods and interpretations are not for everyone. So too do reproductive

losses differ. Kluger-Bell stresses commonalities, such as the unconscious feelings tapped by any type of reproductive loss. However, we should also recognize differences, and realize that factors *outside* the individual may enlarge, and make all the more difficult, our unhappy experiences. For example, fertility specialists' reliance on selective reduction of large multiple pregnancies following ovarian hyper-stimulation; encouraging patients to view one's embryos, many of which will never develop further; or to "bond with" an early ultrasound image.

This hesitation aside, Kluger-Bell's book does take seriously the very difficult personal experience of reproductive loss, whatever its form, and highlights a dimension that rings true for this reader: some sense of sadness and loss may never go away completely. Rather, we find a way to live with the experience, even after 20 years and more.

What to Expect When You're Experiencing Infertility: How to Cope with the Emotional Crisis and Survive

by Debby Peoples and Harriette Rovner Ferguson, C.S.W., W.W. Norton Co., 1998, 251 pp. plus resources. Clothbound. \$25.00

Reviewed by
Molly Berigan Spira

ACCEPTANCE, good health, and long, prosperous lives. It's what everyone desires. But for infertile couples, like those of us exposed to DES, it is a long, hard journey. It begins with the first visit to the gynecologist to

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figure out how we will survive the life crisis DES exposure presents for us.

Our individual journeys have taken us through many difficult trials. For many DES daughters, the road began well before our fertility was even tested. From care providers giving us the "it's all in your head, little girl" attitude, to telling us assuredly yet paternalistically when we reach some golden age that we were well past the age of worry. Somehow we did not believe it. To family members who unknowingly tell us "relax and you'll get pregnant." The constant exposure in the workplace to the fertile world and in our family gatherings to baby showers and pregnant relatives. Having to deal with grief and anger and significant loss through unsuccessful medical interventions, multiple miscarriages or ectopic pregnancies. To making life-altering decisions to forego additional medical treatment and move on to surrogacy or adoption, or accept a childfree life.

These are all painful, life-altering situations and decisions that we may or may not be prepared to make or deal with the consequences. The most important validation we seek is to feel OK with our own selves and the delicate decisions we must make for our own health, our own marriages, and for the rest of our lives, while addressing the grief that accompanies each and every loss along the way.

What to Expect When You're Experiencing Infertility is a first step at addressing those questions to help infertile couples work through the grief of such a significant loss. Debby Peoples, a mem-

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ber of Resolve, and Harriette Rovner Ferguson, a care provider who has counseled infertile couples, equate the infertility crisis to the anxiety and depression levels of people who experience cancer, heart disease, and HIV positive status. Infertility is addressed generically and only occasionally to specific diagnoses including DES exposure. Peoples and Rovner Ferguson sensitively ask the questions that have been on all our minds and provide compassionate answers to help couples move through what they have identified as the four stages of infertility: crisis, acceptance, resolution, and epilogue.

The authors discuss with sensitivity how to deal with obsession with infertility; feeling left out; wanting to be "normal"; how men deal with infertility; communicating with your spouse; living in a fertile world; dealing with the medical community; and working through grief. Religious and personal ceremony is encouraged to help with the grief process.

References and resources are plentiful. They range from a self-help primer focusing on visualization, meditation, mental and physical exercise, to lists of groups (including DES Action) who can help infertile couples

educate and connect themselves to others locked in their same struggles. Suggested readings also are included in the appendix.

A final and worthwhile segment provides a guide for mental health professionals treating infertility. I applaud the authors' efforts to address this neglected issue. All too often infertility clients are met with emotional questions that are neither appropriately addressed by medical professionals who may or may not be equipped to counsel therapeutically, nor adequately understood by therapists who may or may not be sensitive to the infertility experience.

Infertility is a finite state. The ramifications of DES exposure are not. They are hugely unknown and specifically individual. The process of acceptance and moving on with life, however, is similar. Acceptance of grief as a necessary hurdle to work through, on our own time rather than hurried as society expects, is a common theme in this book, and one that DES mothers, daughters and sons can learn from. Recognition of the importance of taking care of your own emotional and mental health throughout this crisis is what makes this book valuable.

NEW DRUG RISKS from page 1...

should be offered semi-annual lifelong surveillance for the early detection of ovarian cancer, at Eli Lilly's expense.

—Samuel S. Epstein M.D.

University of Illinois School of Public Health; Chairman Cancer Prevention Coalition, Chicago; Co-author of The Breast Cancer Prevention Program, Macmillan, 1997

—Pat Cody

President, DES Action, Oakland, CA

Words from an Attorney

Patricia Martin Stanford, Jacksonville FL

Editor's note: Ms Stanford gave this talk at our Symposium luncheon in October 1997.

I am an attorney in Florida where I have practiced for a little over 15 years. For the last five or six years, my practice has concentrated on medical malpractice and product liability litigation, and, to a great extent, that has involved DES-related litigation.

DES law suits, like all litigation, require a significant commitment on your part. DES litigation is legally challenging, financially risky and expensive, and emotionally draining. And that's just for the lawyer! For you, the DES daughter or son, it's all that and more. It's an invasion of privacy, disruption of your home life, and the dredging up of painful memories and events. But while it is all those things, it can also be a means to an end. It can help provide financial resources for fertility treatments, medical care and adoption expenses (although for some people, the money really means nothing). It can help provide some form of closure—a way to sort of confront the enemy.

But most importantly, it forces some accountability on the part of these companies—certainly not an acknowledgment of their responsibility or an apology for their conduct, since nothing will ever get us that—but it does make them accountable to you. How? Because you stood up to them, you took a stand, and you went on record that you

However, I have found in my practice that for many of my clients, there is a great satisfaction or relief in having gone through the process, in having taken a stand.

would not be a silent victim. Unfortunately, you can't change the fact that you are all victims of their corporate greed, but you can refuse to accept that legacy without a fight. I think it is terribly important to take a stand, because the drug companies have gotten away with so much for so long, largely because of a lack of knowledge among DES victims...a lack of knowledge as to the health and reproductive consequences of the exposure, as well as a lack of knowledge as to their legal rights.

What is the reason for that lack of knowledge? Well, as you can imagine, when you take on one or more of the drug companies who made DES, you're facing a formidable adversary. These are typically Fortune 500 companies with pretty much unlimited resources, including high-priced defense lawyers who will bill them thousands of dollars for collecting your medical records and bills, and for taking your deposition and that of your husband, mother, friends and doctors. Many people just do not want to go through this, and they often end up dealing with their exposure in silence.

Despite its benefits, litigation

is certainly not the answer for everyone. However, I have found in my practice that for many of my clients, there is a great satisfaction or relief in having gone through the process, in having taken a stand. Of course, litigation is not the only way to press for accountability. Look at DES Action and this symposium. DES Action has made a huge difference by bringing the drug companies into a different court—the court of public opinion—and of shining on them the unforgiving light of public knowledge and awareness.

So whether it is through a lawsuit or through participation in groups like DES Action, the important thing is to be involved, to continue to get the word out about DES. Believe it or not, many people still don't know the story. There are still many very young women who have been exposed, yet don't know all the ramifications of their exposure. Remember, DES was used in pregnancy up through November of 1971 (sometimes even later by uneducated physicians). That means there are many women only now in their late 20s, many of whom are just now reaching their childbearing years, who are still at risk. This is especially frightening now, since so many doctors, even otherwise knowledgeable ones, tend to believe that the DES story is a thing of the past—that the cancer "scare" is long over with, and that all of the affected women and men have "grown out" of the problems

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associated with DES exposure.

Rather, these doctors should be educating their DES patients that they must continue to be vigilant in their health care. They should not by their comments allow patients to let down their guard. The risks are still there and they are very real. I now have a case of a 42 year old woman diagnosed just nine months ago with clear-cell adenocarcinoma of the vagina. This is why the continued study and research so strongly lobbied for by DES Action is so important, and why public education is so important. It is because of this that I encourage every one of my clients to earmark a portion of their settlement proceeds as a contribution to DES Action.

THE PEOPLE'S MEDICAL SOCIETY a consumer group in Pennsylvania, publishes a monthly newsletter and also a number of books. Their publishing began some years ago with what have been some continual best-sellers: *Take This Book to the Hospital with You*, and *Take This Book to the Gynecologist with You*. Some of their recent titles that may interest our readers include:

Vitamin C: Everything you Need to Know by Jennifer Hay, \$10.95

Vitamin E: Everything you Need to Know by Jennifer Hay, \$10.95

Eat Better, Feel Better by Marie Deidre Donovan, \$18.95

Fast and Lean One-Dish Cuisine by Carol Heding Munson, \$14.95

Medicare Made Easy by Charles B. Inlander & Michael A. Donio, \$18.95

The Herbal Companion: The Essential Guide to Using Herbs for Your Health and Well-Being by Marcus A. Webb, \$16.95

Managed Care Made Easy by Vikram Khanna.M.H.S., \$14.95

The Spice Companion, the Culinary, Cosmetic and Medicinal Uses of Spices by Richard Craze, \$16.95

The Parents' Complete Guide to Ear Infections by A. R. Greene M.D., \$14.95

You can get more information about ordering these books, or getting their complete list, by writing to them at Peoples' Medical Society, 462 Walnut St., Allentown PA 18102, or, e-mail at: Peoplesmed@compuserve.com, or, Website at www.peoplesmed.org

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