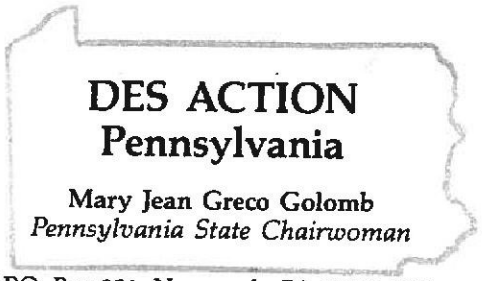

DES ACTION
Pennsylvania

Mary Jean Greco Golomb
Pennsylvania State Chairwoman

P.O. Box 286, Nescopeck, PA 18635-0286
1-717/759-8365 FAX 1-717/752-6717

Appendix A — Estimated number of DES-exposed in the United States

	Mothers	Daughters	Sons	Total
Alabama	80,000	40,000	40,000	160,000
Alaska	10,000	5,000	50,000	20,000
Arizona	60,000	30,000	30,000	120,000
Arkansas	47,500	23,750	23,750	95,000
California	540,000	270,000	270,000	1,080,000
Colorado	60,000	30,000	30,000	120,000
Connecticut	60,000	30,000	30,000	120,000
Delaware	12,000	6,000	60,000	24,000
District of Col.	12,000	6,000	6,000	24,000
Florida	233,500	116,750	116,750	467,000
Georgia	120,000	60,000	60,0002	40,000
Hawaii	20,000	10,000	10,000	40,000
Idaho	20,000	10,000	10,000	40,000
Illinois	231,000	115,500	115,500	462,000
Indiana	110,000	55,000	55,000	220,000
Iowa	57,000	28,500	28,500	114,000
Kansas	49,000	24,500	24,500	98,000
Kentucky	75,000	37,500	37,500	150,000
Louisiana	90,000	45,000	45,000	180,000
Maine	20,000	10,0001	10,000	40,000
Maryland	89,000	44,500	44,500	178,000
Massachusetts	116,500	58,250	58,250	233,000
Michigan	183,000	91,500	91,500	366,000
Minnesota	85,000	42,500	42,500	170,000
Mississippi	50,000	25,000	25,000	100,000
Missouri	100,000	50,000	50,000	200,000
Montana	16,000	8,000	8,000	32,000
Nebraska	32,000	16,000	16,000	64,000
Nevada	20,000	10,000	10,000	40,000
New Hampshire	20,000	10,000	10,000	40,000
New Jersey	152,500	76,250	76,250	305,000
New Mexico	30,000	15,000	15,000	60,000
North Carolina	16,500	63,250	63,250	253,000
N. Dakota	13,500	6,750	6,750	27,000
New York	355,000	177,500	177,500	710,000
Ohio	215,000	107,500	107,500	430,000
Oklahoma	66,000	33,000	33,000	132,000
Oregon	54,000	27,000	27,000	108,000
Pennsylvania	240,000	120,000	120,000	480,000
Rhode Island	20,000	10,000	10,000	40,000
South Carolina	67,500	33,750	33,750	135,000
South Dakota	14,000	7,000	7,000	28,000
Tennessee	96,000	48,000	48,000	192,000
Texas	335,000	167,500	167,500	670,000
Utah	33,000	16,500	16,500	66,000
Vermont	10,000	5,000	5,000	20,000
Virginia	115,000	57,500	57,500	230,000
Washington	90,000	45,000	45,000	180,000
West Virginia	40,000	20,000	20,000	80,000
Wisconsin	95,000	47,500	47,500	190,000
Wyoming	10,000	5,000	5,000	20,000
Totals	4,796,500	2,398,250	2,398,250	9,593,000

DES ACTION

These are the sources DES Action has used in estimating the number of DES exposed mothers, daughters, and sons in the United States.

Cancer (a journal), 1973: The Boston Collaborative Drug Surveillance Program (Boston University Medical Center consulted with two pharmaceutical market research firms and arrived at the following national figure: An average of 2.5 million prescriptions for DES were written each year between 1960 and 1970, of which 100,000 each year were for pregnant women. That would be a total of 1 million prescriptions for pregnant women during the last decade of approved use of DES, when use was reportedly declining.

Request for Proposal from the National Cancer Institute, establishing the DESAD Project (December 1, 1973): "...among 62 million births during the potential exposure time (1943-1959), there would be 31 million females, of whom 2.8 million have been exposed to estrogen in utero, and 1.9 million to synthetic estrogens."

This is the estimate used by the DESAD project. It assumes 1.9 million females, therefore there would also be 1.9 million males during those years for a total of 3.8 million children. Add to that the 1 million prescriptions from 1960-1970 and the total is 4.8 million children plus the same number of mothers, for a total of 9.6 million people exposed.*

Cynthia Orenberg in DES: The Complete Story, 1981, p. 36: "Dr. Herbst and his colleagues have conjectured that 10% of all pregnant women received DES between 1951 and 1960, with that figure dropping to less than one percent during the following decade."

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

July 28, 1992

The Honorable John Dingell
Chairman, Committee on Energy and Commerce
House of Representatives
Washington, D.C.

Dear Mr. Chairman:

The purpose of this letter is to present our views on H.R. 4178, as reported by the Subcommittee on Health and the Environment, which would authorize research programs on the long-term effects of diethylstilbestrol (DES). The Administration does not object to this legislation.

Between 1941 and 1971, DES was prescribed for some pregnant women to reduce their risk of miscarriage. The drug, however, has been linked to cancers and other reproductive difficulties in the daughters, and genitourinary abnormalities in the sons, of mothers exposed to the drug. H.R. 4178 would authorize such sums as necessary over three years for professional and public education concerning, and longitudinal studies of individuals exposed to, DES.

We strongly support initiatives aimed at furthering our knowledge about the long-term effects of DES, and we therefore do not object to the bill's favorable consideration. The National Institutes of Health (NIH) is currently reviewing its DES research portfolio, and recommendations for further research from an April 1992 workshop sponsored by NIH will be published shortly. That agency will continue to increase its efforts in this research area, and will work with other public and private organizations to develop a comprehensive strategy for this program.

We are advised by the Office of Management and Budget that there is no objection to the presentation of this report from the standpoint of the Administration's program.

Sincerely,

Louis W. Sullivan

Louis W. Sullivan, M.D.

to get out of this
o? Stand in front

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until landing a
comedy feature
he and his wife

USA TODAY Life

By Marissa Roth

BELIEVE I
Broadway

who sang in 'The Rothschilds' on
d feature 'Beauty and the Beast.'

are addi
for th

grow a mustache and slick my
ck, I do look older," he says. In
e adds, without the "goo" he's
utting on for the movie, "I have
ray hairs than you'd believe."

MONDAY, NOVEMBER 25, 1991

women, 20 to 70 yea
ate a wheat cereal daily for six
weeks, switching then to six
weeks of oat bran. The other
half ate a diet with 30% or less
of calories from fat.

Among findings:

▶ LDL — the bad cholesterol — dropped for those eating oat bran, rose slightly for wheat cereal eaters and more so for those on the low-fat diet.

▶ LDL fell 15 points for older women eating oat bran. That "can lower their heart attack risk," Ripsin says. Men under 50 had an eight-point drop.

▶ Cholesterol dropped most for those at 225 or higher (200 is borderline, 240 is high).

"Oat bran does lower cholesterol — not by a lot in people overall, but enough to help older women and those with higher cholesterol of all ages," Ripsin says.

COVER STORY

Women, DES and decades of desolation

Pulling drug 20 years ago didn't end an inheritance of cancer and miscarriages

By Kim Painter
USA TODAY

Susan Simpson was just 19 when she went for her first pelvic exam, learned she had cancer — and was told the cure would mean removal of her ovaries, uterus and vagina.

Today, at 35, she's a successful accountant who sings at church services and weddings in Macon, Ga. She is cancer-free.

But she's not over her illness. Every time Simpson urinates she must insert a catheter in her urethra. When she starts a serious relationship with a man, she must explain that she cannot have children and that her reconstructed vagina is not quite the same as other women's. And, every day, she must deal with her anger. That anger is shared by countless U.S. women who've suffered genital cancer, miscarriages and other reproductive difficulties because, scientists say, their pregnant mothers took diethylstilbestrol — DES — a synthetic hormone meant, ironically, to prevent miscarriages.

"I've come to terms with it now and I have people in my life who are supportive and really good friends," says Simpson, who is divorced. "But, damn it, I shouldn't have to deal with it."

The Food and Drug Administration banned DES use by

Please see COVER STORY next page ▶

By Jim Ruymen

LINGERING ANGER: Cancer survivor Susan Simpson, 35, had her reproductive organs removed after her diagnosis at age 19.

Where to get information

For information on DES-related cancer, write the DES Cancer Network at P.O. Box 10185, Rochester, N.Y. 14610. For other information on DES, write DES Action USA at 1615 Broadway, Oakland, Calif. 94612.

SCHWARZKOPF SPEAKS: Stormin' Norman, right, goes into the studio with conductor Leonard Slatkin to narrate the late Aaron Copland's 'Lincoln Portrait,' featured on 'American Portraits,' due in February from RCA Victor.

Emma Samms filed divorce papers in Los Angeles last week. She and Bansi Nagji married Feb. 23 in London and cite irreconcilable differences as grounds for divorce. . . . Gonzo journalist **Hunter S. Thompson** has turned artist. A 12-piece series is on display in Aspen, Colo. One is a poster of late FBI Director J. Edgar Hoover, riddled with bullets and splashed with red paint.

COVER STORY

Diagnosis meant fear, humiliation

Continued from 1D

pregnant women 20 years ago this month, soon after researchers linked the drug to a rare cervical and vaginal cancer in daughters of women who took it. But the ban came 30 years after well-meaning doctors began prescribing DES to an estimated 3 million pregnant U.S. women.

About 300 companies sold DES for miscarriage prevention. Those companies — still fighting lawsuits — insist the statistical link between DES and the rare cancer doesn't prove it caused the cancer.

That link first came to light in early 1971, when doctors at Massachusetts General Hospital in Boston reported the rare vaginal and cervical cancer, called clear cell adenocarcinoma, in eight girls and women ages 14 to 22. They had one thing in common: Their mothers took DES during pregnancy.

Since then, scientists have discovered structural abnormalities in the reproductive organs of women — and some men — whose mothers took DES. DES daughters also have high rates of menstrual problems, tubal pregnancy, miscarriage and premature delivery. As many as half have some reproductive problem, research suggests.

The vaginal and cervical cancer is, by comparison, rare, affecting 1 in 1,000 DES-exposed daughters. Since 1971, Dr. Arthur Herbst of the University of Chicago, one of the doctors who found the original eight cases, has counted 580 clear cell cancer cases and documented DES exposure in 62%. The remaining cases likely include some that are DES-related and some that are not, Herbst says.

About 80% of DES-exposed cancer victims survive. But because the cancer strikes such young women — the risk peaks at age 19 — and because it is so devastating, it is perhaps the most disturbing legacy of DES.

Margaret Lee Braun, diagnosed at 19 and now 39, has lived with that legacy for 20 years.

"Just as you are discovering a sense of your own sexuality, you receive a kind of physical and psychological blow that few people have ever tried to cope with," says the cofounder of The DES Cancer Network. "In a sense, you're a reluctant survivor. You're harmed by medical technology and then saved through medical technology, through this very radical treatment in which your insides are either fried out, so nothing functions properly again, or your insides are cut out."

Braun, who lives in Rochester, N.Y., with her husband of eight years, had surgery — removal of her vagina, uterus, ovaries and bladder, followed by vaginal reconstruction. For a long time afterward, she couldn't talk about what had happened.

"It is so hard to say the word vagina," Braun says. "Women don't even want to say where it happened."

Then, several years after her surgery, Braun began to meet other survivors who, like her, were suing DES makers. The women shared medical and legal horror stories and talked about how they got on with their lives.

Those discussions led to the formation of the network, which publishes newsletters, lobbies health officials and holds annual meetings for the far-flung survivors.

The most recent meeting, held in Los Angeles in October, attracted 25 women — all with painful stories to tell.

One was Georgiann Kensinger, a 32-year-old Los Angeles divorcee who was diagnosed at 15.

"I remember wishing at the time that I had brain cancer," she says. "There were 10 doctors at a time coming in and oohing and ahhing over your cervix. It was not only terribly frightening, it was humiliating."

Network co-founder Susan Helmrich, now 36 and living in Berkeley, Calif., with her husband and adopted son, was 21, just out of college and planning medical school when it happened to her.

"My first question was, 'Was it serious?' My second question was 'Would I be able to have children?' The doctor said 'no' and I cried. It seemed so unreal to me," says Helmrich. She became a health researcher instead of a physician.

Marsha Mainzer, 38, a divorced real estate appraiser from Virginia Beach, Va., was 17. Her parents refused to let doctors remove her reproductive system.

So she got radiation treatment. "I was literally fried inside. My ovaries died. My fallopian tubes shriveled up. I found out I was born without a vaginal canal up high, as a result of the DES. My uterus is still there."

The treatment blackened the skin on the lower part of her body and damaged her colon. Eventually, Mainzer had to have a colostomy, an operation that allows discharge of feces into a disposable bag worn outside the body.

Difficulties with bladders, colons and reconstructed vaginas are common among survivors, says Dr. Leo Lagasse, a gynecological cancer specialist who spoke at the meeting and practices at Cedars-Sinai Medical Center in Los Angeles. However, he says, surgery and radiation techniques have improved considerably in the past 20 years.

Like all cancer survivors, survivors of this cancer live with the fear of recurrences. New cases have been reported up to 20 years after the initial cancer. Network members want to know how common such cases are.

They also want to know how many of their DES-exposed sisters are still at risk. Initial cases, still occurring, have been reported in exposed women as old as 41.

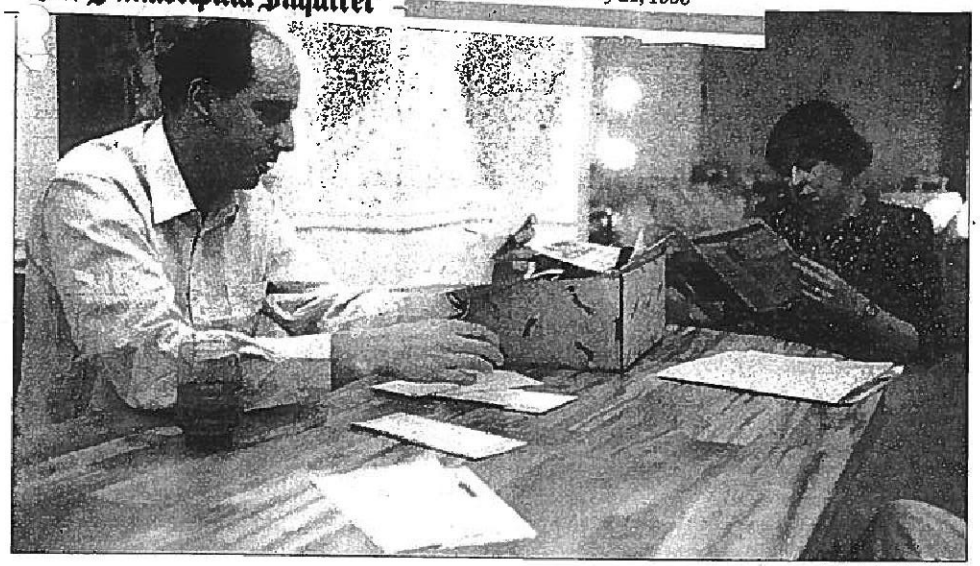
Other important questions — such as whether mothers who took DES have an increased breast cancer risk — have not been answered, Braun says.

The "myth is that the DES story is over," Braun told officials at the National Institutes of Health last spring. She hopes the government's new emphasis on women's health research will bring the spotlight back to DES, which has attracted little research money in recent years.

In any case, she and her fellow survivors, long silent, will keep talking.

"This kind of thing should never have happened to us," says Simpson, the Macon church singer. "It should never have happened to women."

The Philadelphia Inquirer Thursday, January 21, 1993



For The Inquirer / JERRY TRITT

Michael Freilick hadn't even heard of DES when he first got cancer 10 years ago. Now he runs an informal support network from his Cherry Hill home to get information to other DES sons. His wife Carol helps with a newsletter.

No one talked about the pregnancy drug and sons. A victim is breaking the silence.

DES survivor speaks up for others

By Maureen Fitzgerald
INQUIRER CORRESPONDENT

Ten years ago, Michael Freilick was recovering from testicular cancer surgery that sliced him open from his neck to his groin, when the television in his hospital room blew out. And he lost it.

He ripped the catheter from his chest, flew out of bed, grabbed a bottle from his dinner tray and hurled it through a window. Glass shattered. Nurses dashed into the room. "I can't stand it," he shrieked.

"I blew up. It was a low point," said Freilick. "Not knowing who to blame, not knowing if I'd be alive in a month, not having anyone to talk to. . . . I felt very desperate and alone."

Freilick is a DES son. His mother took the synthetic estrogen drug diethylstilbestrol, which has been linked to miscarriages and uterine cancer in daughters of women who took it and may be associated with fertility problems and testicular cancer in sons.

Before he got sick, Freilick had never heard of DES. He had never even heard of testicular cancer. But today, at 39, and completely cured of cancer, he is the national spokesman for DES sons, an informal support network for an estimated two million men who have been exposed to DES. He has been operating the network out of his Cherry Hill home since 1985.

It is the horrible memories of frustration, of not knowing whom to talk to and whom to believe — along with his ultimate triumph over cancer — that have transformed Freilick from a painfully shy and introverted man into a national spokesman.

He now answers phone calls and letters from people all over the country, does speaking engagements and media interviews, and provides information and support to other DES sons and their wives and mothers. His most important message to men, he says, is self-examination, because testicular cancer can be one of the most deadly cancers, but it is also one of the most curable if detected early.

"Men don't like to talk about this kind of stuff," said Freilick. "I talk about two words men don't like to discuss, *testicle* and *cancer*. . . . It's too personal; it's a matter of pride."

"I couldn't have imagined doing this before I got sick. I was really shy, really quiet, kept to myself. I didn't have a lot of friends," said Freilick, a tall and lanky man who is still not completely comfortable talking about himself and his personal odyssey.

"But I knew how much I needed someone to talk to. I guess I figured, hey, I had cancer. I

See DES on B4

DES son shares data, support with others

DES from B1

beat it. I can do anything. I am a stronger person than I realized."

And the fact is, there really is very little information out there about DES sons, he said.

"They have been doing studies on the DES daughters for 20 years, but very few DES sons have been studied, so you can't really come out and say definitively that fertility problems or testicular cancer are related to the drug. But my feeling is, if the drug affected the daughters, why wouldn't it affect the sons?"

DES was widely prescribed to pregnant women in the United States from 1941 until 1971 to prevent bleeding and miscarriage. It was later proved ineffective in preventing miscarriage, and was banned by the federal government in 1972 except to prevent conception in emergencies such as rape or incest.

DES daughters have higher-than-average rates of miscarriage, tubal pregnancy and pre-term delivery, and about 500 cases of a very rare form of cancer — clear cell adenocarcinoma — have been linked to DES exposure in daughters.

Studies of DES sons have documented a higher-than-average incidence of epididymal cysts and, to a lesser degree, cases of extremely small penises, extremely small testicles and undescended testes.

Increased fertility problems as a result have never been scientifically proven; neither has an increased incidence of testicular cancer. Indeed, many doctors remain unconvinced that DES affected sons.

However, as DES sons advance through their child-bearing years and fertility data is available, some new studies are underway.

Dr. Allen Wilcox, of the National Institute of Environmental Health Sciences in Research Triangle Park, North Carolina, recently completed a study of fertility rates of DES sons, but has not yet analyzed the results.

And the National Cancer Institute recently awarded $3 million in research grants for follow-up studies on people exposed to DES, and many of the studies include DES sons.

Since 1985, when Freilick started the informal network, he has received hundreds of letters and phone calls from DES sons, wives and mothers requesting information. Some ask if fertility problems can be attributed to DES. Others talk about health problems, and more than a few have asked about testicular cancer.

"A lot of people are looking for a referral to a urologist who can answer their questions. But the thing is, there really is no national expert," said Freilick. "There is no one doctor to refer them to, and there is no evidence out there to say whether or not what they have is related to DES."

What does help is just to talk, especially to someone who is a DES son, who has had the same questions, who has been through their worst fear — testicular cancer — and survived.

"I've read letters that have brought me to tears," said Freilick. "I've been on the other end of the phone and heard the desperation — a guy who doesn't care if he lives or dies — and I've been there."

Freilick learned shortly after he became sick that his mother had taken DES.

In January of 1983, he first discovered a lump in his testicle, a discovery that launched a two-year ordeal of hospitals; surgery; chemotherapy cycles of five days on, two weeks off; desperate days and sleepless nights.

"They told me it was 95 percent curable, but I don't think I believed them." Especially after a testicle had been removed and he had completed chemotherapy, and then another tumor was found in 1984, this one in his abdomen, the size of a grapefruit.

It was after the second operation, at Memorial Sloan-Kettering Cancer Center in New York, when another cancer victim came to talk to him.

"I remember this guy said, 'If you want me to leave, I will,' and I said, 'Why don't you stay.' And he ended up staying like an hour. It was so good to be able to talk to somebody who had been through what I had been through."

After Freilick got out of the hospital with a clean bill of health, he decided to start volunteering for the Philadelphia chapter of DES Action, a national support and information network for women and men. It was here that he and another male DES volunteer, Fran Lawler, decided to start a network and support group for DES sons. After awhile, Lawler started forwarding all the mail and phone calls to Freilick, who became the spokesman.

"I had to force myself to talk to a reporter the first time," Freilick said, "It wasn't easy, but I felt it was so important for the message to get out."

"I was such a shy person," he continued. "I really kept to myself. I felt inadequate. But having this life-threatening illness really helped me to put things in perspective."

Freilick, who had supported himself through telemarketing sales, moved into a face-to-face sales job after his illness, selling hardware products to retail stores.

"My whole personality changed," he said. "I realized I could do this stuff," he said. He also gained confidence with women, realizing that he could talk to women and go on dates.

Seven months ago, he got marr

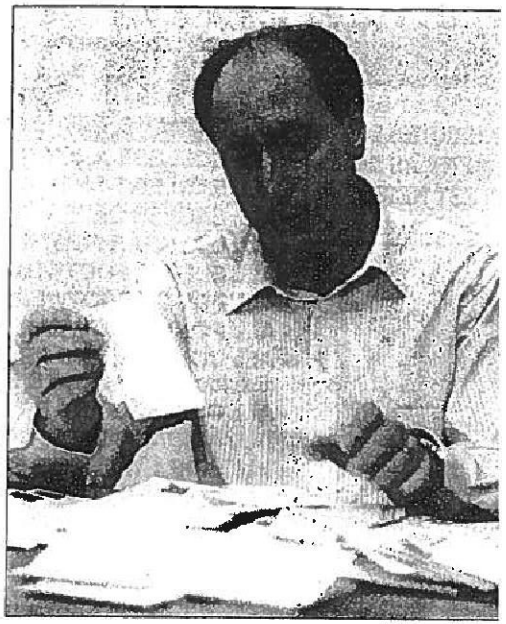
"It's still not easy for him," said wife, Carol. "It is still a very e tional thing for him. . . . But I th once you've been through someth like that it changes you. Yo never the same."

Freilick now speaks to health c es at Cherry Hill East High Sch twice a year, explaining DES and ing about testicular cancer, stres the importance of self-examinati

Although some of the guys squ in their seats and cover their gr when Freilick speaks, they do lis

"Just like women have to exam their breasts for lumps, men hav learn to examine themselves. Te ular cancer can be one of the r deadly forms of cancer becaus the way it can spread through y body so quickly," he said. "But it percent curable if it is caught ear

One reason Freilick is such an fective speaker: He's living pro



For The Inquirer / JERRY

Michael Freilick, a DES son, found the strength to overcome testicular cancer. Then he found the courage to talk about it.

DES: Living with a time bomb

Much more research and education are needed to help these victims of a pregnancy 'wonder drug' that turned into a nightmare.

At 43, Alice Hooper has had three difficult pregnancies, including one miscarriage and two premature births.

She suffers mysterious "aches and pains," which seem to indicate autoimmune disease, and she worries about an increased risk of getting cancer as she gets older.

Alice is a DES-exposed daughter, one of millions of baby boomers, now in adulthood, whose mothers took the powerful synthetic hormone drug while pregnant.

By Rep. Louise M. Slaughter, D-N.Y.

Until DES was banned in 1971, it was widely prescribed for more than three decades as a wonder drug that could produce complication-free pregnancies and "bigger and stronger" babies.

But instead of wonders, DES has produced nightmares for at least 10 million Americans exposed to it.

DES is now linked to a variety of health problems including infertility, pregnancy problems and cancer in DES daughters, increased risk for breast cancer in DES mothers, and infertility and possibly testicular cancer in DES sons.

Like many DES-injured Americans, Alice considers the drug "a time bomb" that not only endangers her own health but also may threaten her two children — a son, 11, and a daughter, 9.

"I have a lot of questions about DES," she says, "but unfortunately there don't appear to be any answers."

No one can answer Alice Hooper's questions authoritatively because no one has done enough research. Wednesday, in fact, the National Institutes of Health will convene its first multidisciplinary conference on DES — exactly 21 years after publication of the first study linking DES to a rare form of cancer.

To make up for two decades of neglect, I have introduced legislation to establish a program of health professional training and public health education so that DES-exposed Americans can find out about their health risks and so that physicians can detect these health problems early.

Until now, no comprehensive attempt has been made to reach out and inform the public about DES. The last government pamphlet on DES, published in 1983, has long since gone out of print.

In addition, my bill would support research to answer the many questions that persist about DES.

For example, how many Americans have been exposed? No one knows for certain, but estimates range as high as 18 million.

What is the full impact of DES on men? Research indicates a threefold increase in genital tract abnormalities among DES sons.

And, of course, there is Alice Hooper's haunting question of DES' potential impact on still another generation of children born to DES daughters and sons.

We do not know whether DES causes genetic damage, but some children of DES daughters have been born with severe handicaps including cerebral palsy as a result of DES-related reproductive abnormalities in their mothers.

One thing we know for sure: The dearth of DES research and education has perpetuated the suffering of the DES-exposed.

The fear and outrage being expressed today at the shocking revelations about silicone breast implants is, in many ways, exactly what DES-exposed men and women have been suffering in virtual silence for the past 21 years. But it's never too late for the truth.

The bottom line is the right to know. Keeping a person ignorant won't keep them alive.

PROMOTING DES: Ads such as this one in 1957 helped sell women on DES as a "wonder drug."

Hold drug makers criminally accountable

Lawsuits are inadequate punishment. Why aren't the executives who made DES and silicone implants arrested and tried?

I am a walking time bomb.

I discovered this 13 years ago, during a routine gynecological exam. The doctor said my condition is rare and primarily found in women whose mothers took diethylstilbestrol, or DES, a drug given to at least 2 million women between 1940 and 1971 to prevent miscarriages.

Five years, four doctors and two miscarriages later, I would discover that I have permanent reproductive disorders and an increased risk of cervical cancer, which keeps ticking away inside my body as well as my mind.

My mother took DES in 1955 — two years after a study that proved DES did not prevent miscarriages. The companies also knew it was potentially deadly to the offspring of DES mothers, but hid this from the public until it was linked to a rare type of cervical cancer and removed from the market. Most of the victims, some of whom died, were teenagers.

The makers of silicone breast implants are just the latest on a growing list of companies to make headlines for such unscrupulous practices. They should be held responsible for their actions. Yet, they simply walk away.

By Maxine Kopel Bookbinder, an Amherst, N.Y., writer currently living in Europe.

No arrests. No penalties. No apologies. No conscience. To them, it's a financial decision; potential liability vs. potential profit. It boils down to a cool, calculated spreadsheet bottom line. If a profit can be made after a victim is paid off by the insurance company, then it's still a worthwhile business venture.

But as a victim of this spreadsheet philosophy, I say enough is enough.

These companies are getting away with murder — literally.

Somewhere, behind the polished desks and pin-striped suits, are real people making the decisions to sell products they know are dangerous. Civil suits are filed and settlements are made. And business goes on as usual.

But companies don't make decisions, people do. The company president, chairman of the board and other top executives must be held responsible. They must be arrested and tried by a jury.

I want to see real people and to hear their names. I want to see them on the nightly news trotted off to criminal court on the arms of their attorneys. I don't want to hear about their company's quarterly earnings and market-share value.

What they are doing is a crime. They are no different from assailants who stab or shoot their victims. The only difference is they don't have to watch us suffer.

Until Congress, the president or the American people ensure that justice is done, corporate heads will continue to hide the truth as long as the courts look the other way and the insurance companies clean up the mess.

And that may be the biggest crime of all.

Recommendations:
Regular testicular self-examination
Examination by physician.

2) Daughters:
More frequent genital abnormalities
- Adenosis - benign condition in up to 90%
- Structural changes - cervical collar or hood, "T-shaped uterus"
- Cancer: clear cell adenocarcinoma of the vagina and cervix - 1 in 1000, ages 7-41 reported; also cervical cancer
- Infertility, with many possible reasons
- Pregnancy: "higher risk"
  - 5 times extopic pregnancies (life-threatening)
  - 2X miscarriage or stillbirth
  - 3X premature labor and delivery

Recommendations:
Special gyn exam every 6 months/one year which should include the following:
- careful visual inspection
- palpation of vaginal wall
- pap smears, cervix and vagina
- iodine staining
- colposcopy
- biopsy may be indicated

Best to avoid oral contraceptives

3) Mothers:
- Over 40% increased risk for breast cancer seen in some studies
- Possibility of other endocrine-related cancers
- Emotional difficulties, esp. guilt

Recommendations:
- Regular monthly breast self-exam
- Annual mammogram

4) Emotional responses in general:
- Feelings of isolation
- Fear
- Resentment
- Anger

LITIGATION

There are no class action suits against the drug companies in the United States, nor are there likely to be. In order for a class action to proceed in the courts, a judge must first certify that a genuine "class" exists under the meaning of the statute. Class actions are designed to save time and money by, for example, joining suits for similar injuries into one suit. In the case of DES, the spectrum of injury is very broad. On the one end are DES daughters with adenosis and annual medical bills for their regular exams, but no other physical changes that they are aware of. On the other end are DES daughters with cancer or with other serious problems such as T-shaped uterus, infertility, still births, miscarriages, and ectopic pregnancies.

Accordingly, DES daughters who do have injuries are suing, under product liability laws, as individual plaintiffs. These are contingency cases: they do not cost you anything unless the suit is successful. But, that means lawyers cannot afford to take cases unless they believe that they can win. The categories of suits currently being taken by lawyers are for cases of cancer, infertility, and "pregnancy disaster" - ectopic pregnancy, miscarriage, premature birth and stillbirth.

These cases are very complicated both medically and legally, and laws vary from state to state. For these reasons plaintiffs need a knowledgeable attorney with experience in DES litigation. DES Action has an attorney referral list and if you need a referral, please send a stamped, self-addressed envelope to our West Coast office.

DES ACTION Pennsylvania

Mary Jean Greco Golomb
Pennsylvania State Chairwoman

P.O. Box 286, Nescopeck, PA 18635-0286
1-717/759-8365 FAX 1-717/752-6717

What is DES ?

Diethylstilbestrol

A Powerful Synthetic Hormone
To Prevent Miscarriages

•

Prescribed From 1941 Until 1971

•

Affects 8 Million People

USA

East Coast Office:
L.I.J. Medical Center, New Hyde Park, NY 11040
1-516/775-3450

West Coast Office:
1615 Broadway, #510, Oakland, CA 94612
1-415/465-4011

FACTS ABOUT DES

- Diethylstilbestrol (DES), a powerful synthetic hormone, was given to prevent miscarriage to an estimated 4.8 million women in the United States from 1941 to 1971 and beyond, despite reports from as early as 1953 (University of Chicago study) that the drug was ineffective for this purpose.
- There are about 2.4 million DES daughters and the same number of DES sons in the United States. DES was also used in other countries, and on U.S. military bases worldwide.
- Approximately one out of every 1,000 DES daughters will develop a rare vaginal cancer from her DES exposure. The age of greatest risk is from 15-22, although DES daughters up to age 41 have developed this cancer. DES daughters also have twice the rate of dysplasia (abnormal cervical cells) as other women. This can, in some cases, be a pre-cancerous condition.
- The problem affecting the greatest number of DES daughters is that of reproduction. Up to half of all DES daughters will have some kind of difficulty, including infertility, ectopic (tubal) pregnancy, miscarriage, and premature delivery. About 80% of DES daughers who want children will eventually have at least one child.
- Some studies have shown an increased risk of genital problems and infertility among DES sons.
- DES mothers are at somewhat higher risk for breast cancer than are mothers who were not given the drug.
- Because of their cancer risk, DES daughers must have special screening examinations by doctors trained in the techniques needed to detect this rare form of cancer. Because of pregnancy risks, DES daughters need high-risk pregnancy care. All this means added worry and medical expense.
- DES is currently authorized for use to treat certain types of cancer, as estrogen replacement treatment for menopausal women, and for prostate cancer. It is *not* authorized for use to suppress lactation in women who choose not to breastfeed; as a postcoital contraceptive (morning after pill), or in animal feed.
- Research studies show a greater risk of permanent impairment of the immune system in DES exposed people. More research is needed for possible effects on other body systems.

BASIC DES INFORMATION

Information: try to learn as much as you can about DES and the health effects of DES exposure. The publications from the national office provide a good overview. There are also some good books on DES, including:

DES: The Complete Story, by Cynthia Orenberg, (avail. from office).

Women and The Crisis in Sex Hormones, by Barbara Seaman, (avail. from office).

Worse Than the Disease: Pitfalls of Medical Progress, by Diana Dutton.

When Technology Wounds: The Human Consequences of Progress, by Chellis Glendinning.

The latter three books include sections on DES.

Here are some basic facts about DES exposure:

BACKGROUND:

1) From 1941-1971 DES was prescribed during pregnancy to "prevent miscarriage." It was prescribed to women who had
- a previous miscarriage
- slight bleeding during pregnancy
- diabetes
- other conditions, at doctor's discretion.

2) In 1953 a study by Dieckmann et al, University of Chicago, showed that DES was ineffective in preventing miscarriage. This had little effect, however, on its distribution and use.

3) DES was used in the following forms:
- prescription pills—over 200 brand names as estrogen and vitamin supplements which included DES.
- injection
- vaginal suppository

4) Key research articles:
- Dodds, 1938, England. Scientist who first developed DES (first synthetic estrogen).
- The Smiths, 1948-49, Harvard. Husband-and-wife team who developed the "Smith regimen" which was widely used for dosages of DES.
- Dieckmann et al, 1953, U. of Chicago. Article showing DES ineffective in preventing miscarriage.
- Herbst et al, 1971, Boston. Article in New England Journal of Medicine which revealed that DES caused clear cell vaginal cancer in seven young women whose mothers had taken DES.

DES EXPOSURE
IN U.S. POPULATION: 9.6 MILLION PEOPLE

1) Mothers: 4.8 million (½ of exposed population)
Sons: 2.4 million (¼ of exposed population)
Daughters: 2.4 million (¼ of exposed population)

Not all women who took DES had successful pregnancy outcomes, but many took DES during more than one pregnancy. Thus, the correlation of numbers of DES mothers and offspring is considered to be 1:1.

2) DES prescribed widely in U.S. military, both at home and abroad. Special concern here is how to obtain medical records.

POSSIBLE EFFECTS OF EXPOSURE TO DES

1) Sons:
- More frequent genital abnormalities
- Undescended testicles: higher risk for testicular cancer.
- Epididymal cysts
- Malformed sperm, decreased sperm motility
- Fertility problems

Note: Research on sons has been very limited and many questions remain unanswered.

Hundreds of thousands of women have been fitted with silicone breast implants since they were first placed on the market over ten years ago. But what these women didn't know was that Dow Corning, manufacturer of the implants, had known of problems with "bleed" since May of 1975 -- a problem which led to painful, debilitating tissue disease. The few lawsuits against Dow Corning were quietly settled under secrecy agreements; meanwhile, women continued to receive the implants at the rate of 150,000 every year until they were pulled under a temporary moratorium by the FDA.

"Any general release of this [the bleed problem] data could be misrepresented or misconstrued, and could result in severe repercussions in the public sector."

- Dow Corning internal memo
March 28, 1977

VOICE

Anti-Secrecy Agreement Movement Grows

Consumer rights activists and survivors of dangerous drugs and products are gaining momentum in efforts to bar "secrecy agreements" in out-of-court settlements. Settling lawsuits too often hinges on plaintiffs agreeing to never publicly discuss the details or reveal the terms of their court cases. Some DES daughters have signed such agreements because it is the only way they can obtain any compensation for their injuries. Secrecy agreements, however, benefit the pharmaceutical manufacturers by allowing them to avoid public scrutiny and the appearance of wrongdoing. Other DES daughters who may be considering lawsuits are not able to learn about settlements and have a harder time assessing their chances for success.

The injuries caused by DES were discovered and made public by medical researchers and injured people themselves. For other drugs and medical devices, however, life-saving information has been withheld because of secrecy agreements. Corporations are able to continue selling products which have injured or even killed people because the record of destruction is sealed and protected by court order.

Last year the state of Florida enacted the "Sunshine in Litigation Act" which forbids courts from entering orders which conceal a "public hazard" or information about a public hazard. The Texas Supreme Court established anti-secrecy guidelines in 1990 as well. Recently DES Action spoke in favor of an anti-secrecy bill which is moving through the California legislature, and similar legislative efforts are underway in many states. More and more people have become aware of the need to put the public interest above corporate interests. DES Action will continues to support legislation which advances the public's right to know.

SECRECY HURTS CONSUMERS

Countless injuries and deaths could have been prevented if safety test records and documents, as well as records of settlements and judgments, had been made public and were accessible. There is no justification for allowing marketing considerations to outweigh public safety.

Hundreds of people have been badly burned, and some even killed, when their Bic lighters either failed to extinguish properly or exploded. Bic has denied responsibility but has refused to hand over design information, safety-test results, and records of complaints and accidents, unless access was limited to the current parties in a lawsuit. In many cases, Bic made secrecy a condition of settling lawsuits.

"America's courts are public, not private, institutions. Secrecy agreements undermine the public's right to know. And critical information hidden from the public can lead to human casualties."

- Ralph Nader

Over the last five years, scores of victims of fiery car crashes have filed lawsuits against General Motors, alleging the auto manufacturer knew GM gas tanks were vulnerable to puncture during high-speed crashes. The victims say these fuel leaks were well-documented by the company, which estimated the cost of fixing the tanks -- from $8.59 to $11.59 a car, by its own estimates -- was too high. GM has consistently used secrecy agreement procedures to keep closely held and controversial documents out of the public eye.

"There is no justification for auto manufacturers withholding safety information from the public. This legislation could result in saving lives and preventing injury -- a consideration that should be foremost in manufacturers' design and marketing strategies."

- Jim Miller
Victims Group Opposed to
Unsafe Restraints

SECRECY HURTS THE ENVIRONMENT

Secrecy orders can block attempts by scientists and health officials to monitor hazardous chemicals. Worse, information is grudgingly released only to plaintiffs in a lawsuit, and then sealed -- continuing the exposure of the public to environmental hazards.

In a confidential settlement, the Xerox Corporation paid two families in New York nearly $5 million in a case alleging that chemical leaks from a Xerox plant caused neurological damage to seven family members. Neighbors still living on the same street cannot obtain information about the hazards they still face -- even the family whose 12-year-old child just developed a rare form of cancer.

"The policy interests of the public and the environment must always be considered before the financial interests of a private company. We have to know more about these problems in order to stop them from happening again."

- Michael Picker, Director
National Toxics Campaign

In California, following an accident at Fiberite's Orange County plant, over 20 people developed serious complications including repiratory problems, liver disease and birth defects in newborns. Despite the potential gravity of the situation -- it happened next to a child care center -- Fiberite refused to settle the case unless all the information regarding the toxic incident was sealed in the process.

"Locking away vital health and environmental data serves no one, and throws up roadblocks to legitimate scientific inquiry into chemical and other types of contamination. The Sierra Club strongly endorses SB 711."

- Michael Paparian, Director
Sierra Club of California

SECRECY HURTS PATIENTS

Patients rely on prescription drugs for their recovery; sometimes, the drugs are instead their death sentence. Too often, pharmaceutical manufacturers knowingly continue to market dangerous products because the business cost of a recall or warning would be so great. They settle the vocal cases only if the plaintiff agrees to seal the file -- and with it, all records of the drug's dangerous legacy.

In 1985, McNeil Pharmaceutical recalled its painkiller Zomax from the market. According to an FDA study in the same year, Zomax was already a factor in 14 deaths and 403 life-threatening allergic reactions. Yet, McNeil chose to quietly settle lawsuits out of court to prevent the disclosure of information collected over the course of the lawsuits. As patients were suffering and successfully challenging McNeil in court, the company stepped up its marketing program.

> *"In order to seal cases, courts repeatedly sealed medical and scientific records, effectively shutting off access to vital technical information and preventing scientists from initiating research projects and publishing results."*
>
> *- Dr. Devra Davis, Toxicologist*
> *National Academy of Sciences*
> *Zomax allergic reaction victim*

SECRECY HURTS SENIOR CITIZENS

Vulnerable seniors are often dependent on their doctors' medical advice and on the drugs that are prescribed. Some companies have chosen to exploit this emotional and financial vulnerability through secret settlement cases in order to discourage additional justifiable lawsuits. This type of secrecy is perhaps one of the most appalling abuses of the civil justice system.

The Pfizer heart valve was taken off the market in 1986 after causing over 150 deaths, but is still implanted in some 50,000 people. Reports of the defective valve have been withheld from the medical community and the public because of protective orders requested by the manufacturer – orders which even prohibited forwarding information to the Food and Drug Administration. Pfizer has paid millions of dollars to settle many lawsuits in return for secrecy orders.

"I learned that Shiley, the company that makes the heart valve, had not provided any information about the problem to patients who had the valves...I learned that many of the patients had filed lawsuits against Pfizer..I learned that documents and information obtained in those lawsuits were never made public because of agreements or court orders which kept the information secret. I believe secrecy killed my wife."

- Fred Barbee, whose wife died when her Pfizer heart valve malfunctioned. Ten years after the first fatality, the Barbees were never notified of a problem.

Oraflex, an anti-arthritic drug, caused kidney and liver damage in many senior citizens. A senior staff physician for Eli Lilly, the manufacturer, knew of its harmful side effects. He instructed staff to change the findings in a scientific study on Oraflex to "play down" its harmful effects. Press kits were sent to over 6,000 newspapers, magazines, radio and TV stations to promote the "wonder drug." Three months later, 49 Americans, most of them senior citizens, were dead and nearly 1,000 injured. Eli Lilly sought protective orders to hide this prime example of corporate greed.

"Senior citizens are exposed to more drugs and medical devices than any other sector of society. Protective orders and secrecy agreements harm the public by keeping hazards quiet. Companies that do not have public hazards have nothing to fear by this legislation."

- Howard Owens, President Congress of California Seniors

SECRECY HURTS WORKERS

Knowingly exposing workers to unsafe working conditions is a criminal act, but settling with some employees in secret to avoid mass litigation is unconscionable. Secrecy agreements affecting the workplace can keep significant findings of health and safety hazards out of the public domain.

Workers at the Goodyear Tire and Rubber Co. filed suit after many of them developed cancer, claiming Goodyear knew many of the chemicals used in the tire-making process were toxic and even carcinogenic. In 1980, Goodyear sought and was granted a broad protective order covering every document it provided to workers. In 1986, Goodyear confidentially settled 34 of the cancer cases. It was not until 1989 that a federal judge overruled confidentiality restrictions on the health-related documents.

"It would have been so helpful for us to have (the chemical exposure document) so it could be used in a preventive manner."

- Louis Beliczky
Director of Industrial Hygiene
United Rubber Workers

In 1929, 11 employees of the Johns-Manville Corporation filed suit against their employer for asbestos exposure. During the trial experts testified about the dangers of silicosis and asbestosis, as well as the hazards that existed for those workers with pulmonary dust exposure. The Johns-Manville Corp. settled the extensive cases with secrecy agreements, safeguarding all public records about the dangerous diseases. It was not until the late '50s that the real facts about the diseases began to emerge.

"Only by documenting and publicizing hazards in the workplace can we be sure we are working together to make our work environment safe and healthy. Letting workers suffer or die because of a 'judicial loophole' is contrary to everything we have fought these last 20 years."

- Jan Chatten-Brown, Coordinator
WORKSAFE!

DRAFT Floor Statement
Sen. Herb Kohl
Open Court Records Act of 1992
7.24.92

Mr. President, I rise to initiate legislation to combat a growing problem: secret court settlements and confidentiality orders which hide vital information about public health and safety. As the recent silicone breast implant revelations dramatically illustrate, concealing health and safety hazards from public scrutiny can have tragic consequences for the American people. Indeed, a variety of product liability, toxic tort, environmental and consumer fraud cases -- in which manufacturer-defendants have made confidentiality orders a prerequisite for settlement -- provides further evidence of the chilling effect of judicially-sanctioned secrecy on public health and safety.

The increasing use of protective orders and secret court settlements in America provides clear and compelling evidence that the scales of justice are tipped unfairly against the public's right to know. Let me tell you why.

Revelations about breast implants are a timely and tragic example. By the early 1980s, scientists at Dow Corning were well aware of the potentially adverse effects, but safety and research memos were restricted from public access. Under an agreement reached in 1984, Dow Corning paid a seven-figure settlement to an

injured woman in exchange for her promise never to tell anyone about the suit or the internal documents. Regulators and citizens could have learned a decade ago about potentially fatal autoimmune reactions from silicone implants, had such crucial information not been protected and sealed from public knowledge.

Recent disclosures about the sleeping pill Halcion revealed a similar tragedy. The manufacturer Upjohn knew about the drug's dangerous side effects as early as 1972 but concealed its internal data from the Food and Drug Administration. Upjohn subsequently entered into secret court settlements, which allowed the company to hide this damaging data. Not until last year did the world learn that Upjohn had falsified and sealed this vital information from the public eye.

At the 1990 hearing on court secrecy that I chaired, we learned firsthand about the public hazards of secrecy. A resident of my home state of Wisconsin, Frederick Barbee, testified that his wife would be alive today if the manufacturer of a defective heart valve had not been allowed to keep safety-related information secret. We received written testimony from New York Attorney General Robert Abrams, who bemoaned a secret court settlement in which Xerox paid several million dollars to two Rochester families injured by the company's leaking toxic chemicals, in exchange for their promise of complete and total secrecy. Texas Supreme Court Justice Lloyd Doggett told us that

protection orders are now routinely requested -- and frequently granted -- in virtually every product liability, automobile design, toxic tort, environmental, medical malpractice, pharmaceutical, and consumer fraud case.

Mr. President, we should not eliminate confidentiality orders entirely -- as some have suggested -- but we must do something to ensure that this type of crucial information becomes public. We must create a safer society. To this end, I am introducing the Open Court Records Act of 1992 with my colleagues Senators Metzenbaum and Kennedy. It is simple, effective and narrow in scope.

The bill amends the Federal Rules of Civil Procedure and creates a new section of the United States Code to require public disclosure by the courts of all discovery, pre-trial and trial information which is "relevant" to the protection of public health and safety. The status quo -- where judges have no obligation to consider the public interest and which too often leads to the triumph of secrecy over safety -- is simply unacceptable. Private litigants are currently allowed to settle at the public's expense because defendants want to cut their losses, plaintiffs want a quick cash guarantee, and judges want to clear their dockets. Our bill would require trial judges to make a factual finding that public health and safety will not be jeopardized by granting a protective order. It is our hope that

this consideration will lead to a more appropriate balance between secrecy and disclosure.

Mr. President, a few special interest groups mistakenly claim that our legislative initiative could bottleneck the courts. They contend that our bill would discourage court settlements and lead to prolonged, costly legal battles. But, in fact, the opposite may be true: several states have passed more sweeping anti-secrecy legislation than we propose today, and the critics have been proven wrong. Justice Doggett recently reported that anti-secrecy legislation in Texas has created court openness without clogging the courts. Industry representatives warned that companies would leave the state, but they have not. New York Court of Appeals Chief Judge Sol Wachtler said recently that settlements have not declined in the face of a New York law restricting protective orders. Even Third Circuit Judge Joseph Weis, Jr. of the U.S. Court of Appeals, who testified at our court secrecy hearing against congressional modification of the Federal Rules, conceded: "I think it is interesting that Texas solved its problem by changing its rules of civil procedure, and I think that the Federal courts should be given the same opportunity."

Evidence at the state level reveals three main reasons why anti-secrecy legislation has reduced rather than promoted litigation. First, openness makes good economic sense. If the

information provided to one party is relevant to other parties in other cases, then sharing information between these parties may lessen the time and cost of litigation. Secrecy orders make every subsequent litigant reinvent the wheel, and this inefficiency makes lawsuits costlier for plaintiffs and defendants alike.

Second, state prohibitions on secrecy orders that harm public health and safety have not discouraged settlement because manufacturers settle for a number of reasons, such as to avoid the possibility of high jury awards, or to mitigate the high cost of litigation. Moreover, settling a case may reduce bad publicity since the damaging information is likely to receive even more publicity at trial.

Mr. President, how many deadly secrets lie buried in courthouse files? We don't know. But the Open Court Records Act of 1992, at the very least, will bring court secrecy out of the shadows and into the public light.

Going Public About Defective Products

Joan Claybrook

Consider the scene: A talented trial lawyer finally wins a three-year battle, forcing the manufacturer to pay significant damages to his client. The lawyer battled resistance to discovery, endless defense motions, and witnesses who would not fully answer questions. He survived unexpected costs for testing, days of searching through largely irrelevant government documents, and a skeptical judge. The lawyer has proved the product is defective. The brain-damaged client is compensated, and the files are sent to storage as the lawyer moves on to the next case.

What's wrong with this picture? In traditional litigation terms—nothing. But in today's environment, it might best be described as societal malpractice. And the reason for it is baffling. Why would trial lawyers, under siege in the press, in the legislature, and in the courts, fail to boast publicly about their achievements in products liability suits and take steps to convert their victories to public policy?

Most critics of the trial bar, of course, lodge the opposite complaint. They characterize trial lawyers as overly boastful about the cases they win. In fact, representatives of defendant corporations make a practice of ridiculing the "slick trial lawyer" who they claim manipulates the law and the jury to win a million-dollar award and takes a big chunk of the victim's damages in fees.

There is, of course, a method in this corporate message. Manufacturers who have been embarrassed by trial lawyers in case after case want legislators and jurors to think trial lawyers are villains, greedy pariahs on the make.

It is a testament to their public relations initiative that manufacturers selling harmful, defective products have so successfully conveyed their message. With constant repetition, they have convinced a significant segment of the public that the victim's lawyer, the advocate who takes cases on a contingent basis without any fee unless the plaintiff wins, is getting a windfall and is undermining the free-enterprise system.

Perhaps their message is taking hold because this debate on the function of the trial bar is not argued on meritorious grounds. In large measure, only one side of the story is being effectively presented because the trial bar is focused on speaking to the client and the jury, not to the public. And, unfortunately, when trial lawyers do talk publicly about their cases, they often speak of the size of the award as a shorthand way of showing the significance of the case, rather than explaining its substantive importance. As a result, the public does not understand the valuable mission of tort law. This is a prescription for disaster. Even though the courts are supposed to be removed from the irrational swings of public opinion, they are not.

If this denigration of the trial bar and tort law continues without any response, increasingly clients will be deprived of effective representation before juries. Also, courts will issue even more protective orders, state legislatures will eviscerate the tort system, and government agencies will ignore petitions for corrective action on products found defective in court cases. This is the power and the importance of public opinion.

Valuable Mission

The remedy for this state of affairs is for the trial bar to tell the world through the public media about its valuable mission and about the defective products it uncovers. This is no simple task, but it can and should become routine for members of the trial bar. The effort should include holding press conferences week after week in state after state as cases are concluded. The bar should warn the public about defective products and services; file petitions with government agencies asking for investigation and recall of particular products, for informative labeling, and for issuance of new safety standards; and urge affected companies to redesign their products and hospitals to adopt improved medical procedures.

If these efforts fail, more aggressive tactics can be initiated. These would include asking for help from members of Congress who oversee the relevant government agency, testifying before congressional hearings, appearing on televised debates or public affairs programs, or pushing public interest groups to sue government agencies to issue standards.

As a former regulator, I know that the facts trial lawyers collect on a product defect are usually far superior to those a government agency collects for an in-

Joan Claybrook is president of Public Citizen, a national public interest group in Washington, D.C. She is the former administrator of the National Highway Traffic Safety Administration.

vestigation. This is true for a number of reasons. Government agencies rarely use subpoenas—the type of official command that companies respond to with accuracy. At the urging of the recipient company and to expedite the response, many government requests for information are informal. Also, written government requests for information are usually prepared by scientists, engineers, or investigators, not lawyers, and thus contain unintended loopholes. Although it is a criminal violation to lie to the government, corporate lawyers are trained to obfuscate and to avoid supplying critical, incriminating information.

Further, because government agencies are authoritative decision makers, they can rely on their own data and analyses. By contrast, trial lawyers as advocates must persuade judges and juries with admissible facts. Thus, trial lawyers seek out every scrap of information to make the case, uncovering critical facts by lengthy discovery motions, detailed personal review of corporate documents, depositions (rarely used in government investigations), and eventually cross-examination at trial.

Often, the facts gleaned by trial lawyers are unknown to the regulatory agency. But, if known, these facts could result in a recall, a labeling requirement, or a safety standard. For all these reasons, trial lawyers are obliged to share their work product with the relevant state or federal government agency. The information will have a far greater impact if a lawyer informs the media as well. Trial lawyers must learn how to communicate their success stories to the press and the public.

Behind Closed Doors

Courtroom secrecy is another issue relevant to the ability of trial lawyers to inform government agencies of their work product. As trial lawyers have improved their discovery skills and their success in litigation, corporations have looked for schemes to avoid producing or disclosing "smoking gun" documents. During the 1980s, corporations have increased the use of three techniques: routine destruction of documents, secrecy requirements for settlements, and protective orders.

The trial bar should launch a concerted campaign with the public interest bar to limit these secrecy tools. Unless there is an organized effort, it will be almost impossible to effectively counteract the corporate maneuvers.

Destruction of documents. A number of companies, particularly larger ones, have adopted systematic programs for discarding certain types of documents—such as product-design reports or critical new product-test results. Some auto companies require disposal of key design documents within a year after initial production of a new vehicle. Some companies also label as "research" any safety-standard "compliance" tests its vehicles fail at the company proving grounds.

Some regulatory agencies prohibit disposal of relevant documents, but there is little consistency and no coordination among agencies. This problem is too critical to battle out case by case. By the time a case is litigated the damage has already been done. The trial bar should confront the issue, make recommendations to the state and federal governments and to professional and technical associations for a uniform law on document retention and attempt to seek sanctions in court in egregious cases if it is violated.

Even though the courts are supposed to be removed from the irrational swings of public opinion, they are not.

The Association of Trial Lawyers of America opposes secrecy requirements as a condition of settlement. But ATLA needs to exert some muscle to support its views.

Secrecy in settlement. Prohibiting discussion of the case or its outcome, requiring destruction or return of documents in the case, or limiting the trial attorney from taking similar cases should be prohibited. One effective way would be developing and adopting new state bar association rules that make requests for secrecy in settlements unethical.

Protective orders. They are now issued wholesale, and courts have become dangerously inured to their issuance. The trial bar is partly responsible, because many trial lawyers think in case-by-case terms rather than in policy terms. In the midst of fights over the availability of documents, many trial lawyers agree, albeit reluctantly, to protective orders. When the case ends, there is little incentive to try to remove them.

Plaintiffs' counsel should resist protective orders for many tactical reasons. They make it far more difficult to check the completeness and accuracy of the defendant's responses. They prevent consultation with other attorneys. They permit defendants to be inconsistent in responses in different cases because the protective order makes it impossible for plaintiffs to compare documents. They also limit the extent to which plaintiffs and their counsel can discuss cases with government regulators and the press.

Trial lawyers should object to any protective orders and insist that they not be issued unless the court clearly defines their necessity. Colorado attorney James Gilbert has written *Confidentiality Orders* (Wiley Law Publications 1988), an excellent book on how to resist and avoid protective orders. If a protective order is issued nevertheless, the lawyer then has a greater responsibility to seek the order's removal at the end of the case. As a last resort, if this is not successful, the attorney should inform the press, citizen groups, and the public at large about the order and encourage citizen groups or the trial bar to seek disclosure of the factual papers that were involved in the case.

Trial lawyers rarely if ever do this—or even consider doing it. Yet, there are citizen groups that would move to request disclosure on behalf of the public interest if only the groups were aware of the case.

In the past few years, Public Citizen filed motions in two different cases seeking disclosure of documents. Although the original cases were either settled or lost, Public Citizen secured disclosure of the documents on the basis of their value to the public interest. (*In re "Agent Orange" Product Liability Litigation*, 821 F.2d 139 (2d Cir. 1987) (motion filed to challenge seal that was part of proposed settlement agreement in 1984), and *Public Citizen v. Liggett Group, Inc.*, 858 F.2d 775 (1st Cir. 1988).)

Despite the involvement of Public Citizen in these two cases and its expertise and experience in securing public disclosure of information over the last 15 years, it has never been asked by a plaintiff's counsel to seek disclosure. As far as I know, no citizen group has ever received such a request.

Federal Preemption

Finally, defense counsel are employing a new tactic to prevent litigation of worthy cases. Defendants are asserting

federal preemption of state tort cases (where 95 percent of the tort cases are litigated), claiming that federal regulatory statutes prevent decisions by state courts. Whether valid or not, these motions are being given serious consideration by the courts. When they are successful, they stop the litigation regardless of the merits of the claim or the dangers posed by the product.

In many ways, preemption claims are the ultimate defense weapon because they put a new burden on the plaintiffs' counsel in an area of law in which few have expertise. And preemption claims take little effort for defense lawyers because counsel can prepare them wholesale. If this simple maneuver works, the case is over, leaving the plaintiff and the public vulnerable. Plaintiffs' attorneys need to jointly develop effective defenses to these motions much as Trial Lawyers for Public Justice has done regarding preemption claims in air-bag suits.

Without question, the trial bar performs an extraordinary service to the public. But it is not achieving the public policy impact that it can and should. Steps to achieve this larger societal effect are neither complex nor extraordinary. They require commitment and organization by the trial bar and a recognition that dissemination of information and resistance to secrecy is in the self-interest of the trial bar as well as of the public. There are not many win-win opportunities. This is one that trial lawyers should recognize and pursue. □

ATLA Member Named Lawyer of the Year

ATLA member Joseph Cotchett has been named Trial Lawyer of the Year by Trial Lawyers for Public Justice. Cotchett, of Burlingame, California, was honored because of his work to protect the average consumer.

Cotchett made legal inroads with his successful securities fraud suit against Technical Equities. He was also the lead attorney in the recent fight to preserve Proposition 103, the California insurance initiative.

Also chosen for the award was James Harrington, director of the Texas Civil Liberties Union. Harrington's recent successful suit against the state mental health department resulted in widespread reform in the state's mental health system. He has also won landmark suits for migrant farm workers. □

SPEAKING OUT

DEMOCRAT AND CHRONICLE, ROCHESTER, N.Y., WEDNESDAY, APRIL 8, 1992

Waiting and worrying

Lifelong effects of DES still coming to light

By Margaret Lee Braun

As horrible as it is to imagine the plight of women with silicone-gel breast implants, and worse to contemplate the fact that manufacturers knew about the risk, it is even more dismaying to consider that we might not learn from these mistakes.

In 1971 diethylstilbestrol (DES), an inadequately tested synthetic estrogen, was found to cause cancer and reproductive tract malformations in the sons and daughters of the women who took the drug. Like silicone implants, DES was a widely popular product, prescribed to 5 million pregnant women during a 30-year-period (1941-1971) to prevent miscarriage.

The internal nature of DES injuries can make the DES story less than vivid to the public imagination. But even as the breast implant story unfolds before us, the DES story is far from over. Ten million people in the U.S. have been exposed to DES. The majority are still in their 30s. They can relate to the breast implant tragedy: Many of them have felt like a walking experiment for years.

Although not everyone exposed to DES has had problems, hundreds of thousands of men and women have been terribly hurt by it. One health educator said, "If society were really to open the door on DES and look at it, case by case, an unbearable human tragedy would be revealed."

The DES story is a prototype of a wonder drug gone wrong:

- It is the DES mother who despairs of her innocent decision, 20 to 30 years ago, to take a drug prescribed in good faith by her doctor — and who now wonders if she'll ever have grandchildren.
- It is the DES daughter who has suffered repeated miscarriages, often at five and six months into her pregnancies, who knows that DES daughters have three times the risk of premature delivery, and wonders if she'll even get that far.
- It is the DES daughter diagnosed with clear cell cancer in her early 20s, whose entry to womanhood is marked by the removal of her vagina and reproductive organs.
- It is the DES son who is unable to get comprehensive information on how DES affects men — who worries if DES injuries will show up in later life.

LONG BEFORE the FDA approved DES for pregnancy use in 1947, there was ample evidence of its hazardous effects. In 1939 researchers reported that DES-exposed laboratory animals had structurally damaged reproductive organs. In the 1940s researchers warned that DES was carcinogenic. In 1953 a study of 2000 pregnant women reported that DES "has no beneficial effect whatsoever on the prevention of miscarriage." In fact more miscarriages occurred in the group of women prescribed DES.

Yet pharmaceutical companies aggressively marketed DES until 1971. At that time physicians at the Massachusetts General Hospital reported seeing teen-age girls with a rare, and often fatal, vaginal cancer. The girls had one thing in common: Their mothers had been prescribed DES.

Today, 21 years after we woke up to the consequences of DES, no one knows the whole story. Young women still die from clear cell cancer in 1992. And although a range of reproductive injuries has been described, there has been little research into how DES affects other body systems — endocrine, immune, and cardiovascular.

One question stands out: What will happen to the DES-exposed as they age?

Laboratory study after laboratory study shows that the effect of DES continues throughout the lifespan of DES-exposed offspring. Also the insufficient testing of the past, current DES research begs for our attention.

- Animal studies show an increased incidence of cancers in DES-exposed females at middle age.
- Animal and clinical studies show that the DES-exposed have evidence of impaired immune systems.
- Late recurrence of DES-related, clear cell cancer is being seen in young women eight to 20 years after their original cancer diagnosis. And the upper age limit for the development of the cancer, once thought to be 27, is now considered unknown. DES daughters have developed it in their 40s.

YET FOLLOW-UP studies of people exposed to DES have drastically declined. Some researchers suggest that the status of DES research demonstrates the bias reflected in the 1990 government report, that just 13 percent of the NIH budget goes to research on women's health.

Silence about DES also stems from the fact that those exposed to it have rarely sought publicity because they're so traumatized by the nature of their injuries — and are unable to find proof of pharmaceutical records from 20 or 30 years ago.

Meanwhile, the pharmaceutical industry, determined to never acknowledge responsibility, prefers to settle its lawsuits silently, out of court. And the medical community, sensitive about being shamed and uncertain about exact medical consequences, has never been obliged to inform its patients that they were exposed to DES. Even to this day, people are just learning the implications of their DES exposure.

All of this conspires, unintentionally, to keep the DES story unknown. This is unfortunate because there is so much about DES exposure that needs investigation, and so much to be learned.

Like silicone implants, DES sums up the fact of consequences — the consequences of improper testing, of the corporate race to the market, of the idea of improving woman's pregnancies with medication.

Joe Heydt Colorado Springs Gazette-Telegraph

Until all of the consequences of exposure to DES are known, it's scientifically logical and ethical to study people exposed to DES. This will lead to more informed decisions by DES patients and their physicians — and shed light on the development of cancer and the use of estrogens.

FORTUNATELY a renewed sense of urgency about DES research is beginning to spring up. A bill for DES research and education (HR4178) has been introduced in Congress by Rep. Louise Slaughter (D-Perinton). If passed, the bill will ensure long-term follow-up studies and public health education, so that men and women exposed to DES, and their physicians, will have the peace of mind of accurate information.

And the NIH will hold a national conference on DES research in April 1992. Responding to growing concern from the scientific community and educational groups like the DES Cancer Network and DES Action USA, 200 researchers, physicians, and health educators will convene in Washington to assess the precarious state of DES research.

Efforts like these are critical to understanding tragedies like DES. Yes, DES is history — but it is also very much the present. Unless we learn all that the DES experience can teach us, DES will be the future.

Braun

Braun is the director of the National DES Cancer Network, based in Rochester. For more information, write DCN, P.O. Box 10165, Rochester, NY 14610.

MARY McGRORY

The Lingering Pain of DES

It was an era when women did not question their doctors. It was, after all, a time when the world was discovering miracle drugs such as penicillin. And was there anything more important than producing bouncing babies?

When DES first went on the market, in 1941, pregnant women took it like aspirin, in increasingly larger doses. The ads for the Eli Lilly and Co. product, which was supposed to safeguard against miscarriage, were pretty persuasive: "Yes . . . to prevent abortion, miscarriage and premature labor."

Experiments conducted on animals as early as 1937 showed serious reproductive malformations.

A 1950 study by William Dieckmann, a University of Chicago doctor, produced evidence that DES-treated women had smaller babies and twice as many miscarriages. Accordingto the Medical Trial Technique Quarterly, "Dr. Dieckmann concluded that DES actually favors premature labor."

Between 1947 and 1971, however, an estimated 6 million pregnant women took DES, a synthetic estrogen formally known as diethyistilbesterol. It was not until the November 1971 issue of the New England Journal of Medicine published the appalling news about young girls with cancer of the vagina—all of them daughters of mothers who had been treated with DES—that the FDA took steps to restrict the use of DES in pregnancy.

Numerous lawsuits brought by women against the drug companies—some 20 marketed DES—have been settled out of court.

The insufficiently tested and promiscuously prescribed "wonder drug" never achieved the notoriety of other products that have victimized women—the Dalkon Shield, Thalidomide, silicone breast implants—although the case of DES has aspects in common with the others. Also, the full consequences of DES use have yet to be measured.

Women think their overworked doctors have relied too much on the word of drug companies.

At the Capitol yesterday, a parade of sad-eyed women told of the havoc DES has caused in their lives: the maiming of beloved children, the brutal end to hopes of grandchildren and the fury that comes with having been imposed on by greedy drug companies.

The women gathered at the summons of Rep. Louise Slaughter (D-N.Y.), who has introduced a bill that would spend $2 million over five years for further education and research. One of its goals: to find out if a third generation of DES children has been affected, and to explore the consequences on the sons of women who took DES. The effects on DES daughters have been well documented; serious fertility problems, susceptibility to all forms of cancer of the reproductive organs.

"It devastates the most intimate parts of our lives," sobbed Judith Helfand of New York City at the news conference.

At 27, she has had a radical hysterectomy because of cancer of the cervix, uterus, lymph nodes and part of her vagina. She first heard of DES on a Phil Donahue program when she was 14 years old. Her mother had been waiting to tell her. They began a series of six-months checks with the doctor and the operations that have left her infertile.

She is black-haired, black-eyed and very angry. "It is a complete waste," she rages. "I try to turn my fury into productive activities. I make documentaries about what is happening to me. We are trying not to be good victims. I was a commercial risk for the drug companies."

Pat Cody of California channeled her anguish into a DES action group and newsletter. She took DES uncomplainingly when she was pregnant with her daughter Martha. She had miscarried the year before and it seemed a sensible precaution. She later found out the mortal dangers of DES from the San Francisco Chronicle, which picked up the horror story from the New England Journal. Cody never heard from the doctor who had prescribed the DES or the drug company that made it, from the FDA or any public-health authorities.

She later found out from Ms. magazine about a special examination for DES daughters, and the importance of having one every six months.

She tried to get in touch with city, county and state authorities about publicizing the importance of monitoring DES daughters. She was told: "We don't want to alarm people." One of Cody's daughters had a hysterectomy at age 34.

Slaughter learned about DES when she was a member of the New York legislature and is hopeful that her modest bill will pass this session.

"It's very little money with a great deal to gain," she says. It would also be a nice way of letting the miserable women know that somebody cares about their suffering.

Honda Civics, Bic lighters, DPT vaccines, Zomax and Feldene painkillers, Zenith television sets, Pfizer heart valves, General Motors fuel tanks, Xerox toxic leak sites—all are examples of cases in which companies have chosen to settle claims confidentially rather than draw attention to an allegedly defective product or other public hazard. And the list keeps expanding.

The reach of protective orders has grown along with the volume. In recent years, companies have started insisting on secrecy at the start of a lawsuit as well as the end.

When a company is sued, it is required by the rules of civil litigation to hand over to the plaintiff a wide array of its private documents, in the legal process called discovery. Many companies now tell the plaintiffs: We will only hand over these documents if you agree not to share them with other lawyers or make them available to the public.

From the company's point of view, this is entirely reasonable.

The public has a right to court records, defense attorneys argue, not to pretrial materials. It's not fair to have a company's private documents offered to the public and press before a case is tried or resolved, simply because a plaintiff's attorney filed a complaint. Not all lawsuits are meritorious, after all, and the mere fact that a lawsuit is filed, or is settled before trial, does not mean its target is truly a public hazard. Often a plaintiff's attorney is fishing for documents he can sell or otherwise market to other lawyers pursuing similar suits.

"Releasing documents publicly without a chance to vindicate, when there's been no trial or verdict, damages reputations," argued Thomas McLaughlin, a corporate defense attorney who testified before the Washington state Legislature on behalf of business associations. "It's called an anti-secrecy law, but we look at it as an anti-privacy law."

Such arguments are simply smoke screens for the companies' desire to avoid litigation, the plaintiffs' attorneys respond. It's one thing to hide the amount of a settlement, they say, another to hide public hazards such as toxic leaks, faulty fuel tanks, exploding lighters and defective drugs. When a company pays, say $700,000, it's not a nuisance settlement—there's a reason. Why shouldn't plaintiffs' lawyers be able to share discovery materials with other lawyers? Why must work that costs up to $100,000 be repeated each time a lawsuit is filed? Why reinvent the wheel?

"It is impossible to justify secrecy orders to the man on the street," said plaintiffs' attorney Ron Perey, who testified at the legislative hearing. "Only lawyers can do that to other lawyers. The only people who could stand up and say we should bury public hazard news are the people who make the public hazards."

Despite their obvious outrage, however, the plaintiffs' attorneys almost always cut the deals. There finally is just too little incentive to resist—fighting for public disclosure doesn't help win the lawsuit. Secret settlements benefit all the players and grease the system's wheels.

The injured plaintiff quickly gets to collect a handsome settlement without the time and duress of extended court appearances. The plaintiff's attorney gets to collect up to a 40% share of that award without shouldering the risk or burden of preparing for a trial. The defendant gets to avoid bad publicity and additional lawsuits. The judge gets to keep his docket trim, the machinery of his courtroom humming.

"It's very seductive," said Michael Withey, a Seattle plaintiffs' attorney associated with Project Access. "The defense attorney brings in a pile of documents and says, you can look at all this if you sign this protective order. The plaintiff's lawyer salivates. The temptation is to sign so you can get your hands on that pile . . . . Then they offer a big settlement if you'll keep quiet . . . . You're representing a client, not a public interest. I have clients with injuries who need the money. What are we supposed to do? Our hands are tied."

So, when Barbara Arbuckle turned to her lawyer for advice, it was no surprise that Ottinger didn't hesitate or agonize for very long. Ottinger did not like the choice—"I felt caught between a rock and a hard place . . . . It was a distasteful proposition." But a trial could last two weeks, cost $30,000 and be appealed forever, and Ottinger had just a one-person office with a phone-answering machine. Arbuckle had as much of an emotional as a financial need to put the matter to bed. This was the time for Barbara to get on with her life. Besides, people could learn the names of the labs they had sued if they checked the courthouse files.

Take the settlement, Ottinger advised.

The lawyer's and client's sense of conflict remained, however. Months later, Ottinger called Arbuckle with a question: Would Barbara be willing to come to the state Capitol to testify on behalf of a bill restricting secret deals?

Arbuckle did not hesitate. You bet, she replied. You bet.

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By design, the national debate about confidentiality orders increasingly is being framed as a consumer protection issue, rather than a fight among attorneys for their own benefit. "Trial lawyers get the image of being greedy sharks," said Rep. Martin Appelwick, chairman of the Washington state House Judiciary Committee. "I try to make clear this is a public interest issue . . . . That's why we asked injured people to testify."

So it was not random chance that brought Arbuckle to a legislative hearing room on the morning of Jan. 18. What unfolded that day mirrored the current scene in a number of state capitols.

The trial lawyers worked to keep the focus on hidden public hazards, while business lobbyists portrayed the whole endeavor as a grab by attorneys for more business.

"Why don't they want this stuff on the record, for people to know?" Arbuckle demanded. "I would never imagine that a manufacturer or lab would try to keep the information from others when someone is harmed by their product or service . . . . Are they that money hungry? It blows my mind."

"The plaintiffs' bar has got to have some sort of public policy rationale to come before the Legislature," responded Richard Ducharme, a business lobbyist. "But my thinking is that their real rationale is [that] it's essentially beneficial to their industry. The plaintiffs' bar has never been down here to ask for anything unless there's money in it for them."

When it was over, the hearing had drawn the intended publicity, including photographs and interviews of Arbuckle in the next day's local newspapers. Weeks later, on March 8, after undergoing revisions that excluded doctors' malpractice from its reach, the bill was passed by the state House and was sent to the Senate, where it is now being considered. It faces an uphill battle there—"All I need to know is that the trial lawyers' association is behind it," one Republican state senator told Appelwick. But some sort of reform is likely eventually, just as it is elsewhere in the country.

The momentum is apparent. In New York, after much public outcry, a state judge ended up ordering the release of court records he had earlier sealed in a $4.75-million Xerox toxic leak settlement. In Maryland, a Baltimore magistrate removed most confidentiality restrictions imposed earlier in toxic exposure lawsuits against a Goodyear Tire & Rubber Co. plant. In Oregon, in response to a challenge by Project Access lawyers, a Superior Court judge vacated a protective order that had been imposed on Honda Motor Co. documents in an all-terrain-vehicle rollover case. New York in February began prohibiting the sealing of court records without a judicial finding of "good cause."

Florida's "Sunshine in Litigation Act" prohibits court orders and private agreements that conceal information about a public hazard. Texas' sweeping new court rules, the country's strongest because they cover discovery documents as well as court records, establish a "presumption of public access" that can't be overcome without notice, a hearing and a court's finding of a "specific, serious and substantial" reason.

Despite these advances, however, Arbuckle remains uneasy, for, from time to time, amid the lawyers' and lobbyists' now familiar exchanges, she hears one particular comment that still gives her pause.

"No one forced that woman to settle" is how the Seattle defense attorney Thomas McLaughlin put it. "She could have gone forward in a public trial. She would have been free to talk then."

True enough, Arbuckle has to allow. Under the relatively loose terms of her deal, she still speaks out publicly, and much is known anyway about Pap smears. But other lawyers and clients, disregarding the great difficulties involved, have started refusing altogether to accept secret deals; "Just Say No" was the title of one recent article in the legal journal Trial.

Last August in Seattle, in a case involving exposure to electromagnetic pulse radiation, the Boeing Co. agreed to pay more than $500,000 to leukemia victim Robert Strom even though Strom refused to accept a gag order. "We basically stared them down—Strom wanted others warned," attorney Mike Withey explained.

There is no such option for Arbuckle now—if she tried to back out of her settlement, she would be breaching a signed contract. So, in the end, Arbuckle wants a new law not just to protect people from public hazards but also to protect countless plaintiffs and their lawyers from facing the temptation of their own self-interest.

COLUMN ONE

Dilemmas of Settling in Secret

L.A. Times 5 Apr 91

■ Companies offer hefty sums in exchange for keeping the details of public-hazard lawsuits quiet. Plaintiffs must chose between their own interest and the public good.

By BARRY SIEGEL
TIMES STAFF WRITER

SEATTLE—There is a moment that recurs with disheartening regularity for Barbara Arbuckle.

It comes during her conversations with women who, like her, have survived faulty Pap smear readings and deadly cervical cancer.

Just as Arbuckle is nodding sympathetically in response to a companion's account of medical travail, just as she's thinking that this lady's story is a film of my own life, the other woman invariably leans forward, eyes narrowing, with questions: So where were your Pap smears done? Do you know anything about my lab? How many tests did you have? How did they botch your case?

Arbuckle has talked in general terms on national television programs about problems with Pap smears. She has testified before a U.S. Senate subcommittee. She has campaigned tirelessly for what she calls "the public's right to know." But she is unable to answer those other women's specific questions.

I can't tell you, she responds, looking away. I just can't.

Such is the price Arbuckle paid in agreeing to a sizable out-of-court settlement of her lawsuit against two laboratories that she said misread her Pap smear results. In exchange for avoiding an expensive, drawn-out trial, Arbuckle agreed not to identify the labs publicly or discuss details of her case or disclose evidence that she and her lawyer had gathered about the labs' problems with other patients' Pap smears. In fact, she agreed to let most of the court records of her suit be sealed from public view.

"Today, I regret that deal," Arbuckle, 27, told a state legislative hearing in Washington state last January. "There are things that you all should know. I can't say some things. And those things could save lots of lives . . . . Lives would be saved if people knew."

With those words of public remorse, Arbuckle joined a mounting national backlash against sealed settlements and protective orders, which over the last 15 years have become a commonplace element of the civil justice system.

In recent months, San Diego County and five states—Virginia, Texas, Florida, North Carolina and New York—have acted by court edict or legislative statute to curtail such arrangements in cases involving public hazards. Bills with similar aims now are being considered in Congress and by several other states, including New Jersey and Washington.

A few individual judges have started preventing secret settlements or reversing their own confidentiality orders. A national trial lawyers' association has begun an offensive called Project Access, which files legal challenges to confidentiality orders and mails out thick information packages full of key cases and sample briefs.

Citizens drive cars, take drugs, operate equipment and live near toxic polluters that have been the subject of lawsuits covered by confidentiality orders. Does the public have an absolute right to know about these cases? Or should plaintiffs and companies be allowed to settle their private disputes as they see fit? Where to draw the line between private rights and public interest? These are the questions being raised by lawyers and lobbyists in a growing national debate.

Barbara Arbuckle takes part in this broad exchange but also sees the matter in more personal and morally vexing terms. The legal system, after all, forced her to choose between her own interests and the public interest.

"My attorney's advice was to let go, move on, because she knew I was wore out," Arbuckle said. "I agreed. I'm not mad at my lawyer. She handled this to the best of her ability. Here was a 23-year-old waitress, just scratching by with no one to help her. But the bottom line is, this hurt the public. It hurt lots of other people. So I have a question: Why should my attorney have to advise me about this in the first place?"

A look at Arbuckle's case and the debate in Washington offers more than one answer to this question.

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Arbuckle was 21 when her troubles began—first discomfort and pain, then problems with menstruation. For two years, she regularly visited her doctor, who took a series of Pap smears but could find nothing wrong. Some girls just go through these things, the doctor would tell her. Your tests are all fine.

Then, watching television late one night in October of 1985, Arbuckle happened on a show in which medical people were sitting around talking about cervical cancer. There was a listing of symptoms. This sounds just like me, Arbuckle thought.

Three weeks later, she underwent a radical hysterectomy to remove advanced cervical cancer.

"I had all the goals in life," she recalled. "I was going to have a little boy, a little girl. Then the doctor told me nope, you don't get it. This shouldn't have happened—it's not just bad fate. I'd been going to my doctor, telling him my symptoms for two years, taking the tests. So I called my attorney."

Eventually, her lawyer came to believe the fault was with two Seattle labs. The labs, attorney Mary Ann Ottinger claimed in a lawsuit, misread Arbuckle's Pap smears. Such misdiagnoses, it emerged, had been a growing problem across the country and were not uncommon at the two labs in question. But the scope of the problem had been obscured by secret court settlements.

"I felt mad as hell," Arbuckle said. "If previous secret court settlements hadn't concealed the problems in reading Pap smears, I might have learned of my cancer at frozen my cervix then. I could have had a child. I started meeting with doctors, victims, victims' widowers. I learned that thousands of women die from cervical cancer, which is curable. I told myself, I don't care what it takes, I'm going to do whatever is in my power to get this known. I wanted to organize protests, lobby, put on the pressure."

Soon, Arbuckle was speaking out in public regularly, being careful not to dwell on the particulars of her own case, because there had been no judgment in court yet. Reporters called every week. Geraldo Rivera invited her on his talk show. So did Larry King.

"The response from all over since I started to talk was so much," Arbuckle said. "It's amazing—people do read, people watch TV, people learn. We were giving the public the knowledge. The only way I knew about Pap smears was that late night TV show. Without that show, I'd be dead. If I can learn about my health watching TV, why not others?"

But, while her public appearances multiplied, her legal battle dragged on without resolution. One trial date was postponed, then another, until the case was 2½ years old. Defense lawyers came back again and again to question Arbuckle.

"They asked hundreds of questions," she said. "When was the first time I saw a doctor? How often did I see him? What about my sex life? How often? For how long?"

Then, in early January of 1988, the defending companies learned Arbuckle was scheduled to testify within days before a subcommittee of Congress that was investigating Pap smear misdiagnoses. "No way did the defendants want their names and the details spread over USA Today," said Ottinger, Arbuckle's attorney. "They did not want it in Congress and the papers."

So, just as Arbuckle was packing for Washington, a generous settlement offer arrived. It had a condition, however: Arbuckle could not talk about the details of her case, and the file would be sealed.

Arbuckle bristled. "After 2½ years of legal fighting, I'm told I have to keep my mouth shut. And the whole record is to be sealed. My case doesn't exist. To what purpose?"

On the other hand, those 2½ years had been draining. Arbuckle's whole life was rotating around this case. She thought about it every night when she lay down to sleep.

Arbuckle wavered.

What should I do? she asked her lawyer.

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Arbuckle and Ottinger's dilemma was not at all an uncommon one. The increasing use of confidentiality orders and sealed settlements is one response to the growing number of complex lawsuits being filed that charge businesses with creating public hazards. More than 90% of all civil cases filed nationally are settled by the contesting parties with little court involvement, and protective orders are now routine in those that involve product liability, auto design, toxic exposure, environmental hazard, medical malpractice and consumer fraud claims.

Drug Firms Lose Plea for Data To Fight Claims Made in DES Suits

By Amy Dockser Marcus
And Paul M. Barrett
Staff Reporters of The Wall Street Journal

Former makers of the pregnancy drug DES lost an important procedural round in litigation over claims that hundreds of women in New York were damaged by exposure to the drug while it was in the womb.

A state appeals court ruled that the drug companies cannot compel the women to turn over copies of medical records pertaining to their fathers, siblings and other family members. The manufacturers were seeking the records to show that the women's injuries may have resulted from genetic or hereditary factors rather than from exposure to the drug.

The drug's manufacturers have always contended that exposure to DES caused no serious injury. "The ruling deprives us of access to material that is vital to our defense," says A. Edward Grashof, a New York lawyer who represents Rexall Corp., a defendant in the case. Other defendants include Eli Lilly & Co., Indianapolis; Bristol-Myers Squibb Co., New York, and Upjohn Co., Kalamazoo, Mich.

A spokeswoman for Eli Lilly said the company planned to appeal. Defense lawyers for several other defendants said their clients were undecided.

DES, or diethylstilbestrol, was prescribed during a 30-year period beginning in the 1940s to reduce the chances of miscarriage during pregnancy. It was banned for this use by the Food and Drug Administration in 1971 after the FDA found abnormally high incidences of vaginal and cervical cancer in daughters of women who had taken the drug.

In the lawsuits, the women plaintiffs contend that their exposure to the drug in the womb caused infertility, cancer and miscarriages. There hasn't been any scientific evidence linking DES to health problems among sons of women who took the drug.

Lawyers for both sides said the implications of the appeals court decision could extend beyond the pharmaceutical industry. In cases involving exposure to man-made toxic substances, more and more courts are being forced to weigh a plaintiff's right to privacy against a defendant's need for medical information that might suggest other causes for diseases or injuries.

The 800 plaintiffs involved in the New York cases had refused to provide the information on the ground that family members who aren't parties to the litigation have a right to privacy under the state's patient-physician confidentiality laws. Last year, the trial court judge who is coordinating all the cases rejected their confidentiality argument.

In reversing that decision, the appeals court wrote that while the women must provide their mothers' medical records during pregnancy, the rest of their families are entitled to privacy. "The mere fact that a relative, distant or near in terms of kinship, has commenced a medical malpractice action alleging a birth defect should not subject all her relatives to the 'long arm' reach of the law authorizing their medical histories opened to all," the appeals court wrote.

Stuart Finz, a New York lawyer representing the plaintiffs, said that in the past many pharmaceutical companies had routinely sought medical information about family members as a way of harassing the plaintiffs. "There is only a minimal possibility that the medical records of distant relatives will be useful to the companies' case. The overriding issue is the families' right to privacy," said Leonard Finz, another lawyer for the plaintiffs.

Defense lawyers responded that the drug companies had sought medical information only for valid purposes. They added that they would be willing to have the medical records kept out of the public record to preserve the families' privacy.

* * *

IUD suit not barred by limitations

A patient's claim that she was unable to conceive because of a Cu-7 IUD was not barred by time, a federal appellate court for Ohio ruled.

The intrauterine device was inserted in 1975. When the patient and her husband had difficulty conceiving a child, a physician said her fallopian tubes were blocked and performed surgery. Later it was discovered one fallopian tube was still blocked. Another physician told her in April 1986 that she could not become pregnant, and the IUD was the most likely cause.

The appellate court said the patient's product liability action against the manufacturer did not accrue until the patient was informed that her inability to conceive was caused by the IUD.

The trial court was ordered to deny summary judgment.

Cacciacame v. G.D. Searle & Co., 908 F. 2d 95 (C.A.6, Ohio, July 19, 1990)

DES case barred by statute of limitations

A patient's negligence action against the manufacturer of diethylstilbestrol was barred by time, the highest court of Massachusetts ruled.

The patient was born on April 14, 1948; her mother had taken DES. The patient underwent an operation for a malignant vaginal tumor in 1969. She filed suit against the DES manufacturer on March 23, 1983. A trial court granted summary judgment, and the high court heard the appeal.

The patient should have been on notice more than three years before she filed suit that her mother's ingestion of DES may have caused her cancer. She had met with a medical researcher, who asked about whether her mother had taken DES. The researcher had sent her a letter indicating an important association between ingestion of DES and vaginal tumors. The patient had received a copy of an article on the subject and had begun to keep a file on the DES controversy, the court said. Summary judgment was affirmed.

Bowen v. Eli Lilly & Co., 557 N.E. 2d 739 (Mass. Sup. Jud. Ct., Aug. 6, 1990)

The Citation is a medicolegal digest published by Citation Publishing Corp., Long Grove, Ill.

Action not barred by limitations

A malpractice action against a pathologist for failure to correctly diagnose lung cancer was not barred by the limitations period, a Minnesota appellate court ruled.

On Nov. 20, 1986, a radiologist at a hospital performed a needle biopsy on the patient's right lung. The pathologist prepared saying the cells obtained were suggestive of small cell carcinoma. The patient's physician based his subsequent diagnosis of small cell carcinoma on this report, among other factors. The patient began chemotherapy and radiation treatments on Dec. 4, 1986.

In mid-April 1987, the physician began to re-evaluate his diagnosis because the patient had not responded as expected to the chemotherapy or the radiation. He ordered a bronchial biopsy performed on the lesion. The same pathologist evaluated the specimens. He diagnosed bronchial carcinoid tumor; chemotherapy and radiation therapy were not indicated.

On Dec. 2, 1988, the patient filed suit against the pathologist. A trial court granted summary judgment for the pathologist on the grounds that the two-year statute of limitations barred the medical malpractice action.

Reversing the decision, the appellate court said there was a patient-physician relationship between the patient and the pathologist even though he had no direct contact with the patient. The patient's physician contracted with the pathologist with the patient's express or implied consent. The court said the statute of limitations did not start to run until the patient was damaged. The patient did not suffer any damage until he received the unnecessary chemotherapy and radiation therapy. The earliest the patient could have brought a cause of action against the pathologist was Dec. 4, 1986, when he received his first treatment for the small cell carcinoma. The action filed on Dec. 2, 1988, was not barred by the two-year statute of limitations, the court said.

Peterson v. St. Cloud Hospital, 460 N.W. 2d 635 (Minn. Ct. of App., Sept. 25, 1991)

Product liability action barred

Compliance with FDA regulations on labeling barred a product liability action against a tampon manufacturer by the estate of a patient who died from toxic shock syndrome, the Washington Supreme Court ruled.

The court said the product liability action was preempted by FDA regulations on labeling tampons. Because the manufacturer complied with the regulations, the patient's estate could not claim inadequate warnings and instructions about the toxic shock risk.

Berger v. Personal Products, 797 P.2d 1148 (Wash. Sup. Ct., Sept. 20, 1990)

The manufacturers were served within the 60-day period provided for by statute but not within the one-year period. Affirming denial of the manufacturers' motions to dismiss, the court said that the one-year statute of limitations could be extended by compliance with the rule allowing delivery of the summons and complaint to the sheriff within the one-year period and personal service within 60 days thereafter.

Clark v. Abbott Labs, 553 N.Y.S.2d 929 (N.Y. Sup. Ct., App. Div., March 16, 1990).

DES complaints not dismissed

A New York appellate court affirmed denial of motions to dismiss complaints against DES manufacturers under the toxic tort revival statute.

A patient born in 1958 claimed that she sustained serious personal injuries from in utero exposure to diethylstilbestrol. The toxic tort revival statute took effect on July 30, 1986. The patient filed her complaint and delivered the summons and complaint to the sheriff within the one-year period.

THE WASHINGTON POST

C6 FRIDAY, APRIL 3, 1992

Corporate Liability Bill Killed in Md.

By Charles Babington
and Richard Tapscott
Washington Post Staff Writers

ANNAPOLIS, April 2—A Maryland Senate committee killed a bill today that would have protected corporations from punitive damage awards in many cases in which their employees injure or kill someone through grossly negligent actions.

The vote surprised corporate groups that had lobbied heavily for the bill, arguing that companies need protection from "runaway juries." It delighted personal injury lawyers, who generally collect one-third of all damages awarded to their clients.

The Judicial Proceedings Committee rejected 6 to 5 an amendment that would have weakened the bill, but removed some of the opposition to it. "The bill's dead!" exclaimed committee Chairman Walter M. Baker (D-Cecil), who supported the bill and appeared surprised by the vote. The panel then voted 8 to 3 to kill the bill.

Backers of the measure were "grossly overreaching" in their efforts to protect companies from punitive damages, which courts can award to punish and deter outrageous behavior, said Dennis C. McCoy, a lobbyist for personal injury lawyers. He said that Maryland juries rarely award punitive damages but that the mere threat encourages corporations to behave responsibly.

Meanwhile, with the regular legislative session scheduled to end Monday, the Senate and House again lapsed into a stalemate over a tax and budget package.

On Wednesday, the conference committee assigned to work out differences between House and Senate tax proposals was near an accord. The lone difference was whether an income tax rate increase for wealthier residents should be permanent. But when House members refused today to agree with Senate plans to make it temporary, talks broke off.

Seeking alternatives, Senate leaders offered a scaled-back tax plan that would balance the budget for next year, raise the gasoline tax from 18.5 cents to 24.5 cents a gallon, increase the cigarette tax by 20 cents a pack and give local governments authority to increase their "piggyback" income tax 20 percent.

Unlike earlier proposals, it would not provide extra money for some local programs, such as police aid to Prince George's County.

House leaders said they are not prepared to accept the new plan.

However, Gov. William Donald Schaefer expressed hope that lawmakers will resolve the differences. "It's just a short move," he said. "They can come to a compromise."

Also today, the Senate passed and sent to the House a bill that would restrict direct campaign contributions from developers to Prince George's County Council members and the county executive. A House committee rejected a similar Senate proposal earlier this week.

12A · FRIDAY, APRIL 24, 1992 · USA TODAY

"USA TODAY hopes to serve as a forum for better understanding and unity to help make the USA truly one nation."
—Allen H. Neuharth
Founder, Sept. 15, 1982

USA TODAY
THE NATION'S NEWSPAPER
PUBLISHED BY GANNETT

Today's debate is on **DANGEROUS DRUGS** and the need for new incentives to keep problem products off the market.

Crack down on peddlers of unsafe products

OUR VIEW **Jail, punitive damages should be among penalties for those who knowingly sell dangerous goods.**

Victims of one-time wonder drug DES told a wrenching tale in Washington this week, leaving an inescapable conclusion: Company leaders who risk lives to bloat profits should get tough treatment — including jail.

DES, introduced in 1941, did once seem wondrous. Want healthier babies? Just pop this little pill, the ads urged. They didn't mention 1937 and 1950 studies linking the synthetic hormone to deformities and increased miscarriages. It wasn't banned until 1971, when several DES daughters suffered rare cancers. By then, 6 million women had taken DES. Their risks still are unknown.

Sound familiar?

Remember Oraflex? Eli Lilly and Co. sold the arthritis drug here knowing it was linked to 25 British deaths. The exploding Pinto gas tank? Ford knew but chose not to fix it. Silicone breast implants? They're sewn into 1 million women, but the FDA still doesn't know whether they ignite disease.

Most companies strive to market wares that build consumer confidence. But too many of the 29,000 yearly product-related deaths spring from corporate decisions that de-emphasize safety.

That's unacceptable, yet states ignore new incentives that could help ensure safety. They should:

▶ Seek jail time for executives who knowingly peddle products that maim or kill. Criminal-negligence statutes allowing such penalties are in place; prosecutors just don't use them.

▶ Mandate that the public be able to see lawsuit documents involving public safety. Breast-implant evidence was kept secret for years; when the FDA finally did see some, it halted sales at once.

▶ Hone laws to encourage punitive damages for firms that knowingly sell unsafe products. Judges should decide such damages according to clear, uniform standards. Awards should go into a fund for all victims. And lawyers' fees should be capped — but not so low that they discourage such litigation.

By far, the majority of U.S. companies manage to survive, even profit, without maiming or killing people. It's past time to force the others follow suit.

INGTON POST

FDA Urged to Treat Tobacco as Drug

Associated Press

Three prominent health organizations said yesterday that they want tobacco to be considered an addictive drug and regulated by the Food and Drug Administration.

"The health of the American people can no longer be sacrificed for the profits of the tobacco industry," the presidents of the American Heart Association, the American Lung Association and the American Cancer Society said in a letter to President Bush.

"If tobacco is to remain on the market, it should be treated for what it is, an addictive drug," said the letter, adding that cigarette smoking is responsible for more than 400,000 U.S. deaths annually.

The FDA is an agency of the Health and Human Services Department, where Secretary Louis W. Sullivan has been an outspoken critic of smoking. Department officials had no comment about the call for FDA regulation.

PRESS-ENTERPRISE/Saturday, March 28, 1992 11

Nation/World

FDA wants makers to track users of medical devices

WASHINGTON (AP) — Makers of dozens of medical devices, including silicone gel implants, heart valves and respirators, would have to keep track of the people who get them under proposed federal rules to speed notification when problems develop.

The Food and Drug Administration, which published the rules Friday in the Federal Register, has found it difficult to let people know there may be something wrong with the devices upon which their lives depend.

Earlier this month, for example, the FDA warned that people with a defectively designed heart valve might want to have it replaced because of the danger that it could break and kill them. But individually notifying all 23,000 people in this country with the valve proved impossible.

The manufacturer has been able to locate only about 61 percent of them.

"Our registry was voluntary and it was retrospective," said Rick Honey, a spokesman for Pfizer Inc., parent company of the manufacturer of the Bjork-Shiley mitral heart valve.

The company had asked hospitals to mail back a registration card when the devices were implanted, but the FDA said that happened less than half the time.

Even then, the cards weren't that helpful. They didn't have the patient's address, Honey said. The company in the meantime has spent more than $2 million trying to find patients.

List of devices

WASHINGTON (AP) — Here is a list of the types of medical devices the Food and Drug Administration says should be tracked from the time they are manufactured.

Permanently Implantable Devices

- Vena cava clip.
- Cardiovascular intravascular filter.
- Vascular graft prosthesis of less than 6 millimeters diameter.
- Vascular graft prosthesis of 6 millimeters and greater diameter.
- Intracardiac patch or pledget made of polypropylene, polyethylene terephthalate, or polytetrafluoroethylene.
- Ventricular bypass (assist) device.
- Implantable pacemaker pulse generator.
- Cardiovascular permanent pacemaker electrode.
- Annuloplasty ring.
- Replacement heart valve.
- Automatic implantable cardioverter-defibrillator.
- Tracheal prosthesis.
- Intravascular occluding catheter.
- Aneurysm clip.
- Central nervous system fluid shunt and components.
- Implanted cerebellar stimulator.
- Implanted diaphragmatic-phrenic nerve stimulator.
- Artificial embolization device.
- Spinal interlaminal fixation orthosis.
- Spinal intervertebral body fixation orthosis.

Life-Sustaining Or Life-Supporting Devices

- Breathing frequency monitors (apnea monitors).
- Pressure regulator, including mechanical oxygen regulators.
- Portable oxygen generator, including oxygen concentrators.
- Portable liquid oxygen unit.
- Tracheostomy tube and tube cuff.
- Continuous ventilator.
- Noncontinuous ventilator (IPPB).
- DC-defibrillator (including paddles).
- Peritoneal dialysis system and accessories, including: chronic ambulatory (adult) and chronic pediatric (infant) peritoneal dialysis systems.
- Infusion pumps.

Silicone Devices

- Silicone inflatable breast prosthesis.
- Silicone gel-filled breast prosthesis.
- Testicular prosthesis, silicone gel-filled.
- Silicone gel-filled chin prosthesis.
- Silicone gel-filled angel chik reflux valve.

Governmental Units Confront Doctrine on Statutes of Limitations

By Daniel B. Moskowitz

Ordinary folks have only a set period of time to bring a damage suit, typically two or three years, but *nullum tempus occurrit regi*—"time does not run against the king."

That relatively obscure legal doctrine lately has been at the heart of a lot of court wrangling about two of the most explosive safety issues of the day. The moral: Huge amounts of money can ride on legal arcania.

It's sending everyone back to their law books and leaving even the judges confused about what the doctrine really means. The basic concept it simple: Statutes of limitations cannot be imposed on the sovereign when he is bringing a suit in his official capacity.

The rule in Britain never applied to suits filed by the king as an individual, and today does not apply to the government when it sues merely as a private party, rather than as the vindicator of public rights.

The governmental unit is asked to point to an "obligation imposed by law" that is being enforced by the tardy suit. The problem comes in applying those principles. The old rule isn't alive in every jurisdiction, but it is in Pennsylvania.

In 1987, for instance, a state court allowed the Philadelphia school district to recover damages stemming from defective electrical equipment, even though under ordinary standards it had waited too long to bring the suit.

The defendants argued that in buying the equipment for its schools, the district was acting just like any other customer, not exercising sovereign powers. But the court reasoned that the state required that safety standards be maintained in schools, so the suit was really carrying out a governmental function.

In recent months, the viability of the *nullum tempus* doctrine has been at the heart of claims for reimbursement for removing two major health hazards—lead-based paints and asbestos-containing fireproofing materials.

In the paint case, the city of Philadelphia and its housing authority in 1990 sued paint manufacturers on behalf of not just themselves but all cities in the country with a population or more than 100,000.

An obscure legal doctrine has been at the heart of removing asbestos and lead-based paint.

The suit claims that the paint companies intentionally misled customers about the safety of their product, and asks for repayment of the entire cost of removing lead-based paints from all municipal buildings.

But, the defendants point out, the dangers of lead-based paints were known long before 1990: Philadelphia itself in 1966 banned paints with a lead content of more than 1 percent in dwellings occupied by children, and Congress in the 1970s passed a series of bills imposing stricter and stricter controls on lead paints until in 1976 it defined as "dangerous" paint in which the lead content was more than six parts in 10,000.

No matter which date is taken as the point at which the city should have known it had a problem on its hand, the statute of limitations would have run out long before 1990. Last August, Judge James J. Giles of the U.S. District Court in Philadelphia said that the wait didn't matter. He applied the *nullum tempus* doctrine, based on federal legislation requiring all public housing authorities to test for lead-based paint and take actions to abate any dangers they find.

In January, a Pennsylvania Superior Court in another suit told school officials they did not have to worry about the statute of limitations in their suit against W.R. Grace & Co., the supplier of asbestos-containing material to a Mount Lebanon school district.

A jury had found Grace had no liability, but the higher court said there should be a new trial because the jury should never have been told to consider the issue of whether the school district waited too long in bringing its court action.

One reason for the Superior Court's decision was the earlier ruling by Giles in the lead paint case. However, Giles didn't know about the state court decision, and he eight days later decided that he had been wrong in August. His January revision: the housing authority can still enjoy *nullum tempus* but the doctrine doesn't apply to the city itself in the lead paint case.

The city, Giles now believes, was—as the defendants have always argued—acting just like any other buyer of paint and therefore has to play by the same litigation rules as an ordinary consumer.

That's not the end of the conflict.

Philadelphia now is going back to Giles courtroom to ask him to reconsider his ruling yet again, given the fact that a state appellate court has endorsed his earlier reading of the law, and that federal courts in such matters are supposed to be following state law. ■

Moskowitz writes about legal trends and their impact on business.

Dow Corning Accused of Withholding Silicone Data

By Dana Priest
Washington Post Staff Writer

When the Food and Drug Administration was reviewing potential health risks of silicone breast implants in 1988, it asked the largest manufacturer of the devices—Dow Corning Corp.—to provide data from long-term toxicity tests and studies in which silicone was injected or implanted in animals.

The company submitted 35 studies, but withheld dozens more containing relevant information for as long as two years, according to an analysis of Dow Corning records by Public Citizen's Health Research Group, a consumer group that advocates a ban on silicone implants.

Among the documents the company failed to provide, the group said, were 27 studies in which animals suffered negative effects from silicone, including birth defects, nervous system problems and death.

Public Citizen analyzed the documents Dow Corning originally gave the government in reponse to the 1988 FDA request, compared with documents the company had in its possession at the time of the 1988 request but did not submit until 1991 or 1992.

Dow Corning spokeswoman Barbara Carmichael said yesterday the company is attempting to verify Public Citizen's allegations but that it appears many of the studies cited were not submitted in 1989 because the FDA agreed to redefine and narrow the definition of the studies it wanted. Some of the tests, she said, appear to involve types of silicone that would not be used in humans.

The FDA is investigating Dow Corning in connection with its admission that some implant quality-control records were falsified, said Carmichael. Dow Corning withdrew from the silicone implant market in March, but continues to supply gel to one implant manufacturer.

In early 1989, Dow Corning sent the FDA the results of 35 relevant studies. In a premarket approval application in July 1991, it submitted 21 other studies conducted before it got the 1988 request, according to Public Citizen. In December 1991, FDA—having learned of the existence of still other studies from a lawsuit by an implant wearer—requested further documents. Dow then identified six tests it had completed by the fall of 1988, the group said, and gave them to the FDA in February 1992.

Among the studies Public Citizen cited as not submitted in 1989 were a 1978 study of the short- and long-term effects of silicone on rabbits that produced an inflammatory response in some of the animals. The results "preclude further human clinical use of the gel" by direct injection, the report said.

In a letter to FDA Commissioner David A. Kessler, Public Citizen asked that the agency seek criminal prosecution of the company for filing incomplete data. The FDA declined to comment.

THE NEW YORK TIMES,

SUNDAY, JANUARY 26, 1992

Questions Raised on Ability Of F.D.A. to Protect Public

By GINA KOLATA

Consumer groups and Federal officials are raising disturbing questions about whether the Food and Drug Administration has adequate powers to protect the public from dangerous drugs and devices. Several recent cases involving silicone breast implants, the sleeping pill Halcion and the sedative Versed suggest that the agency and the public are sometimes the last to learn of reports of dangerous side effects.

The Federal agency does no testing of its own, and in making decisions it must rely entirely on the test results submitted by manufacturers. Officials of the agency and consumer advocates both say that the F.D.A. lacks the subpoena power, which virtually every other Federal agency has, to obtain drug company documents when its suspicions are aroused.

Even when people who are harmed by drugs bring lawsuits, and their lawyers discover reports of side effects in the companies' files, the companies may settle the case on condition that the reports are sealed. As a result, years may pass before the agency gets to hear of vital information about hazards.

In the case of silicone breast implants, the data that caused the Commissioner of Food and Drugs, Dr. David A. Kessler, to ban implants this month pending a review of their safety had long been known to the Dow Corning Corporation. The details were disclosed to trial lawyers eight years ago, but the drug agency learned about them only recently because they had been kept confidential under a court agreement.

"In view of the recent history with generic drugs and the data that are reported with Halcion and that are about to come out with breast implants, it is hard to say there's not a problem," said Dr. Alan Lisook, who is chief of the clinical investigations branch at the drug agency. He said he did not see any immediate solution. Among the disclosures that have shaken the agency are findings that some

Continued on Page 22, Column 1

Questions Raised on F.D.A.'s Powers to Protect Public

Continued From Page 1

generic drug companies falsified the tests that enabled them to get their drugs marketed. Within the last six months there have also been charges by researchers that the Upjohn Company, the maker of the sleeping pill Halcion, falsified and failed to report adverse reactions in its clinical tests, and reports that Dow Corning, the maker of silicone breast implants misrepresented its safety data to the F.D.A.

Companies Deny Wrongdoing

The final verdict on Halcion and the breast implants has not yet been reached. The companies that make them vehemently deny any wrongdoing and say that their data support their products' safety and efficacy.

The Pharmaceutical Manufacturers Association, which represents makers of brand name drugs, said it did not perceive a problem in the F.D.A.'s ability to learn whether companies misrepresented or failed to report data. "To the extent that problems exist, the F.D.A. can detect them," said Dr. John Petricciani, the director for medical and regulatory affairs at the association.

But officials at the F.D.A. and consumer advocates say that the recent cases spotlight the limitations of the agency's abilities to assess the safety of drugs and devices accurately. Adverse data about both Halcion and silicone breast implants were provided by their manufacturers to plaintiffs' lawyers but reached the F.D.A. only fortuitously.

Suspicions About Actions

Drug industry experts say there was no good way of determining whether the few cases that have appeared are anomalies or the tip of an iceberg. But some consumer advocates voice grave concerns that the companies may have hidden adverse data on other drugs.

Arthur Bryant, who is executive director of Trial Lawyers for Public Justice, a national public interest law firm, asserted that the situation seriously endangered patients. "The entire system, where secrecy is permitted, works to enable companies to maximize profits by sacrificing peoples' lives," he said.

Dr. Sidney Wolfe, director of the Health Research Group, a consumer affairs group, agreed. The F.D.A., he added, "is extraordinarily dependent on the companies to be honest."

"But as the line increases of companies that have pleaded guilty to criminal charges, maybe the default position is not to trust the companies," he said.

It might seem that any company that marketed an unsafe drug or device would be found out as adverse reactions accumulated. Yet F.D.A. officials say they have seen companies minimize or ignore adverse reactions in their reports to the agency, even when those side effects eventually forced the company to pull the drug from the market and incur heavy costs.

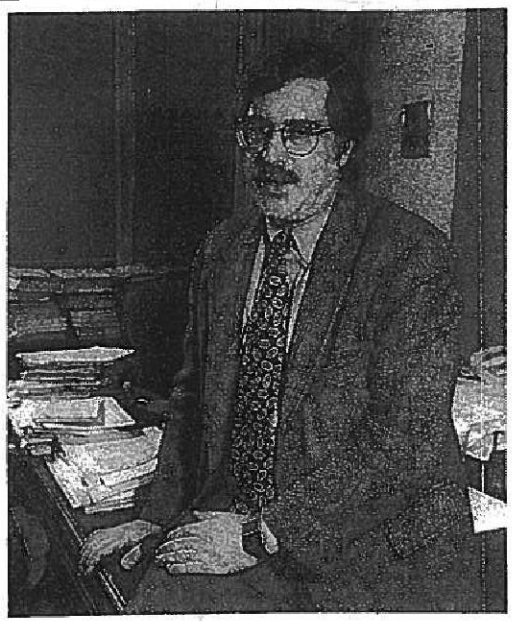
Dr. Robert Temple, director of new drug evaluations at the F.D.A., speculates that companies may grossly play down adverse reactions to their drugs because of "wishful thinking, hopes and dreams" on the part of companies that the reactions are not serious. "The most striking thing we've seen is companies not appreciating the wild horses they were riding," he said.

In addition, he said, he believes companies may fear that "if they tell us about it, we'll get hysterical and we won't make a reasonable judgment."

Dr. Henry Grabowski, an economist at Duke University who has studied the drug industry, said financial considerations could sway a company to downplay adverse data. "Sometimes you can have a mindset that a drug will be very commercially important," he said. "You don't want to hear bad news about it. You don't really develop or acknowledge some problems."

F.D.A. officials and consumer advocates say that the F.D.A. stands virtually alone among Federal agencies in its lack of subpoena power. The Department of Agriculture, the Environmental Protection Agency, the Department of Transportation and the Federal Trade Commission all possess subpoena power. Without it, the F.D.A.'s only stick is to threaten criminal prosecution by the Justice Department if it finds critical data have been withheld.

Dr. Lisook said subpoena power would certainly help the agency to investigate possible withholding of data about adverse drug reactions. "We can only pursue some cases to a certain point because there is information we can't obtain because we lack subpoena power," he said. Instead of forcing companies to produce documents and internal memorandums to establish whether there is any wrongdoing, the F.D.A. has to be certain enough that something is wrong to persuade the Justice Department to begin a criminal prosecution.



Dr. Robert Temple
Director of new drug evaluations at the F.D.A.
"The most striking thing we've seen is companies not appreciating the wild horses they were riding."

Subpoena Power Fought

The Pharmaceutical Manufacturers Association, however, opposes giving the F.D.A. subpoena power and heavily lobbied against it when a bill to give the agency that power was introduced in Congress last year. The bill failed to win approval after after the Secretary of Health and Human Services, Dr. Louis W. Sullivan, said it would be vetoed.

The F.D.A. also has no good way of finding fraud or serious, if inadvertent, misrepresentation of data. In its fraud investigations, Dr. Lisook said, the F.D.A. scrutinizes the records of individual investigators who perform studies for drug companies. On occasion, it has found that the investigators cheated, even making up all of their data. This happened with one independent researcher who studied Halcion, for example. But the agency cannot easily detect the next level of misrepresentation, a company's failure to properly report and analyze researcher's data, Dr. Lisook said.

Dr. Lisook said the F.D.A. has stumbled upon companies that accidentally or purposely overlooked adverse reactions in their reports to the agency. "We can't go to a company and say, 'Tell us if there are adverse reactions you didn't submit,'" Dr. Lisook said. "We don't have any good method to determine whether what is on the case report forms is identical to what is on the tabular summaries."

In the case of Halcion, critics who have examined case report forms in connection with a lawsuit against Upjohn charge that the company left out information about adverse reactions reported on those forms when it prepared its data analyses for the F.D.A. Upjohn denies the charges and the F.D.A. is currently examining the forms and comparing them to the company's data analyses.

A discrepancy between case report forms and company analyses would not ordinarily be apparent to the F.D.A., Dr. Lisook said, partly because the agency does not even receive most case report forms. Since 1984, when F.D.A. regulations were revised, companies have not been required to submit most case report forms to the F.D.A.

A third source of frustration for the F.D.A. is the growing tendency of companies to obtain secrecy orders that seal potentially damning company documents that are produced in product liability suits. These orders prevent the plaintiffs, their expert witnesses, and their lawyers from ever disclosing what they learned. The Halcion data were uncovered in a product liability lawsuit that was settled with a secrecy order. But the order was not written to exclude the company from providing the data to the F.D.A. upon request, and Upjohn agreed to do so.

The Pharmaceutical Manufacturers Association opposes changing secrecy orders to enable the F.D.A. to be guaranteed access to company data.

Secrecy 'a Total Outrage'

Secrecy orders that keep information on the safety of drugs and devices from the public and the F.D.A. "are an outrage, a total outrage," said Mr. Bryant, the public interest lawyer. "The standards for keeping data from the eyes of the public should be far higher than they are now," he said. "Yes, there should be secrecy for certain things like the formula for Coca-Cola. But we are talking about matters that involve threats to the public health and safety, matters that allow the public to evaluate whether the courts and regulatory agencies are doing their jobs."

Drug Safety Problems and the F.D.A.

DRUG	INTRODUCED	REMOVED	COMPANY	PENALTY
Selacryn Blood pressure	May '79	January '80	SmithKline Beckman Corporation	**Fined $100,000** in February '85 after pleading guilty to charges of failing to tell the F.D.A. about lethal side effects.
Oraflex Arthritis	May '82	August '82	Eli Lilly & Company	**Fined $25,000** in August '85 after pleading guilty to charges of failing to inform the Government of four deaths and six illnesses related to the drug.
Merital Anti-depressant	mid-'85	January '86	Hoechst A.G.	**Fined $202,000** in January 1986 after pleading guilty to charges of failing to tell the Government that two patients in Europe had died after taking the drug.

New push for doctors to report adverse drug reactions

By Charles Culhane
AMN CORRESPONDENT

WASHINGTON — The U.S. Food and Drug Administration is preparing to unveil a new, streamlined program to encourage physicians and others to view reporting of serious adverse reactions to drugs or medical devices as a professional duty.

Meanwhile, the AMA's Council on Ethical and Judicial Affairs has prepared a detailed informational report declaring that physicians have a professional obligation to report such adverse reactions.

The AMA's House of Delegates is scheduled to consider the report at its Annual Meeting next month.

AMA approval "would be an enormous thing for this agency," said FDA Commissioner David Kessler, MD. "If the AMA House of Delegates goes along with this, then it's not just the [FDA's] MedWatch program. Then people will say this really should be part of the practice of medicine.

"The health professionals who use the products are absolutely indispensable to us in collecting information about the product after it is on the market," Dr. Kessler said.

In 1990, voluntary reporting of adverse reactions to various FDA-regulated products resulted in 38 product recalls, he noted.

Dr. Kessler plans to announce the program officially at a one-day meeting June 3 in Rockville, Md., where AMA Executive Vice President James S. Todd, MD, is scheduled to speak about the critical role of physicians. Other speakers will include representatives of the American Society of Hospital Pharmacists, American Nurses Assn., American Dental Assn. and Pharmaceutical Manufacturers Assn.

The FDA has designed the MedWatch program to simplify the reporting process, improve the quality of reporting and clarify that the agency seeks reports only on serious adverse reactions, said Stewart L. Nightingale, MD, associate FDA commissioner for health affairs.

"Our hope is that reporting serious adverse events will become embedded into the culture of physicians' professional practice," Dr. Nightingale said.

Although new drugs and devices undergo extensive testing, these premarketing studies cannot guarantee product safety, the AMA report noted. Such studies rarely involve more than 3,000 patients and seldom last more than three years. Uncommon side effects, delayed effects or consequences of long-term use would not be observable before marketing, the report said.

Furthermore, patient populations involved in clinical trials often do not include key groups such as the elderly, adolescents, women, people with complex diseases or those taking other medications.

Reports by physicians frequently have uncovered problems with new drugs, the AMA said. Among the adverse reactions that physicians have identified are pseudomembranous colitis associated with lincomycin; flank pain syndrome associated with suprofen; and, most recently, serious reactions to temafloxacin, which resulted in voluntary recall of the medication. Adverse event reports lead to changes in labeling in up to half of all new chemical compounds, the AMA said.

Current reporting practices are rooted in a system the AMA established in the 1950s to register cases of drug-induced blood dyscrasias. The FDA established its own reporting system several years later.

By the early 1960s, both the AMA and FDA had expanded their systems to include all adverse drug reactions. The AMA focused on reports from physicians and smaller hospitals, while the FDA collected most of its information from larger hospitals, universities and government. The AMA dissolved its system in 1970.

The FDA published a draft version of its new reporting form last February in the *Federal Register*. It consolidates and replaces five existing forms, which the agency will retire within six months after introducing the new form.

The MedWatch program seeks reports on serious adverse events that result in death, life-threatening disability, brief or prolonged episodes of hospitalization, or intervention by health professionals to prevent permanent damage from occurring.

The draft form urges health professionals to report adverse reactions even if they are uncertain whether a specific product caused the event or they don't have full details. The form also urges providers to report any concerns about the quality, performance or safety of a medication or device. Such problems might consist of suspected contamination, defective components, poor packaging or poor labeling, the agency said.

The AMA joined with the FDA last year in surveying physician attitudes toward reporting of adverse events, said Donald R. Bennett, MD, PhD, director of the AMA's office of drugs and toxicology. The two have been working together on the new program for the past year.

"I think it's important to note that 96% of the physicians felt it is a physician's responsibility to do that kind of reporting," Dr. Bennett said at a meeting with Dr. Kessler and other FDA officials here.

The survey found several barriers to physician reporting, however: uncertainty about an adverse event's cause; lack of knowledge about how to file a report; concerns about legal liability; and reluctance to accept more administrative burdens.

An FDA attorney said that preserving reporters' confidentiality would be a priority of the new plan.

AMERICAN MEDICAL NEWS/MAY 24/31, 1993

LAW

FDA Approval Shields Firms In Injury Suits

By Edward Felsenthal
And Lee Berton
Staff Reporters of The Wall Street Journal

A U.S. appeals court ruled that regulatory approval of some medical devices largely shields the products' makers from lawsuits seeking damages for injuries to users.

The First U.S. Circuit Court of Appeals in Boston said approval of the devices by the Food and Drug Administration bars more aggressive state regulation or lawsuits based on state law for claims such as negligence, breach of warranty and fraud.

"This case is probably the single most important case to the medical-device industry in American history," said Peter Hutt, a Washington lawyer and former general counsel of the FDA. Mr. Hutt's law firm, Covington & Burling, represents the Health Industry Manufacturers Association, which filed a friend-of-the-court brief in the case. Mr. Hutt said the decision gives manufacturers "a single national control system for our most important life-saving pharmaceutical-type products."

Although the case specifically applies to only one device and becomes law only in the four-state region covered by the Boston court, lawyers said other courts may choose to adopt the court's reasoning in cases involving an array of products, like heart valves for example. If so, the decision would sharply curtail suits by plaintiffs who allege that devices they used were negligently designed or that the manufacturer failed to adequately warn about side-effects and other health risks, the lawyers said. The decision doesn't apply to drugs, which are regulated by a different set of federal laws.

In the First Circuit case, the plaintiff, Jane King, sued Collagen Corp., of Palo Alto, Calif., alleging she developed an autoimmune disease after using Zyderm, a Collagen cosmetic device that is injected under the skin to correct wrinkles and

Please Turn to Page B10, Column 1

LAW

FDA Approval of Medical Device Is Ruled a Shield From Lawsuits

Continued From Page B1

skin deformities. In her lawsuit, Ms. King made a variety of allegations, including claims that Zyderm, which is still on the market, was negligently designed and manufactured, that it is "unreasonably dangerous to users," and that its package wasn't adequately labeled to warn users of the device's risks.

But the appeals court threw out those claims, saying they were precluded by the FDA's initial approval of the product 1981 and by the agency's "extensive regulation" of Zyderm. The approval process the court said, "is designed to provide 'reasonable assurance of . . . safety an effectiveness' for medical devices whic are too dangerous or unknown to permi less regulation."

Ms. King will appeal the decision to the U.S. Supreme Court, said Susan Allinger, an attorney in Houston who represents Ms. King.

Other lower courts have precluded state-law claims against manufacturers of medical devices. But the First Circuit's decision is apparently the first by a federal appeals court to specifically bar such claims against the group of medical devices that the FDA classifies as requiring greater scrutiny to ensure safe use. In addition to Zyderm, other examples of this type of device include heart valves and lens implants for cataract treatments.

In recent years, the FDA's approval process has been criticized as lax, particularly following allegations that the agency didn't sufficiently scrutinize several companies' breast-implant products. Now some legal specialists worry that, by protecting manufacturers from liability, the First Circuit decision may make the companies less vigilant about making sure their devices are safe. Lawyers said it is unclear whether breast implants would fall under the scope of the decision because they were put on the market before the regulatory law for medical devices took effect. The implants have since been placed under the same classification of devices such as Zyderm.

"It's frightening to think that tomorrow if you were hurt by a medical device, you can't do anything about it because 12 or 15 years ago the FDA looked at it and said it's fine," Ms. Allinger said.

In a concurring opinion, one of the three judges who heard the appeal wrote that in establishing the FDA approval process, Congress intended to encourage development of medical devices and to permit them to be marketed without delay. "Perfection is impossible," the judge wrote, "and a few individuals may be denied full protection at the cost of benefiting the rest."

Lawyers said the case's broad scope leaves open only a narrow window for suits against manufacturers of such devices, possibly allowing claims that involve certain types of fraud or violations of express warranties. Ms. Allinger, however, said she believes the case rules out claims that the manufacturer fraudulently withheld information from the FDA. Federal law prevents plaintiffs from suing the FDA itself.

made against accounting firms in other cases, few have so far been successful. But an out-of-court settlement of $15 million of a RICO charge in 1988 against defunct Laventhol & Horwath, formerly the ninth biggest accounting firm, helped lead to the firm's collapse.

(In re: Crazy Eddie Securities Litigation, U.S. District Court, Eastern District of New York, 87 CV 33)

B10 THE WALL STREET JOURNAL, THURSDAY, JANUARY 21, 1993

Lilly, woman reach settlement on DES

The New York Times

NEW YORK — Had she held out just a little longer, Margaret Perrotte might be $8.5 million richer. But for Mrs. Perrotte, Thursday was still a day to celebrate.

In a court case that had its roots in actions taken 29 years ago, Mrs. Perrotte's lawyer agreed Thursday to accept an estimated $4.25 million in damages for the cancer and infertility Mrs. Perrotte suffered because her mother took the pregnancy drug diethylstilbestrol, or DES.

Moments later, jurors in the case said they had been prepared to award the 28-year-old woman from upstate New York $12.75 million.

Nevertheless, Mrs. Perrotte said she and her husband were "thrilled by the settlement so we can put can try to put this all behind us."

The settlement with Indianapolis-based Eli Lilly & Co. was sealed in State Supreme Court in Manhattan but disclosed by lawyers familiar with the case. Experts in such cases said it was by far the largest award ever in a DES court suit.

The settlement, reached while the jury was still deliberating, also was said to have included $500,000 to the woman's husband — the first time, experts said, that a DES spouse was so rewarded and more than any previous award to a DES victim.

It was also the first settlement in New York state since the Legislature approved a law in 1986 that effectively extended the statute of limitations so that plaintiffs alleging DES damages could still have their day in court years later.

DES, which was manufactured by many drug companies, was withdrawn in the late 1970s after it was shown that the children of mothers who took it suffered from cancer, infertility and birth defects.

Mrs. Perrotte, and her husband, Edward, of Candor, N.Y., tearfully embraced outside the third-floor courtroom moments after Benjamin, who was handling his first big DES case, reached a settlement with the lawyers from Brown & Wood, who were representing Lilly, the last drug company that had remained in the case.

Initially, the six-member jury had reached a partial verdict on Wednesday, awarding Mrs. Perrotte $2 million and her husband $500,000 for pain and suffering they shared since she was struck with cancer that destroyed her reproductive organs.

But there was some confusion over whether the jury also meant to award Mrs. Perrotte an additional $10 million, a figure, jurors said later, that was calculated to give her $200,000 a year for the next 51 years, or a normal lifespan.

After the jury was sent back to continue its deliberations on Thursday by Justice Harold Baer Jr., the lawyers for Lilly and for Mrs. Perotte reached a settlement that was said to be about $4.25 million.

Several jurors who were interviewed afterward said that if they had been asked to reach a verdict they would have awarded the couple a total of $12.75 million, a figure that does not include any money they might have awarded later in punitive damages.

One juror, Mary Ann Long, said she felt there was a "strong possibility" that Mrs. Perrotte's cancer "would strike again."

"This poor woman will never be able to have a baby of her own," she said.

Betty Peterson, a Lilly spokesman, said the company would continue to "vigorously defend its position" against DES damage suits.

Nora Cody, executive director of DES Action, a DES plaintiff's organization in Oakland, Calif., said, "We're thrilled with the settlement," which she described as the largest ever in either a verdict or out-of-court settlement.

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LOS ANGELES TIMES OCT 19 1991

$12.2-Million Verdict Against Lilly in DES Case

■ Litigation: The jury's decision may prompt other drug makers to settle about 1,000 suits over the anti-miscarriage drug.

From Reuters DZ

NEW YORK—Companies could be spurred to settle about 1,000 suits over anti-miscarriage drug DES after a $12.2-million verdict this week against Eli Lilly & Co., the biggest ever stemming from the once-popular medication, lawyers said Friday.

A New York state court jury Wednesday sided with Margaret Perrotte, whose cancer and infertility were linked to the fact that her mother took diethylstilbestrol, known as DES. The drug was taken by millions of women from 1947 to 1971 to prevent miscarriages.

Not only was this the largest verdict in a DES case, it also marked the first time a DES spouse was awarded damages. Perrotte's husband, Ed, won $550,000 in addition to the $12.2 million awarded to his wife.

As the jury was about to reconvene Thursday to determine if punitive damages should also be awarded, the two sides settled the case. The court ruled that terms of the settlement were to be kept confidential.

"This sends a message to Lilly and other manufacturers that the hundreds of cases now pending should be settled," said Aaron Levine, who heads a large group of personal injury lawyers who have pooled resources to handle DES cases.

"This shows that DES litigation is alive and well and that their [manufacturers'] defenses are as weak as they have always been," said Levine, a Washington lawyer.

But Bette Peterson, a spokeswoman for Indianapolis-based Lilly, said the company disagreed with the verdict and maintains that it acted responsibly in the development and marketing of DES. She said Lilly will continue to "vigorously defend its position."

She said the parties in the Perrotte case decided to settle to avoid the risks of further litigation. Lilly most likely would have waged a long legal battle by appealing the verdict.

Although a number of drug companies manufactured DES, Lilly had about 75% of the market. The drug, which has been linked to vaginal and other types of cancers in the daughters of women who took it, was taken off the market in the late 1970s.

Lawyers estimate that there are about 1,000 DES cases pending nationwide, with Lilly named in 600 of them.

Levine said about a dozen DES cases have gone to trial, with plaintiffs winning half. He said the last big verdict was $1.2 million in 1986.

Lawyers believe that Lilly has also settled a large number of suits costing the company millions of dollars, but specifics are unavailable because Lilly insists on confidentiality.

It has been hard for plaintiffs to win DES cases because there is a long period of time between the date when the mother took the drug and when the daughter discovered the injuries. It is also difficult to determine which drug company made the DES that the mother ingested.

Levine said that, at first, personal injury lawyers had been "outclassed" by Lilly's litigation resources. But now that more than 40 plaintiffs' lawyers are sharing evidence and witnesses, he predicted further successes.

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Lilly

★ Continued from Page 1

study linked DES to cancer in daughters of women who took the drug.

More than 300 companies manufactured the product while it was on the market. Hundreds of DES lawsuits have been filed — Lilly is a defendant in about 600 of them — and in many cases it is not possible to tell which firm's product was used.

However, the plaintiffs' attorney in the case settled Thursday was able to show that Lilly's version was used because the doctor for the woman's mother wrote a generic prescription. At the time — 1961 — Lilly had a contract with distributors that ensured that generic DES prescriptions would be filled with the Lilly product, said the attorney, Ronald Benjamin.

This was the first case in which the husband of the victim also was awarded damages, Benjamin said.

The lawsuit was filed in Binghamton in 1989 by Margaret Perrotte, 29, and her husband, Ed, after she was diagnosed with vaginal cancer. She underwent a radical hysterectomy and partial vaginectomy.

Lilly spokeswoman Bette Peterson said Friday that officials of the Indianapolis drug company "strongly disagree" with the verdict.

"To avoid the risks inherent in further litigation, both parties have reached a mutual settlement and have agreed to dismiss this case. The company believes that it acted responsibly in the development and marketing of DES, and we will continue to vigorously defend that position," Peterson said.

Before Thursday, the largest DES jury award occurred in Philadelphia in 1986. The award of $1.2 million was against Squibb Corp., said Washington, D.C., attorney Aaron Levine. He heads the American Trial Lawyers Association's DES Litigation Group.

Most of the lawsuits have been settled before the cases reached trial, he said.

The most recent DES verdict against Lilly was 10 years ago and was for $400,000, Levine said.

The Perrotte case "certainly tells Lilly what a New York jury feels is the value of DES cancer," said Levine.

"I hope this sets a precedent," said Sybil Shainwald, a New York attorney who handles DES cases. "The relationship between DES and clear-cell adenocarcinoma (malignant tumors) of the vagina is so strong that Eli Lilly should settle these cases with these young women."

Lilly won a case on the DES issue in federal court in Milwaukee in 1987, and won another case in 1990 when the jury ruled the plaintiff's mother had not taken DES, said Peterson.

A 1986 New York state law revitalized DES lawsuits that otherwise could not have been pursued because of statute of limitations restrictions.

Lilly's stock plunged $3.75 a share Friday, to $73.75, indicative of investor disappointment with the company's sales picture as well as the DES lawsuit.

The sell-off of Lilly shares was a combination of the two events, said Rita Freedman, a pharmaceutical industry analyst at Provident Bank in Philadelphia. Some Wall Street analysts changed their recommendations from neutral to "sell" or "avoid" Friday morning.

Lilly reported Thursday afternoon that third-quarter sales increased just 5 percent over the same quarter last year.

New York Case May Spur DES Settlements

NEW YORK (Reuter) — Companies could be spurred to settle some 1,000 suits over the anti-miscarriage drug DES following a $12.2 million verdict last week against Eli Lilly & Co., the biggest ever stemming from the once popular medication, lawyers say.

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Although a number of drug companies manufactured DES, Lilly had about 75% of the market. The drug, which has been linked to cancers in the daughters of women who took it, was taken off the market in the late 1970s.

Lilly settles DES suit as big award loomed

By ERIC B. SCHOCH
STAR STAFF WRITER

Eli Lilly and Co. has settled a lawsuit over the controversial drug DES, avoiding what could have been the largest jury award in 20 years of litigation over the drug.

Terms of the settlement with a New York couple were confidential, but the amount was reported to be $4.5 million.

A jury in Binghamton, N.Y., already had decided in favor of the couple and was preparing to award damages, a multistep process in New York, when the settlement was reached Thursday.

The New York Times quoted jurors as saying they were prepared to award the couple $12.75 million. Lilly said the jurors' award was $2.75 million.

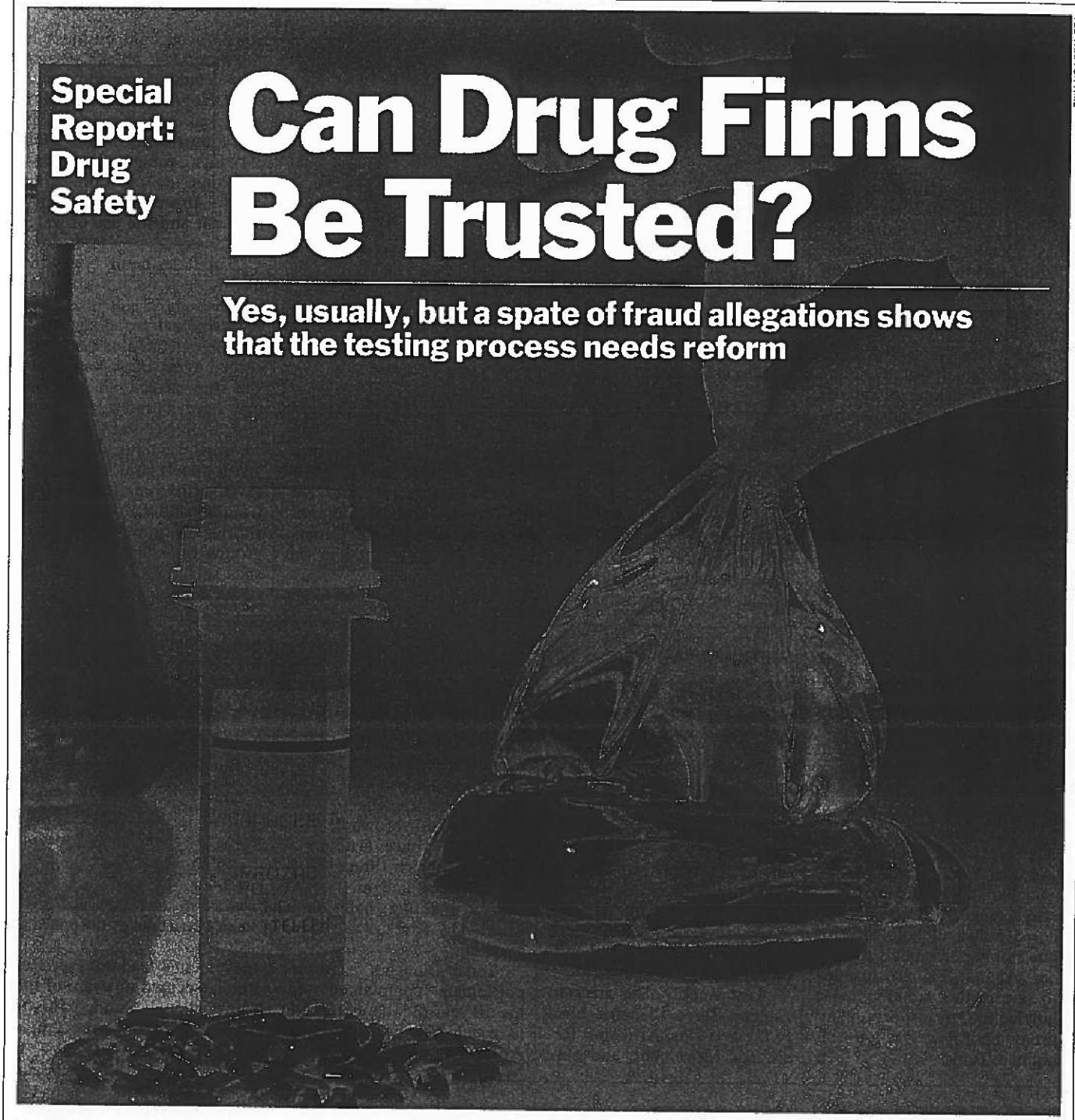
DES — diethylstilbestrol — once was widely prescribed to prevent miscarriages. It was withdrawn from the market in 1971 after a research

See LILLY Page 10

Special Report: Drug Safety

Can Drug Firms Be Trusted?

Yes, usually, but a spate of fraud allegations shows that the testing process needs reform



TED THAI FOR TIME

By CHRISTINE GORMAN

Even to a nation grown accustomed to multibillion-dollar business frauds, the allegations are shocking. A Scottish psychiatrist has charged Upjohn of Kalamazoo, Mich., with falsifying scientific evidence regarding the safety of the sleeping pill Halcion (annual worldwide sales: $240 million). The accusation has prompted a federal investigation. Dow Corning Wright of Arlington, Tenn., stands accused of failing to report that its silicone-gel breast implants were associated with severe side effects—including the development of autoimmune disorders like rheumatoid arthritis and lupus. That product and similar implants made by other manufacturers have been placed in 1 million to 2 million American women. If fraud has occurred, the cost cannot be compared with chicanery in other industries, for at stake is more than the customers' investment. It is their health and, in some cases, their very lives.

The charges of fraud have struck an industry already reeling from allegations of deception, greed and insufficient attention to their products' safety. The Food and Drug Administration is currently investigating an alleged cover-up by Hoffmann-La Roche of the lethal effects of its liquid anesthetic Versed, which has been linked to 40 deaths from respiratory failure. And while fraud has not been alleged against Pfizer, the New York City–based company will set aside $500 million for problems arising from one of its now dis-

continued artificial heart valves, which exhibit a sometimes fatal tendency to crack inside the body.

Meanwhile, Eli Lilly is battling several lawsuits that claim, on the basis of scant evidence, that the antidepressant Prozac can cause extreme agitation, suicidal tendencies and even an impulse to murder.

A critical social contract between manufacturers, regulators and the public seems to be unraveling. "I just don't trust the drug companies as much as I once did," says New York City real estate agent Peggy Mathews. "Halcion and silicone implants stand out like beacons, putting us all on the alert." She has reason to worry, says Dr. Sidney Wolfe, a consumer activist who heads Public Citizen's Health Research Group. "The heart of the problem is the dangerous amount of control the industry has over testing. Hundreds of people have been killed and thousands injured because data have been falsified."

Is Wolfe just crying wolf? Or has a pervasive corruption—which the FDA seems powerless to stop—spread throughout the pharmaceutical and medical-device industries? Upjohn and Dow Corning strenuously deny any wrongdoing.They point out, rightly, that only a small proportion of consumers report problems with their products, and that it is naive to expect perfection in so large and complex a business. In the U.S. alone, there are 3,000 types of drugs on the market and more than 1.5 billion prescriptions written every year. A small number of incidents with a handful of drugs is hardly an indictment of the entire system.

	HALCION	SILICONE-GEL BREAST IMPLANTS	PROZAC	VERSED	BJORK-SHILEY HEART VALVE (C-C model)	GENERIC DYAZIDE
	Upjohn	Dow Corning Wright and others	Eli Lilly	Hoffmann-La Roche	Pfizer	Bolar
MARKET	**$240 million** estimated 1991 worldwide sales	**1 million to 2 million** implants in the U.S.	**$1 billion** estimated 1991 worldwide sales	**$150 million** estimated 1991 U.S. sales	**86,000** implants worldwide	**$50 million** estimated 1989 U.S. sales
ALLEGATIONS	Company scientists omitted data from a 1972 summary of studies that would have linked the sleeping pill with paranoia and agitation.	Complaints about leakage, ruptures and autoimmune disorders spurred the FDA last year to take a closer look. Internal company documents suggest that Dow knew about problems in the mid-1970s.	Media stories, fueled in part by the Church of Scientology, linked the antidepressant to extreme agitation and suicidal tendencies.	In 1988 a congressional subcommittee investigated evidence that tied 40 deaths to breathing and heart problems associated with concentrated doses of the liquid anesthetic.	By 1984 the FDA knew of dozens of incidents of valve fractures, possibly associated with weak welds. More than 300 deaths have since been blamed on the device.	In 1987 Bolar forged documents in seeking FDA approval. In addition, its generic version of the high-blood-pressure pill was found to be defective.
STATUS	Britain banned sales last year; Upjohn is appealing. In the U.S., small doses are urged and stronger warnings are in place.	In January the FDA declared a moratorium on the implants until an expert advisory panel reports on new information.	After a scientific survey, the FDA ruled last fall that the drug does not cause suicidal or violent behavior.	The drug remains on the market in both stronger and weaker concentrations.	Taken off the market in 1986. Pfizer will set aside $500 million to settle claims.	Bolar's pills were recalled in 1990, and the company was fined $10 million.

TIME Graphic by Steve Hart

In addition, say some drug-industry experts, the system has a built-in incentive for companies to be honest about their products' quality. "The negative fallout of dangerous drugs is much worse in many cases than not getting the drug approved to begin with," says Dr. Kenneth Kaitin, assistant director of the Center for the Study of Drug Development at Tufts University. "If a drug has to be pulled from the market, it's very bad for public relations, financially and in every possible way. It just doesn't make sense that they would intentionally conceal real problems."

That kind of thinking had been the basis for a relationship of trust between the medical-products industry and the FDA. Historically, the agency has counted on the pharmaceutical firms, when they apply for approval of a new drug or device, to carry out the necessary testing themselves and to do it honestly. Though agency panels scrutinize the results of industry research, they rarely demand the raw data, relying instead on the analyses and conclusions drawn by the company. The FDA simply does not have the personnel or the budget to do all the research itself—nor would it be practical for it to do so. "That road leads to madness," says Dr. Jere Goyan, dean of the school of pharmacy at the University of California, San Francisco, and former head of the FDA. The FDA is designed to act as a brake, not a developer.

But relying on drug marketers to analyze research data has serious drawbacks. Raw data are often ambiguous; the medicine vial can be half empty or half full. Considering that it can take an investment of $200 million and 10 years to bring a drug from the lab bench to the pharmacy, manufacturers have a powerful incentive to look on the bright side, particularly when problems turn up late in the game after millions have been expended. "They definitely have rose-colored glasses," admits Robert Temple, chief of the FDA's office of drug evaluation.

Still, the system mostly seems to work. Last year the government carried out 203 random inspections of clinical investigators and discovered just eight studies that were significantly flawed. (Offending researchers can be permanently barred from submitting any drug tests to the FDA.) The low rate of skulduggery has remained constant since 1962, which helps explain why there has historically been a "gentlemanly working relationship between the FDA and industry," says Dr. Norman Anderson, a professor at the Johns Hopkins University School of Medicine who has served on numerous science advisory panels for the FDA.

The silicone breast-implant scandal may, however, change that relationship. Anderson's own trust in the system was shattered on Dec. 12, when he sat down and read scores of Dow Corning documents, including 17 internal memos dating as far back as the mid-1970s, about silicone-gel breast implants. The information surfaced during a liability suit in Michigan. When he finished, Anderson wrote and hand-delivered both the documents and an urgent letter to the FDA demanding that all such implants be promptly removed from the marketplace. "This appeal is not made lightly," Anderson wrote. He noted that Dow Corning officials had assured an FDA review panel, of which Anderson was a member, that the company had disclosed all relevant information on implants. "I am now in possession of unprotected court documents which indicate this was not true." Anderson's conclusion: the memos leave "little doubt of [Dow Corning's] misrepresentation of the facts."

The resulting furor rattled the FDA like no scandal since the thalidomide scare of the early 1960s. Following Anderson's appeal, the agency declared a moratorium on all silicone-gel implants, pending further review. "It's the ultimate case as to why you need a strong agency," says FDA Commissioner David Kessler. Now, says Kessler, "the honor system is out the window." He promises that companies will be subject to intensive audits in which investi-

gators will scrutinize how data are analyzed and presented by the manufacturers. Says he: "People have to know that we have the will and resolve to deal with those who have crossed the line."

Brave words from a bureaucrat with limited power. Although the FDA is entrusted with guaranteeing the safety of all medical drugs and devices in the U.S., it is poorly armed for the job. For example, unlike almost every other federal agency, the FDA lacks the legal clout to subpoena a company's internal records if a problem is suspected. Congress woke up to the problem last fall, at Kessler's prodding, and introduced a bill that would have enabled the agency to seize corporate documents. The threat of a presidential veto halted the measure, though the new revelations about Halcion and breast implants seem likely to revive the initiative.

The drugs scandals of the '90s are prompting other calls for heightened regulation. One proposal, currently making its way through Congress, would give the FDA commissioner emergency powers to pull any drug from the market. At present, about all he can do is jawbone a recalcitrant company into withdrawing a dangerous product. "It's easier for the Consumer Products Safety Division to recall a toaster than for the commissioner of the FDA to recall a dangerous drug," grouses a Capitol Hill staff member. Even so, the measure is strenuously opposed by both the Pharmaceutical Manufacturers Association and the White House, which sees it as burdensome regulation.

Would-be reformers are also pushing the FDA to adopt a more strenuous review of drugs after they have been approved for marketing. Such postapproval monitoring is already being tried in Canada, Britain and Sweden, where officials can tap into data from a national health-care system. The reasoning behind the push is quite straightforward. Clinical trials typically include a few thousand people and can therefore pick up only the most obvious and prevalent side effects. Once a drug enters the market, hundreds of thousands or even millions of people start using it, often for sustained periods of time—when more subtle or long-term risks may come to light. Such was the case with "beta-blocker blues," a syndrome of fatigue and mild depression sometimes associated with regular use of a popular category of heart drugs called beta blockers. The syndrome went undetected in clinical trials.

Currently the FDA relies on spontaneous reporting of postmarketing problems by physicians who prescribe the drugs or manufacturers who may receive complaints from doctors. It is a seriously flawed system, says Joe Graedon, author of several consumer-oriented books about prescription drugs. First, says Graedon, if a patient has a problem—say an upset stomach or itching skin—he or she may not make the connection to a drug or medical device. Second, even if the patient does make the link, the doctor may dismiss it. Third, a physician simply may not take the time to report a suspicious problem to the FDA or drug manufacturer. "It means extra time, extra paperwork, and there is always the fear of litigation." Graedon believes the FDA should contract with large medical groups—major HMOs, for instance—to keep data bases on adverse reactions.

The Bush Administration might even be persuaded to go along with this extra regulatory step. For several years now, it has been pressuring the FDA to streamline its approval process. Agency officials have been reluctant, and the recent scandals have proved them right. But streamlining approval may make more sense if postapproval surveillance is beefed up.

Drug companies are marshaling their forces to oppose increased government oversight. Those that stand accused are also conducting somewhat belated counteroffensives to limit the legal damage and repair their frayed reputations. Dow Corning, which has been widely criticized for reacting insensitively to the implant debacle, announced that it has retained former Attorney General Griffin Bell to lead an independent investigation into its development and marketing of implants. The company has also agreed to make public 90 additional documents and to ensure that it provides accurate information to the thousands of women calling the company for advice.

CHARLES TASNADI—AP

"The honor system is out the window . . . We have the will and resolve to deal with those who have crossed the line."

—FDA CHIEF KESSLER

Upjohn is meanwhile reassuring physicians that reported problems with Halcion occur only at high doses and if the drug is taken for long periods of time. At the FDA's request, Upjohn revised the drug's package insert to warn patients not to extend its use beyond 10 days without consulting their physician. Last week the firm filed a libel suit against its Scottish accuser, Dr. Ian Oswald, and the British Broadcasting Corporation for televising allegations of fraud. Upjohn is also actively appealing the British Department of Health's decision last fall to ban Halcion.

The negative publicity has affected the whole industry, prompting several companies to curry favor with the public. Last month Bristol-Myers Squibb announced that it will donate 17 different brands of blood pressure– and cholesterol-lowering drugs for use by patients whose doctors will certify that they have no insurance or other means of paying. In addition, Bristol Myers, Syntex and Merck have announced that they will provide 12.5% price rebates on drugs dispensed in federally financed public health programs for the poor.

All the goodwill gestures in the world seem unlikely to deflect the growing movement toward further government regulations of the pharmaceutical industry. Experts caution, however, that hastily written rules, even if they are produced with the best of intentions, can backfire. The Orphan Drug Act, for instance, was passed in 1983 to encourage the development of drugs for rare diseases. The law provides an extra economic incentive, in the form of a seven-year monopoly, to companies that market products for maladies that afflict

fewer than 200,000 people. Though it has done some good, it has also been widely blamed for the outrageous prices of certain medications, including aerosolized pentamidine for AIDS patients, and for allowing some companies to make a killing when an "orphan drug" has turned out to be useful for a common disease. Congress is working on revising the measure.

Despite such regulatory pitfalls, the time is ripe for putting some teeth into the FDA. A profit-driven system cannot be so dependent on trust, particularly when lives hang in the balance. Doctors and their patients also bear some responsibility for using drugs wisely. "All drugs have risk," observes physician-activist Wolfe. "Most of the time the benefits outweigh the risks. But there is abysmal ignorance on the part of the public about side effects." In a culture that has long been addicted to the quick fix, a healthy respect for the power of the pill—negative as well as positive—may prove to be the best medicine of all. ***—Reported by Mary Cronin and Andrew Purvis/New York and Dick Thompson/Washington***

Special Report: Drug Safety

Lawyers to the Rescue

Legal action helps keep drug companies honest, but it's a crazy way to regulate an industry

By MICHAEL D. LEMONICK

The news about the dangers of silicone implants may have struck terror into the hearts of thousands of women, but for many trial lawyers it represents a bonanza. More than 1,000 implant-related lawsuits have already been filed by women who claim they were disfigured or debilitated by the devices. And the revelation that manufacturers may have knowingly buried facts about the dangers is causing the numbers to skyrocket. Some attorneys have even set up toll-free numbers to handle—and encourage—the surge.

The most aggressive of them advertise in newspapers, on billboards and even on TV with come-ons such as "Has your breast-implant surgery gone wrong? We can help." Doctors find this alarming. "They're scaring the hell out of the women who have had these things put in," complains Dr. Mark Gorney, medical director of the Doctors' Co., a large malpractice insurer. "Any woman with an implant who has a twinge in her shoulder says, 'Oh, my God, I'm going to die.'" Many attorneys also worry about the appearance of a feeding frenzy.

JOHN GIORDANO—SABA FOR TIME

New York attorneys Arthur Luxenberg, left, and Perry Weitz see no problem with their recent decision to advertise in newspapers. Says Luxenberg: "Women are delighted that they have someplace to turn."

Alas, massive lawsuits and ambulance-chasing lawyers have become a major part of America's beleaguered system for regulating medical products. To be fair, legal action is not only a valuable recourse for patients who have been harmed; it can also expose problems overlooked by regulators. It was lawsuits in Michigan and California—and aggressive reporting by newspapers—that revealed Dow Corning Wright's internal memos concerning the risks of silicone-gel implants.

The fear of lawsuits also forces drug companies to be honest. "I will sue people so that I can protect women," says Connecticut attorney Karen Koskoff. An implant recipient herself, Koskoff co-chairs the implant litigation group at the Association of Trial Lawyers of America (ATLA).

Of course, forces other than altruism may be at work. Attorneys usually work on a contingency fee, collecting nothing if the action fails but pocketing at least 30% of the proceeds if the defendants pay up. The three judgments so far in implant cases have ranged from $4.5 million to $7.3 million. Cases settled out of court can bring $500,000 to $750,000.

For all the virtues of the judicial system, the courtroom is not the best place to work out scientific truths. Lawyers pursuing drug-liability suits often depend on a small cadre of "expert witnesses" to help make their case. These hired guns, complains Frank Woodside, a doctor and attorney for Dow Corning Wright, "don't always have qualifications, and prey upon the sympathy of the jurors."

Last fall, for instance, despite ambiguous evidence, a jury ordered Merrell Dow to pay a Texas couple $33.8 million; they claimed the antinausea drug Bendectin had maimed their child in the womb. And patients around the country are lining up to sue Eli Lilly, alleging that the antidepressant Prozac induces violent thoughts—despite FDA findings to the contrary. In some cases, companies decide to settle out of court rather than take their chances with juries. Upjohn, for example, paid an undisclosed sum to a woman who claimed the drug Halcion had driven her to commit murder. Most doctors believe the allegation is absurd.

Nor is truth served by the publicity and lobbying battles between medical societies and legal organizations. ATLA holds conventions twice a year to discuss strategies in breast-implant suits, and issues ATLA alerts to warn the public about drugs and medical products it considers dangerous. Such announcements are supposedly issued as a public service, though the lawyers clearly have an interest in the matter.

Doctors are just as organized and just as eager to get their version of the facts across. The plastic surgeons' society plans to spend about $500,000 over the next year to "tell the other side of the breast-implant story." The society has even formed a political-action committee—PlastyPAC—with a war chest of $120,000 to lobby and reward policymakers who help keep implants on the market.

No one can argue against compensating the victims of dangerous products. But a system based on political influence and courtroom science is just as dangerous as drug firms that hide test data. Inappropriate awards and public relations battles drive up the cost of products and can make companies think twice about bringing to market new, potentially lifesaving drugs. The best way to assure safety is through a more rigorous and independent approval process rather than scattershot lawsuits once the damage is done. ***—Reported by Andrew Purvis/New York***