



DEPARTMENT OF HEALTH & HUMAN SERVICES

Chief of Staff

JUN 13 REC'D

Washington, D.C. 20201

JUN 13 1994

file

To: Carol Rasco
From: Kevin Thurn *[Signature]*
Re: Breast Cancer Detection Device

The Wall Street Journal article of April 12 describes a company's attempts to market in the U.S. a device purported to aid in the early detection of breast cancer, and FDA's attempts to obtain the scientific evidence needed for approval of the device.

This device, called a sensor pad, is two sealed plastic sheets with a lubricant between them that, when placed over the breast, is intended to reduce friction and increase the ability to detect lumps.

FDA is concerned that because the sensor pad is between the breast and the fingers, it might actually make detection of lumps more difficult. For this reason the FDA has requested from Inventive Products, the maker of the sensor pad, clinical studies showing the pad's safety and effectiveness.

At this time, Inventive Products has not submitted the necessary information for approval. FDA has met with Inventive Products since their initial contact with FDA in 1985 and continues to meet with them to produce the information necessary to show the product's safety and effectiveness.

Attached is a copy of the WSJ article and a fact sheet used by FDA to explain the situation. If you have any other questions please call.

**FDA
TALK PAPER****FOOD AND DRUG ADMINISTRATION**
U.S. Department of Health and Human Services
Public Health Service 5600 Fishers Lane Rockville, Maryland 20857

FDA Talk Papers are prepared by the Press Office to guide FDA personnel in responding with consistency and accuracy to questions from the public on subjects of current interest. Talk Papers are subject to change as more information becomes available. Talk Papers are not intended for general distribution outside FDA. See all information in these Talk Papers, and full ones are available upon request.

T94-19
April 13, 1994Sharon Snider
(301) 463-3385**Sensor Pad**

FDA is receiving inquiries about Sensor Pad, a thin plastic pad filled with liquid silicone designed to aid in breast self examination.

This product is not currently approved as safe and effective by FDA. The agency has informed the manufacturer, Inventive Products Inc. of Decatur, Ill., that it must conduct clinical studies on the product's safety and effectiveness and obtain pre-market approval from FDA in order to legally market it.

FDA is requiring the firm to conduct clinical trials because the agency has not seen valid scientific evidence that the product will actually help women detect lumps and aid in the detection of breast cancer.

FDA is concerned that rather than aid in detection, the product might actually miss lumps or mask their presence. Detection of lumps has important health implications for American women. If a product making this claim does not perform as intended, women who depend on it are put at grave risk.

Inventive Products submitted a pre-market notification (510k) for Sensor Pad in 1985, saying the device was substantially equivalent to a legally marketed product. Upon review, FDA concluded that the device and its use were different from other

-MORE-

Page 2, FS-19, Sensor Pad

devices. The firm was told that it would need to submit a full premarket approval application (PMA).

Despite the denial of its application, in 1987 the firm began illegally marketing sensor pads to hospitals. This led to a series of seizures of the product by FDA. When the firm contested the original seizure, a federal court ruled in favor of FDA, concluding that the pad was an adulterated medical device. The firm appealed the ruling, contending that the product was not a medical device.

In 1991, a federal appeals court affirmed the original ruling that the pad was a medical device and that an approved PMA would be required before the device could be marketed. Following the initial seizure and throughout the legal process, the firm continued to distribute the device, and FDA continued to seize it.

In 1989, following the initial seizure, the firm submitted a PMA to the agency. This application contained little information and it was inadequate as a basis for determining safety and effectiveness.

FDA has been working with Inventive Products for the past nine years to assist in its attempt to bring its product to market. The agency is continuing to work with the firm to help it identify what is necessary to show the product is safe and effective. FDA has met numerous times with the manufacturer to discuss the type and quality of data that are needed and the ways clinical trials can be conducted so as to be the least burdensome on the firm yet still provide the necessary information on safety and effectiveness.

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THE GREEN SHEET 49

Safety First Wall St. J. (4-12-94) p. 1

How a Device to Aid In Breast Self-Exams Is Kept Off the Market

Other Nations Approved It. But U.S. Demands Proof Simple Pad Isn't Risky

Nine-Year Battle With FDA

By BARRY BRONSTEIN
Wall Street Journal

It is about as simple as a medical device can get: two sealed plastic sheets with lubricant in between. It is laid over a woman's breast like a cloth during an examination, to reduce friction.

Clotilda Richardson thinks it probably spared her death from breast cancer. John Withers, a surgeon at the Māui Clinic in Hawaii, says it is one of the most effective weapons against breast cancer in years. And Patricia Radmond, a New York radiologist, says it "can absolutely save lives."

But don't try buying it in the U.S. Though many doctors and cancer special-

Revolving Product Approvals
While the FDA keeps many medical-device producers in limbo with long delays in approving new products, it can also take away approvals—often with devastating results. *Entrepreneur*, page 82.

ists hail the Sensor Pad as a useful tool in detecting the disease that many women fear most, and though it years ago sailed through approval processes in countries in Europe and Asia, the Food and Drug Administration won't let Inventive Products Inc. sell it in this country.

Grant Wright, the president of Inventive Products, and his father, Earl, the pad's co-inventor, have been fighting for nine years to get clearance for the product. What began as an FDA request for more information has degenerated into a long, debilitating struggle and allegations that the Wrights violated federal law. So frustrated did the Wrights become about the bureaucratic maze that six years ago they started selling the pad to U.S. hospitals without FDA clearance. That triggered a court battle that they lost in 1992. Now they are back to trying to win FDA clearing for the pad.

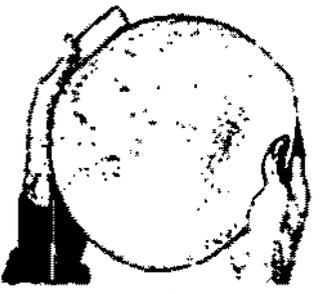
Missing Information?

But if the company isn't required soon, Grant Wright says, he will close his Decatur, Ill., company, which costs about \$4,000 a month to operate and has already burned through \$26,000 in legal fees. "I'm 53, with a wife and three kids," he says. "I've got to do something with my life."

Mr. Wright's struggle, in the eyes of some, is more than just the tale of a small-town entrepreneur's tangle with far-away bureaucrats: It is more, too, than a story of how the medical-device industry in the U.S. copes with the world's most stringent regulatory system. To some advocates of his simple device, it is a manifestation of the way the nation's litigation-driven system to risk can stifle innovation in the medical marketplace. "We as a society refuse to take risks and want 100% guarantees that our lives are going to be perfect," says Mary Palmore, a Chicago gynecologist.

Dr. Palmore acknowledges that the FDA has a legal duty to ensure that the pad isn't falsely promoted as a diagnostic tool, but suggests that the agency itself may be caught up in what she sees as a national obsession with safety. "The FDA is concerned that in any litigious society, a woman will say, 'I used it, and I got cancer anyway,'" Dr. Palmore says.

The agency says that safety, not litigation, is its main concern. And it strongly



defends its refusal to authorize the Sensor Pad. "Their position is very worthy," Susan Albert, director of the FDA's Office of Device Evaluation, says of the Wrights. "But the issue for the agency is of ensuring that we don't allow to market any device that poses significant risk without an attendant benefit."

Indeed, many consumer advocates and health-care specialists applaud the FDA's rigor in screening devices, and some complain that it doesn't act forcefully enough. The FDA, meanwhile, faces a huge backlog of applications for new medical devices, which has stretched the average review time to 136 days. The agency says it is working hard to shorten the backlog of more than 1,600 applications.

Breast cancer took an estimated 46,000 lives in the U.S. last year and was the second-highest cancer killer of women. Early detection is essential to detecting it, and frequent self-examination is essential to that effort. But many women don't find this easy, and that is where the pad comes in. Its lower sheet clings to the skin while the top sheet "slides" on a thin layer of liquid silicone, eliminating friction so a finger can explore the contours of an object as small as a grain of salt.

"The thing that amazes me," says the court, "is our market place."

W.T. TAMM: 6-12-94

3M Will Pay \$325 Million To Settle Implant Suits

ST. PAUL, April 11 — The Minnesota Mining & Manufacturing Company announced today that it had agreed to compensate \$325 million to a fund to compensate women who received silicone breast implants.

The agreement leaves the General Electric Company as the last major holdout against the huge legal settlements, which in some cases exceed \$4.3 billion, according to lawyers for the women who have sued, concluding that the plaintiffs are responsible for medical problems.

Spokesmen for 3M said the company would contribute the money over three years, recording a \$22 million after-tax charge in the first quarter of this year. In addition, Inamed Inc., the Los Vegas-based owner of 3M's former unit, the McChes Medical Corporation, will contribute \$25 million.

The Union Carbide Corporation also agreed to pay \$18 million to settlements that concluded on Friday, the company announced.

Paying Over 20 Years

The other main contributors, Dow Corning Inc., Bristol-Myers Squibb and Becton Dickinson International, have agreed to pay into the fund over 20 years. The settlements agreement, which has been approved by a Federal district judge in Birmingham, Ala., is intended to end most lawsuits over the devices.

General Electric supplied raw silicone to implant manufacturers from 1972 to 1976 but does not believe it is liable for any injuries caused by the substance, said a spokeswoman, Phyllis Pineda.

Under the terms of the overall agreement, reached in February, women will receive payments of about \$200,000 to \$2 million for diagnosis, treatment and removal of leaking silicone breast implants. An estimated one million to two million American women have received the implants over the past 20 years, women have sued and thousands of lawsuits against the manufacturers, asserting that the silicone seeped from the implants throughout their bodies, causing a variety of diseases, including life-threatening autoimmune disorders like lupus.

The 3M company manufactured breast implants from 1977 to 1984, when it sold McChes. It agreed to join the settlement a month after it had started with a \$140 million jury verdict in Houston in a lawsuit by three women who had received implants.

from previous page.

Younger Mr. Wright, "is that the research spreading (on breast cancer) keeps going up and I can't get the device I product into the hands of women who want it."

His father, Earl, once thought the Sensor Pad would be a big success. Mr. Wright, 43, is an established inventor whose products range from a blood-serum filter used in laboratories to nonpowered foaming pumps used by hospital surgeons. Mr. Wright in 1986 set up Inventive Products as a subsidiary of his Earl Wright Co. solely to make and market the Sensor Pad. He put his son in charge.

Gaining approval to use it in other countries wasn't a problem. Inventive Products applied for marketing authorization in Canada in 1983 and got it within 30 days. Grant Wright says. He also says the pad has been approved in Japan, Singapore, Korea, Thailand and most West European countries, although Inventive Products hasn't actively promoted it abroad. "We've had no problems anywhere in the world," he says.

Except at home. When the Wrights sought FDA clearance for the device in 1983, the agency's initial response was positive. Still, the government wanted more information. "Every time we submitted information, they asked for more," the son recalls. After several months, the agency denied approval for the pad - but indicated its concerns might be met by extensive labeling changes.

The FDA wanted the labeling to state that the Sensor Pad could be sold by prescription only. And it wanted all references to breast cancer deleted. The label was to include the chemical composition of the device. It also was to describe the 10-inch-diameter pad's "susceptibility to heat, sunlight, soap, formalin, alcohol and other mechanical agents."

Mr. Wright says he immediately set about complying with the requests. But about three months later, he says, the FDA inexplicably notified him that it wouldn't reconsider approving the product. Instead, he was told, Inventive Products would have to go through a laborious "premarket approval" process for new medical devices.

This process is meant to keep new, costly high-technology instruments off the market until they can be adequately tested for safety. Few people would disagree that the FDA should get convincing evidence that invasive devices are safe. More than 200 people died in the 1980s when their Spont-Shiley heart valves fractured. By instance, that Mr. Wright argues that the Sensor Pad poses no direct risk to users.

The FDA responds that the indirect risk - that a cancerous lump would go undetected - is potentially lethal.

The agency's Dr. Albert says the fact that a device is simple doesn't necessarily mean it is benign: everything depends on its "intended use." She dismisses endorsements from doctors and patients - which, she says, many device makers try out - as anecdotal evidence that is insufficient to make a scientific case. "Reporting doesn't do it - data does," she says.

In 1982, only 12 medical devices were given FDA premarket approval, including heart pacemakers. Issues that are unrelated to the eye after cataract surgery and devices for stimulating kidney stones. Of the simple, noninvasive pad, "I've never seen a product like this held off the market," says John Isaacs, a gynecologist at Evanston, Ill., who is the author of a textbook on breast disease.

But the FDA says the Sensor Pad needs to be scrutinized because it isn't "substantially equivalent" to a product already on the market, a legal requirement for quick approval of simple devices. The Wrights argue that the pad is substantially equivalent to soap and water, a mixture the medical community has long recommended to reduce friction in breast self-examination.

To obtain premarket approval, the FDA said, Inventive Products would have to conduct exhaustive clinical tests on women, comparing the number of breast-cancer cases detected through self-examination with and without the Sensor Pad. Such tests, Mr. Wright says, would require a huge sample - a minimum of 82,000 women - to produce statistically meaningful results. An FDA spokeswoman disputes that figure. "We want to be as reasonable as we can," she says. "The number will be much less than that."

Mr. Wright says he has already done two trials with simulated breast models, which he claims yield more accurate results. In the first, women examined the artificial breasts for lumps using both the pad and their bare hands. In the second, they used both those methods and also a third method - soap and water on their hands. The tests showed that the pad enhanced sensitivity and resulted in increased lump detection, Mr. Wright says.

The FDA rejected his trials as insufficient. The prospect of starting over with the lengthy, expensive tests the FDA demanded pushed the Wrights to change their course. Because they never considered the pad to be a medical device as defined by federal law, they decided in 1988 to market the product directly to hospitals. The Wrights say they - and their attorney - figured the FDA either would recognize its lack of jurisdiction or take Inventive Products to court and force the issue.

Over 15 months, the Wrights sold 250-300 pads to some 200 hospitals. But in April 1989, federal agents raided the company's Decatur plant and a number of hospitals and confiscated the pads.

The action came one day after Earl Wright was named a trustee in the Executive Property Owners Foundation's conversion-of-the-year contest for his "touch-sensing device."

Grant Wright challenged the FDA's claim to jurisdiction over the pad. But in 1989, a U.S. district court in Danville, Ill., ruled for the FDA. Mr. Wright appealed, and two years later an appellate court in Chicago upheld the ruling. At that point, Inventive Products told the FDA it had ceased marketing the pad.

But Mr. Wright didn't give up. In March 1992, he filed an ethics complaint with the FDA's integrity office against some agency officials after learning that they had met with a minority shareholder of the company without his knowledge. After he filed the complaint, he says, the FDA turned hostile. At a meeting in Washington in August 1992 to discuss requirements for premarket approval, he says, an FDA lawyer - flanked by 10 other agency officials and a Justice Department lawyer - "told us we'd never get our product to market."

An agency spokeswoman says it is doubtful such a remark was made. "We have gone out of our way to show the Wrights how to get their product marketed. Such a comment doesn't make sense," she says.

Mr. Wright promptly fired off letters of complaint about the meeting to the FDA and to Rep. John Dingell of Michigan, who is known for railing on the FDA for its missteps. More letters flew back and forth. An FDA integrity officer wrote that the FDA was acting in good faith. Mr. Wright responded by demanding an investigation of the FDA lawyer who attended the August meeting. A couple of days later, his Washington lawyer sent a seven-page letter to a Dingell staffer, accusing the FDA of "hounding" Inventive Products.

Four months later, the Wrights received notice from an FDA compliance officer that the agency was investigating them for possible violations of federal law for selling the pad in 1989-91. Mr. Grant says he has received no word about the investigation since an FDA administrative hearing in Chicago last June. But, he says, he has gotten the message: "If you squeak, they will slap you around." The FDA denies taking any retaliatory ac-

tions.

Meanwhile, members of the community continue to support the Sensor Pad. Dr. Withers, the surgeon at the Cancer Clinic, says the pad has twice enabled him to feel otherwise undetectable lumps. He scoffs at the idea that using it might give women a false sense of security, one of the FDA's main concerns. "There is no question that the Sensor Pad increases my tactile ability," he says. "It makes it 100% easier."

Gale Katterhagen, medical director of the cancer center at St. Joseph Medical Center in Burbank, Calif., says tests he conducted for Inventive Products several years ago indicated that women who used the pad were 25% more likely to perform monthly breast exams. "This device is marvelous," Dr. Katterhagen says.

Women who use the pad swear by it. Ms. Richardson, a 43-year-old Decatur resident, doubts that she would have found two small lumps without the pad. She had a double mastectomy. "It probably saved my life," she says, adding that she gave one to her 17-year-old daughter.

Mary Gorman, a 55-year-old writer in Washington, is certain the pad saved her breast. "I found my cancer before it was detectable on a mammogram," she says. Her surgeon, Katherine Alley, says the device may have saved Ms. Gorman's life. Considering the lethality of breast cancer, Dr. Alley says, "it is just ridiculous" to keep the pad off the market.

Potential demand appears to be huge. When a Pittsburgh hospital offered on local TV in 1989 to send out free samples, it was flooded with 35,000 calls and letters.

For all that, the FDA's Dr. Albert believes that Inventive Products is largely responsible for the delays it has encountered. "There are lots of different trials they could do to show this is true," she says. "It doesn't have years and years."

The elder Mr. Wright has managed to commercialize the Sensor Pad's anti-friction technology for a much smaller market. He has built the Stryp, a nylon and plastic sheet used in hospitals to transfer patients from a gurney to a bed. About 500 have been sold.

But his son spends much of his time in his nearly empty headquarters explaining to doctors why he can't send them samples of the Sensor Pad. Last year, he laid off his own brother, reducing his work force to himself and his secretary from a peak of 25 six years ago. "We're at the point of surrender," he says.



Grant Wright

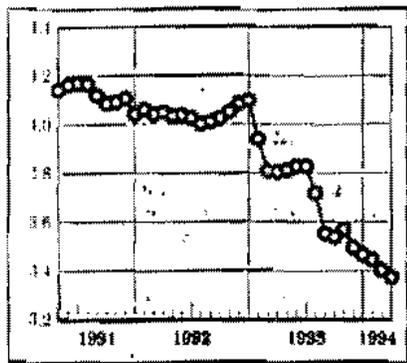


Earl Wright

Crater
What's the deal on this? - Council
Surveyed over 100,000
7300

Aluminum Production

Annual rate, in millions of metric tons.



ALUMINUM PRODUCTION in the U.S. fell to an annual rate of 3,371,658 metric tons in March from 3,401,096 metric tons in February, the Aluminum Association reports.

First Lady's Top Aide Brings New Clout To the East Wing

Presiding Over Hillaryland, Maggie Williams Finds Power Comes at a Price

By MICHAEL K. DYBRY

WASHINGTON — Margaret Williams has resumed writing poetry again, a pastime she gave up years ago. "The only thing you have to hold on to is what's inside you," she says. "They can rant and rave about what I've done, or what they think I've done."

And just what has she done, the 39-year-old chief of staff to Hillary Rodham Clinton? By all accounts, Ms. Williams—known as Maggie—has become the most



Maggie Williams

powerful African-American woman ever to serve in the White House. In the process, she also has become the most powerful chief of staff that the East Wing—the first lady's domain at the White House—has ever seen; in status-conscious Washington, it is extremely significant that Ms. Williams's own office is located in the White House's West Wing.

But there are questions about what Ms. Williams has done regarding the vexing controversy over President and Mrs. Clinton's investment in the Whitewater Development Co. real-estate venture. Her boss, having been viewed as an inspiration for women, is increasingly portrayed in the press as an uptight lawyer who is at the center of many of the administration's problems. Ms. Williams herself is one of three people who went into Deputy White House Counsel Vincent Foster's office the night he committed suicide. She has been the target of conspiracy theories concerning what might have happened to Mr. Foster's files on the Clintons' investments in Whitewater, which later

Labor Letter

A Special News Report on People And Their Jobs in Offices, Fields and Factories

COMPANY SMOKING BANS: Do they actually help workers quit?

Merck Chairman Roy Vagelos says the number of employees who smoke fell 25% during the first 18 months of a companywide ban; more than a third of the employees who took smoking-cessation classes stayed off cigarettes for two years. State Farm reports similar results. "I've had employees come up and say to me that this is the only way they ever could have quit smoking," says personnel director Ron Prewitt.

But Country Companies Insurance, Bloomington, Ill., which boasted a 25% success rate when it launched antismoking programs in 1987 and 1988, now drops them for lack of worker interest; many people just leave at lunch to smoke, or smoke at home, says spokeswoman Deanna Frautschi. Bell Atlantic, which instituted a smoke-free workplace in 1988, also stops paying for smoking-cessation programs, as does Consolidated Papers, Wisconsin Rapids, Wis.

Public Service Electric & Gas of Newark, N.J., though, helps some 3,370 employees who smoke—28% of its work force—through American Cancer Society and other programs.

IT'S STILL THE BACK of the plane for most business travelers.

The end of the recession hasn't brought much more first-class travel for executives, companies say. Electronic Data Systems, which ended such perks in 1991, pays for first class only if a critical contract is at stake. American General, a Houston insurer, reserves the wide seats for its executive vice presidents and unit presidents.

Home builder Centex Corp. and others ban first-class travel unless executives use frequent-flyer certificates. Most companies let executives keep their miles, then trade them in for free flights or upgrades. Encore Computer, Plantation, Fla., reimburses employees half of the discounted rate for any flight in which personal frequent-flyer miles are used.

GAY RETIREES soon will have their own retirement community.

The Palms of Manasota, a 20-villa complex, is on the drawing boards outside Sarasota, Fla. Bill Laing, who is building the property, is still searching for the right site, but expects to find it soon. He already has received more than 300 inquiries after ads in gay publications such as 10 Percent and the Advocate tout "The First Alternative Retirement Home."

"There is nothing in the country like this, not one retirement home" for gays and lesbians, says Mr. Laing, who plans to include a permanent-care home for residents unable to cook and handle daily chores. What about heterosexual applicants? "If I get straight people who want to come in, I cannot by law keep them out," he says. "But they must know that it's going to be made up of gay and lesbian people."

Mr. Laing says he is pleasantly surprised about a lack of backlash. "We haven't gotten any homophobic mail. Not any."

THE FEDERAL GOVERNMENT kicks off a massive effort to spur early retirements. U.S. officials hope to lure as many as

Safety First

How a Device to Aid In Breast Self-Exams Is Kept Off the Market

Other Nations Approved It, But U.S. Demands Proof Simple Pad Isn't Risky Nine-Year Battle With FDA

By BRENT BOWERS

Staff Reporter of THE WALL STREET JOURNAL

It is about as simple as a medical device can get: two sealed plastic sheets with lubricant in between. It is laid over a woman's breast like a cloth during an examination, to reduce friction.

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Grant Wright, the president of Inventive Products, and his father, Earl, the pad's co-inventor, have been fighting for nine years to get clearance for the product. What began as an FDA request for more information has degenerated into a long, debilitating struggle and allegations that the Wrights violated federal law. So frustrated did the Wrights become about the bureaucratic maze that six years ago they started selling the pad to U.S. hospitals without FDA clearance. That triggered a court battle that they lost in 1992. Now they are back to trying to win FDA blessing for the pad.

Stifling Innovation?

But if the dispute isn't resolved soon, Grant Wright says, he will close his Decatur, Ill., company, which costs about \$4,000 a month to operate and has already burned through \$356,000 in legal fees. "I'm 33, with a wife and three kids," he says. "I've got to do something with my life."

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Her boss, having been viewed as an inspiration for women, is increasingly portrayed in the press as an uptight lawyer who is at the center of many of the administration's problems. Ms. Williams herself is one of three people who went into Deputy White House Counsel Vincent Foster's office the night he committed suicide. She has been the target of conspiracy theories concerning what might have happened to Mr. Foster's files on the Clintons' investments in Whitewater, which later were removed and handed over to the Clintons' personal lawyer.

The theories mostly center on the possibility that Ms. Williams went into Mr. Foster's office, not out of grief, as she says, or to look for a suicide note, as other White House aides have said, but to retrieve any documents that might hurt the first lady. That is one of the issues Special Counsel Robert Fiske is investigating. He also is probing whether there were improper contacts between White House and Treasury officials over the failed Madison Guaranty Savings & Loan run by the Clintons' Whitewater partner. Ms. Williams was present at a February meeting with Deputy Treasury Secretary Roger Altman.

Sympathy Cards

Her involvement in the controversy has been painful and ironic for a woman who came to the White House as an idealistic, new-generation Democrat hoping to restore faith in government. Instead of accolades for her influential position at the White House, Ms. Williams receives sympathy cards from family friends. Some send flowers.

Unflinchingly loyal to the first lady, Ms. Williams declines to talk publicly about the Whitewater controversy, or about "anything that has to do with my work." But however Whitewater turns out for her, she says it is nothing compared with other struggles she already has endured in her life and career.

"You have to look at everything
Please Turn to Page A5, Column 1

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THE FEDERAL GOVERNMENT kicks off a massive effort to spur early retirements. U.S. officials hope to lure as many as 100,000 workers to bail out, as part of the five-year goal of reducing the federal work force by 272,000. Buyout offers begin at seven agencies, including the Agriculture and State departments.

MONEY GETS 'EM, but management keeps 'em, recent studies show. Search firm Challenger, Gray & Christmas found in a survey that job candidates are wooed to new firms mostly by big salaries. But a separate survey by Wilson Learning Corp. says that what keeps employees happy is strong leadership skills among top management.

CHEMICAL WORKFARE: Nearly two of three workers world-wide are exposed to chemicals at work, the International Labor Organization reports. The United Nations arm says many problems involve agricultural pesticides and chemical production. "The problem is quite chronic in developing countries," says Isaac Obadia, ILO's health and safety expert. Training and better information are crucial solutions, he says.

TRADING PLACES: Chemical companies switch employees to learn new tricks.

Dow Chemical Co. sent employee John Latham on a two-year stint to show Nalco Chemical Co. a few things about environmental and safety operations. In exchange, Dow gets Nalco employee Steven Curtis to share his expertise in sales and marketing with Dow's Advanced Cleaning Systems business.

Such a swap is almost unheard of in the corporate world. Dow North America Vice President John Duren says the exchange resulted from the firms' mutual respect. "They buy things from us, we buy things from them, and we like the way they do business," Mr. Duren says. "We are going to borrow from each other's strengths," adds Nalco President Ted Mooney.

The swap also saves the companies a bit of money. Without the swap, Mr. Mooney says, Nalco would have had to hire someone with environmental and safety expertise.

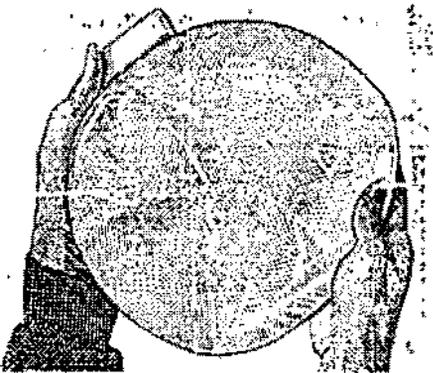
THE CHECKOFF: Only 400,000 women in the U.S. earn more than \$75,000 a year, about one-eighth of the number of men making that much, notes Women's Bureau Director Karen Nussbaum in Working Mother magazine. . . . About a quarter of all unfair labor practice complaints filed with the NLRB relate to the U.S. Postal Service, postal board Chairman William Gould IV estimates.

—KEVIN G. SALWEN

Mr. Wright's struggle, in the eyes of some, is more than just the tale of a small-town entrepreneur's tangle with far-away bureaucrats; it is more, too, than a study of how the medical-devices industry in the U.S. copes with the world's most stringent regulatory system. To some advocates of his simple device, it is a manifestation of the way the nation's litigation-driven aversion to risk can stifle innovation in the medical marketplace. "We as a society refuse to take risks and want 100% guarantees that our lives are going to be perfect," says Mary Palmore, a Chicago gynecologist.

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defends its refusal to authorize the Sensor Pad. "Their intention is very worthy," Susan Alpert, director of the FDA's Office of Device Evaluation, says of the Wrights. "But the issue for the agency is of ensuring that we don't allow to market any device that poses significant risk without an attendant benefit."

Indeed, many consumer advocates and health-care specialists applaud the FDA's rigor in screening devices, and some complain that it doesn't act forcefully enough. The FDA, meanwhile, faces a huge backlog of applications for new medical devices, which has stretched the average review time to 196 days. The agency says it is working hard to whittle the backlog of more than 5,000 applications.

Breast cancer took an estimated 46,000 lives in the U.S. last year and was the second-biggest cancer killer of women. Early detection is essential in defeating it, and frequent self-examination is essential to that effort. But many women don't find this easy, and that is where the pad comes in. Its lower sheet clings to the skin while the top sheet "floats" on a thin layer of liquid silicon, eliminating friction so a finger can explore the contours of an object as small as a grain of salt.

"The thing that amazes me," says the
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Safety First: A Long FDA-Company Fight Keeps Simple Aid to Breast Self-Examination Off Market

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younger Mr. Wright, "Is that the research spending [on breast cancer] keeps going up and I can't get this simple \$7 product into the hands of women who want it."

His father, Earl, once thought the Sensor Pad would be a big success. Mr. Wright, 63, is an established inventor whose products range from a blood-serum filter used in laboratories to nonaerosol foaming pumps used by hospital surgeons. Mr. Wright in 1986 set up Inventive Products as a subsidiary of his Earl Wright Co. solely to make and market the Sensor Pad. He put his son in charge.

Gaining approval to sell it in other countries wasn't a problem. Inventive Products applied for marketing authorization in Canada in 1985 and got it within 30 days, Grant Wright says. He also says the pad has been approved in Japan, Singapore, Korea, Thailand and most West European countries, although Inventive Products hasn't actively promoted it abroad. "We've had no problems anywhere in the world," he says.

Except at home. When the Wrights sought FDA clearance for the device in 1985, the agency's initial response was positive. Still, the government wanted more information. "Every time we submitted information, they asked for more," the son recalls. After several months, the agency denied approval for the pad — but indicated its concerns might be met by extensive labeling changes.



Grant Wright

The FDA wanted the labeling to state that the Sensor Pad could be sold by prescription only. And it wanted all references to breast cancer deleted. The label was to include the chemical composition of the device. It also was to describe the 10-inch-diameter pad's "susceptibility to heat, sunlight, soap, formalin, alcohol and other mechanical agents."

Mr. Wright says he immediately set about complying with the requests. But about three months later, he says, the FDA inexplicably notified him that it wouldn't reconsider approving the product. Instead, he was told, Inventive Products would have to go through a laborious "premarket approval" process for new medical devices.

This process is meant to keep new, mostly high-technology instruments off the market until they can be adequately tested for safety. Few people would disagree that the FDA should get convincing evidence that invasive devices are safe. More than 200 people died in the 1980s when their Bjork-Shiley heart valves fractured, for instance. But Mr. Wright argues that the Sensor Pad poses no direct risk to users.

The FDA responds that the indirect risk — that a cancerous lump would go undetected — is potentially lethal.

The agency's Dr. Alpert says the fact that a device is simple doesn't necessarily mean it is benign; everything depends on its "intended use." She dismisses endorsements from doctors and patients — which, she says, many device makers trot out — as anecdotal evidence that is insufficient to make a scientific case. "Reporting doesn't do it — data does," she says.

In 1992, only 12 medical devices were given FDA premarket approval, including heart pacemakers, lenses that are implanted into the eye after cataract surgery and devices for smashing kidney stones. Of the simple, noninvasive pad, "I've never seen a product like this held off the market," says John Isaacs, a gynecologist in Evanston, Ill., who is the author of a textbook on breast disease.

But the FDA says the sensor pad needs to be scrutinized because it isn't "substantially equivalent" to a product already on the market, a legal requirement for quick approval of simple devices. The Wrights argue that the pad is substantially equivalent to soap and water, a mixture the medical community has long recommended to reduce friction in breast self-examination.

To obtain premarket approval, the FDA

said, Inventive Products would have to conduct exhaustive clinical tests on women, comparing the number of breast-cancer cases detected through self-examination with and without the Sensor Pad. Such tests, Mr. Wright says, would require a huge sample — a minimum of 82,000 women — to produce statistically meaningful results. An FDA spokeswoman disputes that figure. "We want to be as reasonable as we can," she says. "The number will be much less than that."

Mr. Wright says he has already done two trials with simulated breast models, which he claims yield more accurate results. In the first, women examined the artificial breasts for lumps using both the pad and their bare hands. In the second, they used both those methods and also a third method — soap and water on their hands. The tests showed that the pad enhanced sensitivity and resulted in increased lump detection, Mr. Wright says.

The FDA rejected his trials as insufficient. The prospect of starting over with the lengthy, expensive tests the FDA demanded pushed the Wrights to change their course. Because they never considered the pad to be a medical device as defined by federal law, they decided in 1988 to market the product directly to hospitals. The Wrights say they — and their attorney — figured the FDA either would recognize its lack of jurisdiction or take Inventive Products to court and force the issue.



Earl Wright

Over 15 months, the Wrights sold 250,000 pads to some 200 hospitals. But in April 1989, federal agents raided the company's Decatur plant and a number of hospitals and confiscated the pads.

The action came one day after Earl Wright was named a finalist in the Intellectual Property Owners Foundation's inventor-of-the-year contest for his "touch-enhancing device."

Grant Wright challenged the FDA's claim to jurisdiction over the pad. But in 1990, a U.S. district court in Danville, Ill., ruled for the FDA. Mr. Wright appealed, and two years later an appellate court in Chicago upheld the ruling. At that point, Inventive Products told the FDA it had ceased marketing the pad.

But Mr. Wright didn't give up. In March 1992, he filed an ethics complaint with the FDA's integrity office against some agency officials after learning that they had met with a minority shareholder of the company without his knowledge. After he filed the complaint, he says, the FDA turned hostile. At a meeting in Washington in August 1992 to discuss requirements for premarket approval, he says, an FDA lawyer — flanked by 10 other agency officials and a Justice Department lawyer — "told us we'd never get our product to market."

An agency spokeswoman says it is doubtful such a remark was made. "We have gone out of our way to show the Wrights how to get their product marketed. Such a comment doesn't make sense," she says.

Mr. Wright promptly fired off letters of complaint about the meeting to the FDA and to Rep. John Dingell of Michigan, who is known for flailing the FDA for its missteps. More letters flew back and forth. An FDA integrity officer wrote that the FDA was acting in good faith. Mr. Wright responded by demanding an investigation of the FDA lawyer who attended the August meeting. A couple of days later, his Washington lawyer sent a seven-page letter to a Dingell staffer, accusing the FDA of "hounding" Inventive Products.

Four months later, the Wrights received notice from an FDA compliance officer that the agency was investigating them for possible violations of federal law for selling the pad in 1990-91. Mr. Grant says he has received no word about the investigation since an FDA administrative hearing in Chicago last June. But, he says, he has gotten the message: "If you squawk, they will slap you around." The FDA denies taking any retaliatory ac-

tions. Meanwhile, members of the medical community continue to support the Sensor Pad. Dr. Withers, the surgeon at Maui Clinic, says the pad has twice enabled him to feel otherwise undetectable lumps. He scoffs at the idea that using it might give women a false sense of security, one of the FDA's main concerns. "There is no question that the Sensor Pad increases my tactile ability," he says. "It makes it 100% easier."

Gale Katterhagen, medical director of the cancer center at St. Joseph Medical Center in Burbank, Calif., says tests he conducted for Inventive Products several years ago indicated that women who used the pad were 22% more likely to perform monthly breast exams. "This device is harmless," Dr. Katterhagen says.

Women who use the pad swear by it. Ms. Richardson, a 43-year-old Decatur resident, doubts that she would have found two small lumps without the pad. She had a double mastectomy. "It probably saved my life," she says, adding that she gave one to her 19-year-old daughter.

Mary Gorman, a 55-year-old writer in Washington, is certain the pad saved her breast. "I found my cancer before it was detectable on a mammogram," she says. Her surgeon, Katherine Alley, says the device may have saved Ms. Gorman's life. Considering the lethality of breast cancer, Dr. Alley says, "It is just ridiculous" to keep the pad off the market.

Potential demand appears to be huge. When a Pittsburgh hospital offered on local TV in 1990 to send out free samples, it was flooded with 36,000 calls and letters.

For all that, the FDA's Dr. Alpert believes that Inventive Products is largely responsible for the delays it has encountered. "There are lots of different kinds of trials they could do to show this is effective," she says. "It doesn't have to be years and years."

The elder Mr. Wright has managed to commercialize the Sensor Pad's antifriction technology for a much smaller market. He has built the Slipp, a nylon and plastic sheet used in hospitals to transfer patients from a gurney to a bed. About 500 have been sold.

But his son spends much of his time in his nearly empty headquarters explaining to doctors why he can't send them samples of the Sensor Pad. Last year, he laid off his own brother, reducing his work force to himself and his secretary from a peak of 28 six years ago. "We're at the point of surrender," he says.

