Down with the pride of Dixie

By Margaret Mannix

MATTHEW FORTNER—THE POST AND COURIER / SIPA

The Confederate flag may not fly much longer over the South Carolina statehouse.

The Confederate flag is about to lose its controversial perch atop the South Carolina statehouse. After years of bitter debate, members of the state's House of Representatives last week narrowly passed a Senate measure to move the flag and position it near the Confederate Soldiers Monument on the Capitol grounds. Ironically, the decision has stirred the ire of both flag supporters, who want to keep the banner on the dome, and opponents, who say the flag is too offensive to fly. The National Association for the Advancement of Colored People says it will continue its tourism boycott, which has already cost the state nearly $20 million. If the bill becomes law, the flag will be moved July 1.

● *Virginia tourist attractions won't face a similar fate. Gov. James Gilmore dodged similar sanctions in his state by agreeing to reconsider his recent move proclaiming April as Confederate History Month.*

CAR SAFETY

Keep on truckin'

An unlikely voice has joined the chorus of critics of sport utility vehicles: Ford Motor Co. In a new report, Ford for the first time said it was worried about the safety of the road hogs and their impact on the environment and pledged to develop technology to alleviate those concerns. Chairman William Ford even remarked that auto companies are in danger of developing reputations as bad as those of cigarette companies. Still, SUV sales are hugely profitable, and Ford keeps churning out new models.

● *Despite speculation that the light truck phenomenon will fizzle, Americans buy more each year. Indeed, a new wave of hybrids that combine car- and truck-like features could actually whet appetites.*

WOMEN'S HEALTH

Slipping and sliding

Saline breast implants just got a nod of approval from the U.S. Food and Drug Administration, more than 30 years after they first became available. The silicone variety was taken off the market earlier this decade for safety reasons, prompting the FDA's examination of the health risks of its water-based cousin. After years of study, FDA says there are no serious hazards associated with saline implants, but they do have "relatively high complication and failure rates." Those tend to be cosmetic, such as wrinkling, sloshing, asymmetry, and leaking.

● *But such problems aren't easy fixes. About 1 of every 3 women with an implant eventually needs additional surgery to replace or remove the implants.*

THE INTERNET

Tax-free zone

If only the Internet could fend off viruses as effectively as it sidesteps taxes. The House voted last week to extend a moratorium set to expire next year on any new Internet taxes, such as state or local surcharges on access fees. The extension also cancels existing Internet levies currently imposed in a handful of states. If the Senate and White House go along, the grace period will last until October 2006.

● *The moratorium doesn't bar sales tax on online purchases. But that tariff is uncollectible in many cases because states often can't force out-of-state merchants to impose it. What's more, debate still rages over whether it should be collected at all.*

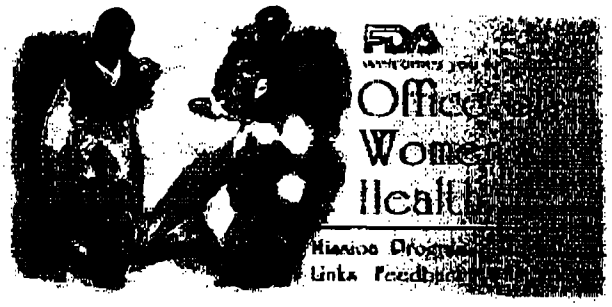
TELEVISION

Take that, Pikachu!

Leave it to four uncool kids to whip the *Pokémon* monsters. On Saturday, April 29, more TV viewers ages 2-11 watched *The Weekenders*, a new ABC cartoon about middle-school pals, than the WB's 10 a.m. *Pokémon*, whose numbers have been sliding this year. Nor do kids crave the cards as they once did. "They're going the way of Cabbage Patch dolls," says Ace Aguilera, manager of Meltdown Comics & Collectibles in Los Angeles. A July *Pokémon* movie, new Nintendo games, and a new fall TV series should boost the show's stock. But with 13 episodes airing a week, *Pokémon* may dilute itself into an early grave.

● Pokémon *still has plenty of life and so does the popular Fox-TV rip-off,* Digimon. *But one day soon, a weird new show will knock them both on their butts for good. Don't expect extinction. The ancient* Power Rangers *rule the 8 a.m. Saturday slot.*

With W. Thomas Smith Jr., William J. Holstein, John S. MacNeil, Leonard Wiener, and Marc Silver



5600 Fishers Lane, Room 15-61
Rockville, MD 20857
http://www.fda.gov/womens

Food and Drug Administration
Office of Women's Health

Margaret Hulla 7-0537

To Heather Howard 202 456-2878

per your request to Susan Wood.

HHS *NEWS*

U.S. Department of Health and Human Services

P00-11
FOR IMMEDIATE RELEASE
May 10, 2000

FOOD AND DRUG ADMININSTRATION
Sharon Snider: 301-827-
Broadcast Media: 301-827-
Consumer Inquiries: 888-INFO

TWO FIRMS GET FDA APPROVAL TO CONTINUE MARKETING SALINE-FILLED BREAST IMPLANTS

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The saline breast implants, which are made of a silicone shell filled with sterile salt water, were approved for breast augmentation in women 18 years or older and breast reconstruction.

In clinical studies required by the FDA, the companies looked at various short-term or "local" complications associated with the products, such as infection, hardening of tissue surrounding the implant (a condition known as capsular contracture), leakage/deflation, and implant removal. The firms also looked at the effectiveness parameters of patient satisfaction, body esteem, self-esteem, and breast size. Altogether some 9,000 women were enrolled in three McGhan studies and two Mentor studies.

"Although there is benefit to some women from having breast implants available, there is now a much clearer understanding of the risks involved," said FDA Commissioner Jane E. Henney, M.D. "With the data that has been presented, women and their physicians will be able to make informed decisions about whether the benefits are worth the risks."

Said David Feigal, M.D., director of FDA's Center for Devices and Radiological Health, "It's clear from these studies that there is a possibility that a substantial number of women who get these implants will require additional surgery at some point to remove or replace their implants because of complications.

"Women should understand that breast implants do not last a lifetime. And they should be aware that women who choose not to replace their implants after removal may have cosmetically unacceptable dimpling or puckering," he said.

McGhan's primary study involved 901 women who received saline-filled implants for augmentation. After three years, 689 patients (76%) were still in the study. Some of the three-year cumulative risk rates were 21% for additional surgeries, 16% for breast pain, 11% for wrinkling, 10% for asymmetry, 9% for capsular contracture, 8% for implant removal, and 5% for leakage/deflation. Some women experienced more than one of these complications.

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Despite the complications experienced by some women, the majority of those women still in the McGhan and Mentor studies after three years reported being satisfied with their implants; however, this does not include women who had their implants removed due to problems and were dropped from the studies.

FDA's decision to allow continued marketing of McGhan and Mentor saline-filled breast implants was based on a review of the firms' clinical studies, on inspection of the firms' manufacturing facilities, and on the recommendation of the Plastic and Reconstructive Surgery Devices Panel of FDA's medical Devices Advisory Committee.

FDA's decision on these two saline-filled breast implants does not affect silicone gel-filled breast implants. Silicone gel-filled breast implants currently cannot be commercially marketed. They are available only to women participating in FDA-approved clinical studies designed to answer similar questions about safety and effectiveness.

Saline-filled breast implants have been marketed for over 30 years, well before FDA was given the authority to regulate medical devices. Like most medical devices marketed prior to passage of the 1976 medical device law, they were presumed to be safe and effective. However, in the late 1980s, questions began to arise about their safety. Little scientific data was available about the nature, type and frequency of problems being reported about the products. Information that was available was inadequate or conflicting, particularly about how often complications occurred. As a result, FDA decided to call for specific safety and effectiveness data from manufacturers.

Today's action is the result of the review of marketing applications submitted by those two companies. The information that will enable women to make a fully informed decision is contained in the package insert that accompanies the products and in patient informed decision brochures. The patient labeling can be found on FDA's website at: http://www.fda.gov/cdrh/breastimplants/. A comprehensive package of information on all types of breast implants is available at the same website.

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HHS NEWS

S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

P00-11
FOR IMMEDIATE RELEASE
May 10, 2000

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Sharon Snider: 301-827-6242
Broadcast Media: 301-827-3434
Consumer Inquiries: 888-INFO-FDA

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-More-

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Page 6, P00-11, Saline Implants

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ATTENTION TV BROADCASTERS: Please use open caption for the hearing impaired.

FDA ON THE INTERNET: http://www.fda.gov/

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5/9 Breast implant

CJ Summary don't know of it's approval —
announcements are Wed or Friday (there are 2 applications)

180 days core clue

will send whatever "talk paper" they get

5/9

Susan Wood ● regulatory deadlines

Louise Brenton — NCI study
FDA asked "is there anything in your study that should influence safety decision?" — No

increased mortality of ♀ w/ implants for silicon
focuses mostly on silicon

Peggy Miller — FDA Office on ♀ Health

will get us Q&A

5/8

Saline Breast Implants

Shirley

Diana Zuckerman - 216-9507
- BC nonprofit
inside info FDA or Wed approving
saline breast implants
aware of studies linking saline implants to cancer
[FDA has never approved them]

Call HHS - 9's Health + Liz Summy

Liz Summy 690-7431

Diana Zuckerman - Natl. Center for Policy Research for Women + Families
translating complicated medical info into plain English

FDA had never approved breast implants
1976 - medical devices added to jurisdiction of FDA
Implants already on market so grandfathered in
by 1990 - 1 million had implants
but studies were done
had hearings - humiliated FDA
asking Congress to have studies
FDA requested studies on silicon gel
required Mfr. to do the studies
studies were bad

couldn't approve silicon but allowed in saline

didn't review saline implants

FDA – Nov. 1999 – required saline studies
FDA advisory cmte met in March
got press – advisory cmte members expressed
concern – can't approve until we
see better studies....
but FDA strongly urged + they voted to approve
– that got press
will also require studies, but what's
the basis

a Scientific Advisory Cmte for NIH
NIH doing studies for 8 years (req. by Congress)
studies not public yet
not supposed to tell anyone
show that implants aren't safe – increased risk of certain kinds of cancer

FDA commissioner handing over NCI study

concerned about the # of ♀ increasing
more teenagers are getting breast implants
never look as good after they're removed

vote was only a recommendation
FDA will announce Wed.

FDA is weak now - not a consumer watchdog

Best case: delay decision until NCI studies - 10 years of implants are public

require mfrs to do longer term follow ups
- the studies are 2-3 years
- focus only on local complications - not cancer, other studies

have FDA defer until we know more

call HHS - let them know it's coming
Suzanne Haynes - looking at 2nd generation problems
(of who breast fed)

public it NCI studies - none are published
on corrective issue - not done & being done
breast cancer, + other cancers
studies are not enough to pull product - but enough to say
we should look more closely
suicide rate high for those w/ implants - (4X)
not statistically significant

heard that results show serious problems
what is need to approve it now?
There is a deadline, but deadlines are missed all the time
they will still be available, just not approved

research needs to be better

staff of D.s + R.s a Commerce met head of Devices
expressed concern - what's risk & approval
[on Friday]
criminal invest. of implant mfr. (public) (Kessler)

Susan Ward

IOM study - long term risks of silicon
no data showing long term systemic problems - no cancer, immune
local complications are bad - add'l surgical risk, etc.

evaluated existing data

saline - FDA had adv. cmte meetings on saline +
recommended approval of 2 of 3 applications
-strong informed consent - may exempt pictures

aware of NCI studies on rupture rates
70-80% rupture w/in certain year

strong labelling

anti-implant people ~~don't~~ don't believe the IOM study

SW - data doesn't confirm long-term systemic effects -
not good enough data to stop saline
www.4women.gov
They wait for silicon
but there ~~are~~ is evidence of further local effects

NATIONAL CENTER FOR POLICY RESEARCH (CPR)

FOR WOMEN AND FAMILIES

FACSIMILE TRANSMITTAL SHEET

Heather Howard	FROM: Diana Zuckerman, Ph.D. , Executive Dir.
COMPANY: Office of the First Lady	DATE: 05/08/00
FAX NUMBER: 202 456-~~7263~~ 2878	TOTAL NO. OF PAGES INCLUDING COVER:
PHONE NUMBER:	SENDER'S REFERENCE NUMBER:
RE:	YOUR REFERENCE NUMBER:

☐ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

NOTES/COMMENTS:

Here are some faxes that could be helpful for background information, including a letter I sent to President Clinton in March, a copy of the USA Today article, and a few letters from Bliley and 2 organizations. I also e mailed you a copy of the letter that the Commerce Dems sent to Dr. Henney.

Thanks for your interest. I think that the political ramifications (as they relate to the impression of FDA as a paper tiger) are pretty worrisome, as well as the implications for women's health.

1444 EYE STREET, NW, SUITE 900, WASHINGTON, DC 20005

202 216-9507

NATIONAL CENTER FOR POLICY RESEARCH FOR WOMEN AND FAMILIES

The Food and Drug Administration (FDA) is scheduled to decide whether to approve saline breast implants on Wednesday, May 10. FDA Approval would be a boon to implant manufacturers and to plastic surgeons, who implanted almost 200,000 women last year, an all-time record.

Although they have been on the market for almost 30 years, saline breast implants were never tested on human beings, and manufacturers never have provided evidence of their safety. Only now, twenty-four years after the 1976 law requiring the FDA to regulate medical devices, has the FDA reviewed the manufacturers' recently required data on safety and effectiveness.

Of the three implant makers that presented data at an FDA Advisory Committee meeting on March 1-3, 2000, two companies, Mentor Corporation and McGhan Medical, are still under consideration by FDA, despite extremely high complication rates. Those "complications" included breasts that were extremely hard or painful, rupture and deflation of the implant, infection, and the need for surgical removal of the implant.

- Seventy-three percent of mastectomy patients and forty-three percent of cosmetic patients with Mentor saline implants had at least one complication within three years.
- Eighty-two percent of mastectomy patients and sixty percent of cosmetic patients with McGhan implants had at least one complication within four years.
- The complication rates were still rising when the studies were completed and had not leveled off, so that the long-term health risks were unknown.

These statistics suggest that the FDA will have to change the definition of "safe" if they want to approve these medical devices.

When they reviewed the manufacturers studies, members of the FDA's Advisory Panel expressed dismay at the poor quality of the studies and the high complication rates for the devices:

- Nancy Dubler, a bioethicist at the Albert Einstein College of Medicine, was "concerned about the 5.8% deflation rate and by the 43% complication rate and 73% complication rate in reconstruction patients. I think that's very, very high, and the combinations of all of that makes me reluctant to say that we can provide reasonable assurance that, in fact, they're safe."

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www.cpr4womenandfamilies.org

- Industry representative, Cindy Domecus of Concepts, Inc. said, "In my experience I don't know that I've ever seen a medically indicated product have that high of a complication rate and have it be a favorable risk-benefit ratio."

- Dr. Brent Blumenstein of the American College of Surgeons Oncology Group said, "I cannot feel good about any of the data presented with respect to accuracy and giving that information to an individual patient and having that patient understand what the real risks are."

- Dr. Joseph Boykin, a plastic surgeon at Columbia Retreat Hospital in Virginia, explained that if implants are removed, the breasts are stretched out of shape and very unattractive, "patients that get involved with breast implants need to understand that this is a life-long road. Once you put these implants in, whatever you decide to do with them is going to irreversibly change the shape of your native breast tissue."

- Maxine Brinkman, the consumer representative and a nurse at Women's and Children's Service at North Iowa Mercy Health Center, compared the situation to cigarettes, because manufacturers, "have seen a market in a younger population and that's where the money lies so they have aimed products towards that population.... I think that's a very sad comment on our society."

Despite those concerns, the advisory panel recommended that the devices be approved as "reasonably safe" with the condition that additional studies be performed to address long-term safety and that comprehensive informed consent be given to women. Unfortunately, informed consent is impossible because manufacturers and plastic surgeons habitually minimize the risks of breast augmentation and reconstruction to potential patients, including teenage girls. For example, a recent "Dear Doctor" letter from McGhan cites fewer complications than the FDA's own analysis of the same study.

The upcoming FDA decision has inspired letters of concern from leading Democrats and Republicans on the House Commerce Committee, which oversees the FDA, as well as national health organizations and breast cancer activists.

NATIONAL CENTER FOR POLICY RESEARCH
FOR WOMEN & FAMILIES
CPR

March 10, 2000

The Honorable William Jefferson Clinton
1600 Pennsylvania Avenue
Washington, DC 20500

Dear President Clinton:

As a former senior policy advisor in your Administration, and former Congressional investigator on health issues, I am writing to express my grave concerns about the apparent weakening of the Food and Drug Administration (FDA) in recent years. American consumers depend on the FDA to be a vigilant watchdog. The FDA saves lives, and helps preserve the quality of our lives. At this point in your Administration, FDA's ability to protect the public is in jeopardy.

Two very different examples of this problem are demonstrated in the recent revelations about federally funded research on gene therapy and the March 1-3, 2000 FDA advisory panel meeting on saline breast implants. In both cases, the physicians who are providing the investigational treatment are also conducting the research and providing information about its safety to the patient, the patient's family, and the public. At last week's FDA meeting on saline implants, the panel's bioethics expert, Nancy Dubler of the Albert Einstein College of Medicine, pointed out that there is a fundamental conflict of interest when those two roles – practitioner and researcher – are held by the same person. The result is often a cover-up of adverse reactions, even fatal ones, and a lack of informed consent for patients.

Your administration is appropriately responding to the well-publicized problems regarding the gene therapy experiments, and I applaud those efforts. Unfortunately, the saline breast implant meeting indicates that the underlying problems are widespread at FDA, and will undermine the safeguards that are intended to protect consumers of medical products.

The saline implant meeting was one of the FDA's first efforts to follow a new policy of "least burdensome provisions" of the FDA Modernization Act, designed to make it easier for manufacturers to get approval for their medical products. The meeting made it clear that the result will be much more burdensome for consumers: the buyers will have to beware. In this letter I will focus on how the saline implant meeting raises important, fundamental questions about FDA's role as a federal watchdog.

In addition to the above-described problem of having to rely on studies conducted by the doctors who treat the patients, the advisory panel was provided with conflicting information and given inappropriate instructions about how to weigh that information. For example, they heard clear, concise statistical analyses by FDA scientists, indicating that the manufacturers had misrepresented their data. The FDA scientists concluded that the implants had much higher complication rates than the manufacturers admitted -- 73-84% for mastectomy patients during the first 3-4 years. The studies did not continue for enough years to determine long-term safety, but the FDA scientists pointed out that the number of women with complications kept increasing every year.

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These views were consistent with the testimony of implant patients, who traveled from all over the country to attend the meeting, and publicly described their problems with saline implants. Unfortunately, the panel was instructed to ignore their testimony. Instead, several plastic surgeons, including two panel members, reassured the advisory panel that women were satisfied with the implants despite the high complication rate. In fact, most of the "information" presented at the meeting was provided by the manufacturers and the plastic surgeons, both of which have a strong financial interest in keeping implants on the market.

As scientists and physicians, the role of the panel members should have been to make sense of the discrepancies between the rosy picture of implants presented by the manufacturers and the plastic surgeons, and the patients' problems. This would have been even easier if the panel had also received relevant research information from other sources, such as the National Cancer Institute's ongoing (but as yet unpublished) study of breast implants, and other unpublished studies that have been conducted by scientists at NIH, FDA, and elsewhere.

After reviewing the research data, panel members expressed concerns about the safety of the implants and vehemently urged that additional research should be conducted to prove whether they are safe. Despite these reservations, the panel was openly encouraged by FDA officials to vote for approval to keep the implants on the market. After the exhausting first 12+-hour day of the three-day meeting, the panel acquiesced to the FDA's implicit and explicit instructions, and voted to approve the implants as "reasonably safe and effective." During the last day of the meetings, the panel made it clear that consumers needed better "informed consent" than they had been getting, but acknowledged that this would be difficult to achieve since the plastic surgeons tend to tell patients about their surgical successes, not their failures, and since long-term safety data are unavailable.

The FDA must now decide which of the panel's many recommendations to follow. In this decision, and future decisions regarding medical products, the FDA should carefully consider the research evidence. If that evidence does not truly prove that a product is safe, it should not be approved. If, instead, the FDA decides it is acceptable to approve medical products with extremely high failure, re-surgery, and other complication rates, "FDA approval" will mean nothing, and your Administration will have undermined a critically important safeguard for consumers.

As president, you have made a very clear commitment to the health and safety of all Americans, and especially our children. I urge you to quickly address the problems at FDA so that this legacy is preserved. In the meantime, our non-profit organization will conduct a thorough review of the implant safety data, and will write a more detailed letter describing our concerns to the FDA.

Sincerely,

Diana Zuckerman, Ph.D.
Executive Director

Cc: Jane Henney, M.D., Commissioner, Food and Drug Administration

SECTION: NEWS; Pg. 1A

HEADLINE: Breast implant manufacturer under investigation by FDA

BYLINE: Rita Rubin

BODY:
A major breast implant maker that recently got a favorable review from a Food and Drug Administration advisory panel is the subject of a criminal investigation by that agency for "allegations of serious irregularities in breast implant studies."

Rep. Tom Bliley, R-Va., chairman of the House Commerce Committee, which oversees the FDA, wrote Commissioner Jane Henney last Friday asking why the company was permitted to come before the saline breast implant panel March 1.

Although Bliley's letter does not name the firm, a memo on March 9 from the FDA's Office of Criminal Investigations says: "We have an open investigation on Mentor Corporation at this time" involving allegations of research irregularities.

"I note that an open investigation does not necessarily reflect the credibility of the allegations," Bliley writes. "Nevertheless, I question why the FDA proceeded to the Advisory Committee under these circumstances." An FDA spokeswoman said the agency would not comment until it had responded to Bliley.

Silicone-gel implants were virtually banned in 1992 because of safety concerns, and the FDA is examining the safety of saline implants. The advisory panel concluded that Mentor's implants were safe and effective and recommended that the FDA allow them to stay on the market.

Knowing about it might not have changed the panel's vote. "Ford and GM get criminal investigations from time to time, but they still make damn good cars," said panelist Bob Burkhardt, a Tucson plastic surgeon. Douglas Altschuler, Mentor's general counsel,

USA TODAY
March 23, 2000 Thursday, FINAL EDITION

said the allegations were without merit and were made by two employees who had been fired for harassing co-workers. He learned of the inquiry, he said, when he was contacted in 1998 by the U.S. attorney's office in Dallas, home of Mentor's plant. "They asked me some questions. I provided responses. I considered the case closed."

The probe is still open, Altschuler said, because "they're overworked, and someone may not have formally put a closed sticker on a file."

But an FDA spokesman said that "in general, when there's a criminal investigation, when the issue is resolved, the FDA will close the case."

April 3, 2000

The Honorable Arthur Levitt
Chairman
Securities and Exchange Commission
450 5th Street, NW
Washington, D.C. 20549

Dear Chairman Levitt:

I am writing to bring to your attention a matter for consideration by the SEC Enforcement Division.

On March 17, 2000, I wrote the Food and Drug Administration (FDA) questioning the agency's decision to present data from a breast-implant manufacturer before an FDA advisory panel for an approvability recommendation while the manufacturer continued to be under an open FDA criminal investigation. The FDA provided documentation to the Committee confirming that the company is under criminal investigation for "allegations of serious irregularities in breast implant studies." [Attachment 1].

On March 23, 2000, USA Today published a page one article that "[a] major breast implant maker [identified as Mentor Corporation] that recently got a favorable review from a Food and Drug Administration advisory panel is the subject of a criminal investigation by that agency for 'allegations of serious irregularities in breast implant studies.'" [Attachment 2]. According to Dow Jones News, shares of Mentor Corporation were down as much as 40% Thursday morning after USA Today reported that the breast-implant manufacturer was being investigated by the FDA. Trading on Mentor stock was halted at midday to allow investors to digest the news. [Attachment 3]

By mid-day, Mentor issued a public statement denying that there was an FDA criminal investigation based on allegations of serious irregularities in breast implant studies. According to Mentor's statement: "The Company has contacted the FDA and although they have confirmed that there is an investigation stemming from 1998 manufacturing issues, Mentor is unaware, and the office of the FDA conducting the investigation, has denied that the investigation has any connection whatsoever with 'allegations of serious irregularities in breast implant studies' as quoted by USA Today." [Attachment 4] According to Reuters, "[s]hares in Santa Barbara, California-based Mentor rebounded sharply after the company issued its statement around midday, having tumbled as much as 50% percent at the open before trading was halted." [Attachment 5]

Because Mentor publicly attributed to FDA a denial of FDA's statement to the Committee, the Committee staff asked the FDA, in light of Mentor Corporation's public statement, whether the FDA stood by its original description of the criminal investigation as relating to "allegations of serious irregularities in breast implant studies." In response to the Committee staff's request, the FDA provided a written statement on March 29, 2000 confirming that FDA stands by its statement that described the criminal investigation as relating to "allegations of serious irregularities in breast implant studies." [Attachment 6]

Since Mentor's public statement affected the trading of its stock, and material information in Mentor's public statement is in conflict with information provided by the FDA, I am forwarding this matter to the SEC to determine whether federal securities laws were violated.

Thank you for your assistance. If you have any questions, please contact Alan Slobodin of the Committee staff at (202) 225-2927.

Sincerely,

Tom Billey
Chairman

cc: The Honorable John D. Dingell, Ranking Member
The Honorable Fred Upton, Chairman, Subcommittee on Oversight and Investigations
The Honorable Ron Klink, Ranking Member, Subcommittee on Oversight and Investigations

BREAST
CANCER
ACTION

Via Facsimile: (202) 228-4741

The Honorable Dianne Feinstein
U.S. Senate
331 Hart Building
Washington, DC 20510

Dear Senator Feinstein:

I write to you on behalf of Breast Cancer Action and as your constituent to ask for your assistance on an urgent FDA matter. In light of your work in support of women's health, I believe you will share our concerns.

On March 1-3, the FDA will convene an advisory committee meeting to review the new research on salir breast implants. As you know, saline breast implants have been sold in this country for more than 20 years, but manufacturers have never been required to provide proof that they are safe or effective to the FDA. Now, for the first time, the FDA will make a judgment about whether the implants are safe and effective, and they will only stay on the market if that is proven.

Unfortunately, FDA officials appear to be under the impression that Congress wants them to approve these devices whether they are safe or not. While I hope that is not true, I am writing to request that you write a letter to Dr. Jane Henney, the FDA Commissioner, and Dr. David Feigal, who is Director of the Center for Devices and Radiological Health at FDA, to assure them that, as a senator who is committed to improving women's health, you are concerned that saline implants be approved only if they are prove safe and effective. I am especially concerned that the data prove long-term safety (at least 5-10 years) and that they be proven safe for breast cancer patients who use them for reconstruction, and not just for cosmetic "augmentation" patients.

There has never been a well-designed study of the safety of implants for mastectomy patients. We have seen too often the dire consequences of approving something first, and evaluating its safety later. Women with breast cancer do not need to be guinea pigs in the search for a marketable implant produc

I would be very grateful if you could send a letter to FDA prior to February 25, 2000 to express your concern that any decision be based on sound research that includes mastectomy patients.

Thank you so much for your help.

Sincerely,

Barbara A. Brenner

Barbara A. Brenner
Executive Director

55 New Montgomery, Suite 323 San Francisco, California 94105
Tel: 415.243.9301 Fax: 415.243.3996 Toll free: 1.877.2STOPBC Website: www.bcaction.org

The 1998 edition: Our Bodies, Ourselves for the New Century

BOSTON WOMEN'S HEALTH BOOK COLLECTIVE

PO Box 192, 240A Elm Street, Somerville, MA 02144
Telephone: 617.625.0277 Facsimile: 617.625.0294
Email: office@bwhbc.org
Website: www.ourbodiesourselves.org

A Member Agency of Community Works

March 1, 2000

Jane Henney, MD
Commissioner, FDA
Rockville, MD

Dear Dr. Henney:

The Boston Women's Health Book Collective has long been concerned that breast implants have been marketed for so many years without adequate safety data available to allow women to make informed choices.

We are glad that the FDA has finally required implant manufacturers to submit safety data, but we are concerned that no outside experts were invited to testify at the PMA meetings on March 1-2 before the voting takes place.

We are also concerned that the FDA has asked only for "at least 2 years" follow-up on patients for a device that is intended to last as long as possible. What is needed is AT LEAST 5-10 years worth of data.

In addition, separate analyses are needed on large numbers of mastectomy patients using implants for reconstruction as well as large numbers of augmentation patients.

If silicone causes autoimmune diseases, that could happen with saline or silicone implants (since both have silicone envelopes) and would probably take many years to develop for most women. Studies following women for 2-5 years are not enough.

Since it is known that bacteria and mold can grow in saline implants, it's important to know if women face health risks when they break. Therefore, studies are needed on women whose saline implants have broken.

We look forward to hearing from you about these matters.

Sincerely,

Judy Norsigian

Judy Norsigian
Program Director, BWHBC
Co-author, ***Our Bodies, Ourselves for the New Century***

inspiring a movement of women's health around the world

CPR4WandF@aol.com
05/08/2000 12:43:31 PM

Record Type: Record

To: Heather H. Howard/OPD/EOP

cc:
Subject: here's the letter from Dems on Commerce to FDA Commissioner

---

> April 14, 2000
>
>
> The Honorable Jane Henney, Commissioner
> Food and Drug Administration
> 5600 Fishers Lane
> Rockville, Maryland 20857
>
> Dear Commissioner Henney:
>
> Congress has long been interested in assuring that breast implants are safe
> and effective. Over the last year the Subcommittee on Oversight and
> Investigations has been looking at FDA's activities regarding the safety of
> breast implants. In light of the recent testimony before the Food and Drug
> Administration (FDA) Advisory Panel on Plastic Surgery, combined with the
> recent press reports concerning the criminal investigation of a breast
> implant manufacturer, we request a briefing for Democratic members of the
> Subcommittee to discuss these and other related matters. By copy of this
> letter, we are inviting our Republican colleagues on the Subcommittee.
>
> Since the passage of the Medical Device Amendments of 1976, the FDA has had
> jurisdiction over all medical devices. Current law requires manufacturers
> of new medical devices to first show that they are safe and effective
> before they can be marketed. Nevertheless, devices that were in use before
> 1976, such as breast implants, have been allowed to stay on the market
> subject to an FDA safety and effectiveness review.
>
> Fifteen years later, in April 1991, the FDA asked manufacturers to submit
> evidence that silicone gel-filled implants were safe and effective.
> Initially, due to a lack of data, the FDA determined that breast implants
> could not be approved. In 1992, gel-filled implants were removed from the
> market. Nonetheless, citing the strong public health need for gel-filled
> implants in certain cases, and under the auspices of an adjunct study, FDA
> decided that silicone gel-filled implants would be available for women
> with "special needs." These included women who have had breast cancer
> surgery, a severe injury to the breast, a severe abnormality, or who
> already had gel implants that needed to be removed. This adjunct study has
> been running since 1992.
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> In January 1993, FDA first called for the manufacturers to conduct studies
> on the safety and effectiveness data on saline-filled implants. Unlike
> silicone-filled implants, the FDA decided to leave saline-filled implants
> on the market for "cosmetic" purposes (for all women) while data was being
> collected. Clinical trials were ordered in 1994 and Pre-Market
> Applications were eventually submitted to the FDA in November 1999.
>
> At the recent March 1-3 meeting, the advisory panel discussed the research
> submitted to the FDA in applications by three manufacturers of saline
> breast implants. It is our understanding that there was significant
> concern voiced by some in that session regarding the safety and
> effectiveness of saline-filled breast implants. The panel nonetheless
> endorsed the applications of two of the manufacturers despite what we
> understand to be major questions pertaining to the quality of the
> research, the high complication rate of these products, high failure and
> re-surgery rates, and testimony showing that saline breast implants can
> obscure breast tissue and make it more likely that the diagnosis of breast
> cancer will be delayed.
>
> Although the panel attached a list of conditions which the manufacturers
> would have to meet if and when the FDA approves saline breast implants, our
> goal is to make sure that these devices are safe and effective before they
> are approved by FDA. We are concerned that post-market conditions would
> give manufacturers insufficient incentive to improve their product, after
> their applications are approved by FDA.
>
> While we are very sensitive to making sure that breast cancer survivors
> have access to implants for breast reconstruction, we are also concerned
> about how the FDA has handled this issue since the 1976 Amendments.
> Frankly, the variety of concerns about the FDA's oversight of the adjunct
> study, review of adverse events reported to FDA, the reportedly open
> criminal investigation into allegations relating to one of the sponsors,
> and the recent meeting of the advisory board, do not engender confidence
> in the minds of patients, legislators, or the public.
>
> It would be exceedingly unfortunate if FDA rushed its review of this matter
> only to contribute to the lingering perception by many that its handling of
> the entire breast implant matter has been less than adequate. Therefore,
> we request a briefing from you and Dr. David Feigal on these matters in
> early May. To schedule the briefing, please have your staff contact
> Christopher Knauer of the Minority staff at (202) 226-3400.
>
> Sincerely,
>
> JOHN D. DINGELL, RANKING MEMBER
> COMMITTEE ON COMMERCE
>
> RON KLINK, RANKING MEMBER
> SUBCOMMITTEE ON OVERSIGHTAND INVESTIGATIONS
>
> cc: The Honorable Tom Bliley, Chairman
> Committee on Commerce
>
> The Honorable Fred Upton, Chairman

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