IN SUPPORT OF H.R. 1323, SILICONE BREAST IMPLANT RESEARCH AND INFORMATION ACT

The SPEAKER pro tempore. Under a previous order of the House, the gentleman from Texas (Mr. GREEN) is recognized for 5 minutes.

Mr. GREEN of Texas. Mr. Speaker, the reason this evening that I am asking for a 5-minute special order is to talk about some legislation that I have been working on and we have a great many cosponsors, H.R. 1323. As I begin to talk about it, Members need to understand when I first was brought to the problem's attention by some constituents of mine, I realized the first issue we need to deal with is what I call the candy effect, we need to get over the snicker factor and then really get on to dealing with the problems that some women in our country are having.

H.R. 1323 deals with breast implants, an issue that has been the subject of court cases. But my concern, Mr. Speaker, is that the Federal Food and Drug Administration, who is supposed to be America's watchdog, our protector, to make sure that we are not harmed by faulty drugs or medical devices. In fact, the FDA's own Web site calls itself the Nation's foremost consumer protection agency, and we pour millions and millions of Federal tax dollars into this agency every year. Unfortunately, when it comes to medical devices, the FDA is neither our watchdog nor our protector.

In May, I was disappointed to learn that the FDA approved saline breast implants for the general market. The FDA approved these breast implants despite data presented by the manufacturers showing that three out of four mastectomy patients who opt for saline breast implant reconstruction experience painful local complications.

The FDA approved breast implants despite the fact that the majority of implants rupture within the first 3 to 4 years. The FDA's own scientists concluded that the manufacturers have incorrectly carried out their statistical analyses and therefore determined that the complication rates were as high as 84 percent with mastectomy patients within the first 3 to 4 years. These complication rates continue to increase over time.

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But, now with the FDA approval, the two leading manufacturers are able to market their saline breast implants. In fact, one of the manufacturers even has a pending FDA criminal investigation regarding its breast implant production and testing hanging over its head, and it still received approval by the FDA.

My concern for women who opt for a saline breast implant stems from hundreds of women who have contacted me with their experience, and I have heard from my own constituents and women from across the country who have suffered from the long-term consequences of reconstruction and cosmetic surgery, including infections, deformity and rupture.

These women also have suffered from inaccurate mammogram readings due to implants concealing breast tissue which is critical in detecting a reoccurrence of cancer. Studies show that up to 35 percent of the breast tissue can be obscured by these implants.

In addition, these women are experiencing difficulties with health insurance coverage to pay for the high cost of repeated surgeries and examinations. The cost of faulty implants is paid for by all of us. Just consider the number of women who have had breast implants. The Institute of Medicine estimated by 1997, 1.5 to 1.8 million American women had breast implants, with nearly one-third of these women being breast cancer survivors.

The American Society of Plastic and Reconstructive Surgeons cites breast augmentation as the most popular procedure for women ages 19 to 34. In 1998, nearly 80,000 women in this age bracket received breast implants for purely cosmetic reasons. By 1999, an additional 130,000 women received saline breast implants.

In spite of these escalating numbers, very little is known about the long-term effects of the silicone of these breast implants on the body. Few patients understand that even when they opt for the saline breast implants, the envelope of the implant is made of the silicone.

Following the FDA's decision to approve saline breast implants, the agency did warn women of the potential risk. FDA officials called upon implant manufacturers and plastic surgeons to ensure that thorough patient information is provided to women before they undergo the surgery.

So, now with the FDA approval process behind us, the only course of action to safeguard future women is an informed consent document. Somehow, a piece of paper is supposed to make up for the manufacturer's insufficient mechanical testing, revision data and retrieval analysis. It is supposed to make up for inaccurate labeling and risk estimates. It is supposed to make up for the plastic surgeon's obligation to fully inform their patients of the potential complications and reoperations and the doctor's chosen surgical procedures.

There is so much we don't know, and yet the one government agency mandated to safeguard the public's food, drug and medical devices is willing to jeopardize women with a medical device that has alarmingly high failure rights.

In spite of the agency's call for post-market studies, the FDA approval of saline breast implants provides no incentive for the manufacturers to make data better or a safer medical device. I highly doubt the post-market studies will be conducted in a meaningful and timely manner, and I doubt that the FDA has the ability to properly oversee these studies anyway. One of the manufacturers is already predicting to its stockholders it will have FDA's approval of its silicone breast implants in a couple of years, and I believe the need for more research is especially compelling in light of the FDA's own study on the rupture of saline breast implants.

Mr. Speaker, I include for the RECORD two articles from The Washington Post and the Los Angeles Times.

On May 18 of this year, Dr. S. Lori Brown's research was presented. The study examined women through the use of MRIs in order to detect whether their implants had ruptured and concluded that 69 percent of the women had at least one ruptured breast implant.

The FDA concluded that rupture of silicone breast implants is the primary concern although ''the relationship of free silicone to development or progression of disease is unknown.''

My colleagues have joined me in trying to get some critically needed independent research into silicone breast implants. We have sponsored ''The Silicone Breast Implant Research and Information Act,'' H.R. 1323, which calls upon the National Institutes of Health to conduct clinical research on women with silicone breast implants.

Our bill places a special emphasis upon mastectomy women, who are adversely affected at a much higher rate than women receiving implants for cosmetic reasons.

While that research is being conducted, the bill would also bolster the informed consent procedures and information given to women when they consider breast reconstructive surgery or breast augmentation.

I urge my colleagues to join me in sponsoring this bill, and ensuring the health and well-being of American women. Since the FDA won't do it's job, we'll have to.

Mr. Speaker, I include the following articles from the Washington Post and the Los Angeles Times for the RECORD.

[From the Washington Post, May 21, 2000]

HOW SAFE IS SAFE?

The Food and Drug Administration ruled last week that saline-filled breast implants, the only kind still available, can remain on the market. They had been in regulatory limbo; a 1976 law allowed medical devices then available to continue to be sold pending further testing, only now completed. But for those who hoped the long-awaited FDA ruling would give a firm yes or no on safety, the agency's judgment is less than definitive.

Saline implants may be sold, the agency ruled, but women must be made aware of their many potential complications, including pain, infection, cosmetic problems and a 20 to 40 percent chance they will need replacing by another operation within three years. A serious effort needs to be mounted to warn women of these risks, the agency believes. Not exactly a ringing endorsement.

Why, then, approve at all? Critics accuse the FDA of diluting the meaning of its seal of approval. Many products legally on the market carry risks. Drugs commonly come with warnings of side effects. But the critics argue that the agency should take a harder line toward optional cosmetic products and procedures. And in fact, most optional devices with complication rates this high have been kept from the market.

The FDA says it is trying to draw difficult lines between protecting people and allowing them to weigh their own risks at a time

when both demand for ''lifestyle products'' like cosmetic surgery and the variety available are skyrocketing. Should people be protected from liposuction and laser eye surgery? From cosmetic procedures with a remote risk of serious harm but a high risk of moderate harm?

The implant ruling reflects an FDA choice to become, at least for cosmetic surgery, less a goalie and more a disseminator of information. It's a defensible but risky approach that can only work if accompanied by close oversight, especially of the implant manufacturers and plastic surgeons who benefit financially from use of these products. For most consumers, the FDA's stamp of approval still speaks more loudly than any warnings it may tack on.

[From the Los Angeles Times, June 15, 2000]

WOMEN CAN'T COUNT ON THE FDA

(By Patricia Lieberman)

The Food and Drug Administration is known worldwide for having the most rigorous safety standards. Unfortunately, it lowered its standard last month when it approved saline-filled silicone breast implants. That decision will have an impact on the lives of as many as 150,000 women and teenage girls who get those implants each year. And if implant makers have their way, the FDA will approve even riskier silicone gel-filled implants next.

To win approval of their saline implants, two Santa Barbara-based corporations presented the FDA with results of their studies of women who get saline implants three to four years ago. They claimed their patients were satisfied. but reported serious problems such as broken implants, breast pain, infection, deformity and additional surgeries to fix those problems.

The manufacturers touted their implants safety, and they were backed up by plastic surgeons, who told the FDA about the wonderful successes in their practices. Like the children of Garrison Keillor's mythical Lake Wobegon, the surgeons all seemed to be ''better than average,'' with complication rates that were much lower than the research found and patients more enthusiastic about the changes implants made.

Yet analysis by FDA scientists showed that the manufacturers and physicians had underestimated the true rates of complications. Using data gathered by the manufactures, the FDA calculated that for one manufacture, Mentor Corp., 43% of women who got implants for augmentation had at least one complication within three years. For mastectomy patients, it was even worse: Within three years, 73% of women who got implants had at least one complication, and 27% had their implants removed. The statistics were even more troubling for the implants made by McGhan Medical. For both brands, the FDA explained that the complication rates were still rising when the studies were completed, so the long-term health risks are unknown.

The FDA also heard heart-wrenching testimony from women with health problems due to saline breast implants. They heard from women who got sick but are too poor because of extensive medical bills to have the implants removed. They heard from women who were denied health insurance because they were considered highrisk due to their implants and subsequent complications. They heard from women whose symptoms did not improve until after their implants were removed. The FDA utterly ignored these devastating stories.

The FDA also heard a radiology expert testify that breast implants can interfere with mammography. Failure to detect cancer is twice as likely for women with implants. Of the 1.5 million to 2 million women with implants, it is likely that the breast cancer diagnosis of 20,000 to 40,000 if them could be delayed because their implants obscured a tumor. Such a delay can be deadly. When breast cancer is detected and treated in its earliest stages, 90% to 95% of those women are healthy 10 years later. Only 40% live 10 years if the cancer is more advanced.

Although the health risks clearly outweigh the cosmetic benefits for most women and teenage girls, the FDA approved saline implants anyway. The FDA will require that manufacturers provide detailed information about the risks to patients, but what does that mean? Will companies that misrepresented their data to the agency realistically portray the risks to their potential customers? It doesn't look likely.

Instead, the manufacturers are looking for more business. After the FDA announced its approval of saline implants, McGhan boasted that it would seek FDA approval for silicone-gel implants. The FDA's own research proves that this would be a tragic mistake. Scientists found that even among women who had not sought medical treatment for implant problems, almost 80% had at least one broken implant after 10 to 15 years. Even more worrisome, the silicone was migrating away from the implants in 21% of those women.

The FDA made no effort to publicize those results. Instead, it issues no warnings and still permits unapproved silicone-gel implants to be sold.

Consumers should have the peace of mind that the term ''FDA approved'' means that a product has been thoroughly tested and proved safe. Unfortunately, when it comes to breast implants, the FDA has placed the burden on women instead. Women will have to sift through the plastic surgeons' and manufacturers' glossy promotional brochures to seek the information they need because we can no longer rely on the FDA to look out for us.

The SPEAKER pro tempore (Mr. SIMPSON). Under a previous order of the House, the gentleman from Washington (Mr. METCALF) is recognized for 5 minutes.

(Mr. METCALF addressed the House. His remarks will appear hereafter in the Extensions of Remarks.)

PROTECTING AMERICA'S NUCLEAR ENERGY SUPPLIES

The SPEAKER pro tempore. Under a previous order of the House, the gentleman from Ohio (Mr. STRICKLAND) is recognized for 5 minutes.

Mr. STRICKLAND. Mr. Speaker, I rise to speak about a subject that is of great importance to those who are Members of this House, but also to every citizen in this country.

Some 2 years ago, a decision was made to privatize the uranium enrichment industry in this country. The individual who oversaw that privatization, Mr. Nick Timbers, as a government employee was compensated around $350,000 per year. After privatization occurred, Mr. Timbers' salary went to approximately $2.48 million a year. I think it was a terrible conflict of interest to allow an individual who was in a position to enrich himself to be involved in the decisions which led this industry from being privatized.

The results of privatization have been very, very grave to this country. The American citizen needs to know that approximately 23 percent of all of the electricity generated in this country is generated through nuclear power, and, as a result of decisions being made by this privatized company, we are in danger of losing the capacity to enrich uranium and to create the fuel necessary to produce 23 percent of our Nation's electricity.

The Nuclear Regulatory Commission is charged with doing an analysis, and they must do an analysis to determine whether or not this private company can be depended upon to continue to produce a reliable domestic supply of nuclear fuel needed to meet our Nation's needs. It has come to my attention that the staff of the Nuclear Regulatory Commission has done their analysis and has taken that analysis to members of the commission, but they have been sent back to the drawing board, so-to-speak.

In the interim period, it has also come to my attention that the management of this new privatized corporation, and I have been told that specifically Mr. Timbers himself, is trying to interfere with the conclusions of the staff of the Nuclear Regulatory Commission. Put simply, this private company is now arguing that ''domestic'' does not include simply the material that is produced within the United States of America, but they are arguing that we should also include the material that is being imported from Russia as a part of the ''domestic supply.'' They are also arguing that ''reliable'' does not mean the ability to produce 100 percent of our Nation's needs, but ''reliable'' could mean 60 percent or 50 percent or 40 percent of our Nation's needs.

Mr. Speaker, it is important that this Congress not allow this external influence to affect the conclusions reached by the staff of the Nuclear Regulatory Commission. It is important for us as a Congress and it is important for this administration to say very clearly that ''domestic'' means the material that is produced within the continental United States. We cannot depend upon Russia to meet our domestic needs.

We should also make it clear that when we talk about reliable, we mean 100 percent of our Nation's needs should be met, not 60 percent nor 40 percent.

These are esoteric matters, but they are important matters, because if this Congress does not take responsible action, and if this administration does not take responsible action, we could find ourselves in a relatively short period of time being dependent upon foreign sources, especially Russian sources, for the fuel that it takes to generate 23 percent of our Nation's electricity.

Mr. Speaker, we know what happens when we rely too heavily upon foreign sources for oil. Gasoline prices skyrocket. But this Congress now has an