

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.

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#### 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 manufacturers, the FDA calculated that for one manufacturer, 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 they 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