

# POLICY BUST

VIRGINIA I. POSTREL

**S**erious people don't spend much time stalking about breast implants—at least if they want to continue to be considered serious people. Artificially enhanced décolletage is a subject for *Geraldo*, not *Nightline*; *The Star*, not *The New York Times*.

Until recently. The latest manifestation of the Food and Drug Administration's campaign to enlarge its regulatory empire is an attack on silicone-gel breast implants. The FDA has called for a moratorium on sales of the implants and may very well wind up outlawing them.

The evidence against the implants is of varying quality. In many women, they lead to scarring between the implant and the inside of the breast, a condition that may be trivial, quite painful, or serious enough to require additional surgery. Cosmetic surgeons routinely warn implant patients of this risk.

Another undisputed risk is that implants block mammograms, making early-stage breast cancers more difficult to detect. But the availability of implants for reconstructive surgery also leads some women, who would otherwise be deterred by the prospect of mutilating surgery, to get their breasts checked for cancer.

Some implants leak, usually small quantities of silicone. There isn't any good evidence that small amounts of silicone are dangerous to the body. Silicone is used in other implants, such as joint replacements, the Norplant contraceptive, and testicular implants, with no signs of any ill effects. Also, diabetics who use silicone-coated needles every day absorb a great deal over the course of a lifetime.

In rarer instances, breast implants may rupture. This poses a risk of infection and requires surgery to remove the implant.

Those are the documented risks. There

are also a lot of undocumented ones, which implant opponents use to scare regulators and win lawsuits. The main scare story is that implants can cause autoimmune diseases—a claim for which there is no epidemiological evidence. (Silicone, like other foreign substances, can trigger antibodies, but that reaction is not the same thing at all.)

*Nightline*, for instance, featured a woman who had had an implant and later developed sclerodoma, a rare connective-tissue disease that causes a painful tightening of the skin over the bones. The reporter said the woman's doctor "believes the disease was caused by silicone leaking from the breast implant." It's easy to understand why a doctor trying to explain a rare disease would settle on such an explanation. Looking at the big picture, however, there is no evidence that sclerodoma is any more common among breast-implant recipients than it is in the general population.

That's the evidence. Women (and a few pectorally conscious men) who receive silicone breast implants do take risks. The real question is, Should David Kessler, the head of the FDA, and his informal adviser Sidney Wolfe, the director of Public Citizen's Health Research Group, get to decide whether women can take those risks? There is a lot more at stake here than big breasts.

The core argument against the implants isn't that they're unsafe. It's that they're unnecessary. "Plain and simple, there is no public health need for these extremely unsafe devices to remain on the market. They are cosmetic devices for which far better alternatives exist," Wolfe said in a press release.

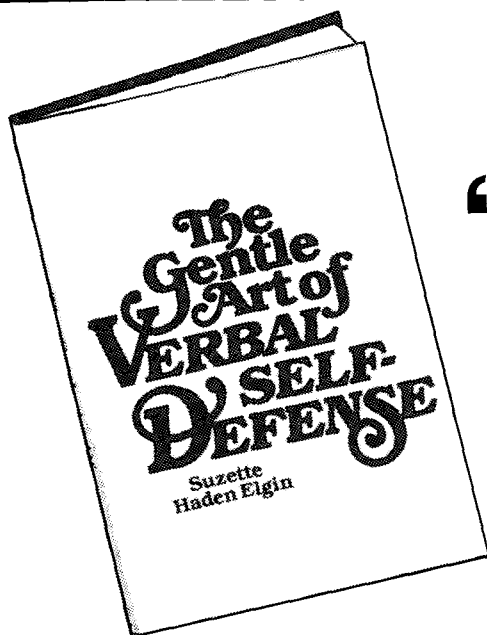
Consider the implications of that argument: Any "unnecessary" device that

poses risks should be banned as long as "better" (that is, safer) alternatives exist. And political appointees will decree what's necessary and what's better, with help from puritanical pressure groups.

For women, the stakes are very high. Let's not even talk about abortion, where there is at least an arguable third party involved. Nobody "needs" the Pill. It presents health risks (although it may also have health benefits). Indeed, the Boston Women's Health Book Collective, a major opponent of breast implants, ranks the Pill below various forms of the rhythm method and below abstinence on its list of birth control methods. Applying Wolfe's criteria, the FDA would ban the Pill on the grounds that we can just use diaphragms and condoms.

On the same grounds, the FDA could ban tampons, which, like silicone breast implants, are medical devices that were already in use when Congress expanded the FDA's regulatory authority to encompass devices. Like implants, tampons are grandfathered at the FDA's discretion. They, too, are "unnecessary"—safer alternative technologies exist—and, unlike breast implants, they have been definitively linked with fatalities, caused by Toxic Shock Syndrome. What's more, tampons are currently under attack by some environmentalists and ecofeminists. Wolfe's "vital needs" approach has no logical stopping place, short of a Third World lifestyle.

**I**f there is an argument for government regulation of drugs and medical devices, it is that regulation protects patients who don't have time to get the information they need to weigh risks and benefits. Like many medical arguments, this assumes that decisions are made in emer-



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## About the Author

Psycholinguist Suzette Haden Elgin has presented her innovative self-defense principles in a variety of formats. She has given workshops and seminars all over the U.S., including verbal self-defense sessions for doctors, lawyers, and other professionals. Dr. Elgin has also created a self-defense tape and a training manual for people who teach her self-defense techniques.

gencies and that the government-patient relationship is sounder than the doctor-patient relationship.

Now I am not a great truster of doctors, so I understand the allure of bringing a third party in as a protector. But history is full of once-independent countries who asked budding empires to protect them from their enemies—only to wind up as colonies. And Kessler's FDA is looking more imperial every day.

Most breast implants are, in fact, used for purely cosmetic reasons; 80 percent of the women who get them just want larger or firmer breasts (of course, reconstructive surgery is also cosmetic). This makes implants easier to attack politically, especially since East Coast intellectuals tend to consider all cosmetic surgery bizarre.

But the very frivolity of implants ar-

gues *against* regulation. Cosmetic-surgery patients have plenty of time to shop around, to do research, even to call up Public Citizen and hear warnings of doom. They can be as fully informed as they want to be. Then, if they proceed to spend their own money—insurance doesn't cover these things—on their own bodies, it's hard to say how the "public interest" is involved in any way.

Breast implants may make for tabloid television, but they're as important as any medical issue facing policy makers. They raise a far more basic question than how to trim a few dollars off Medicare spending: Who owns your body—you, or David Kessler? Before we embark on health-care reform, or make major breakthroughs in genetic engineering, we might want to think about that question. ■

## NO GUARANTEES

JACOB SULLUM

**W**hen George Bush threw up at a state dinner in Tokyo last January, he inadvertently expressed the appropriate response to the special pleadings of America's Big Three automakers. Unfortunately, it was Japanese Prime Minister Kiichi Miyazawa, rather than Chrysler chairman Lee Iacocca, who bore the brunt of the president's nausea.

Though a public-relations disaster, Bush's trip, by highlighting the hypocrisy of Iacocca et al., may yet have a positive impact on trade policy. It's difficult to see how anyone who followed the story could have failed to see the mendacity of these self-proclaimed free-trade advocates: We're not protectionists, they said, but we may not be able to stop Congress from slapping more tariffs on Japanese imports unless trade relations improve.

There is room for improvement. Like the United States, Japan maintains various trade barriers, including some in the auto industry. But the sort of improvement the Big Three have in mind is evident from their response to Japanese concessions.

Among other things, the Japanese government agreed to offer low-interest loans and tax incentives to U.S. firms doing business in Japan. Japanese car companies said they would buy more foreign-made auto parts and try to double the number of U.S. cars sold in Japan each year. American automakers objected not to the nature of these commitments but to their size. They like the idea of special assistance and guaranteed sales.

You might think that the Big Three would be embarrassed by the implication of this approach—that American manufacturers cannot compete without affirmative action. But like arrogant beggars, the heads of America's car companies consider a handout a matter of right rather than charity. "We didn't ask them to make concessions," insisted G.M. chairman Robert C. Stempel. "We're not asking that they give us anything. We're just asking to compete."

Of course, they're asking for much more than that: They're asking—really, demanding—to compete without risk.

When asked why they don't open manufacturing plants in Japan, why they don't set up their own distribution systems, why until recently they couldn't even produce a car with the steering wheel on the right side to accommodate Japanese drivers, U.S. automakers always give the same response: Too risky. We can't make those kinds of investments until we have enough sales volume to justify them.

"It would be nice to have factories here, but you go where you are wanted," Iacocca said. "Obviously, if the market really starts to grow, you would like your own distribution system," Stempel said, "but we are not considering that now."

**J**apanese automakers think their U.S. counterparts have it exactly backwards: You build sales by making investments up front, by adapting your product to the new market, by taking a chance. The evidence suggests that this approach works. Such companies as Applied Materials, Schick, and Coca-Cola have pursued it successfully in Japan. And Japanese companies have used it to capture one-third of the U.S. car market. By contrast, American companies make less than 1 percent of the cars sold in Japan.

It's not credible to attribute this huge difference entirely to exclusionary trade practices, as the Big Three implicitly do. While some Japanese policies discourage private car ownership and raise the prices of foreign vehicles, they cannot account for the virtual absence of American cars from the Japanese marketplace. They certainly cannot explain why European carmakers are much more successful in Japan than their U.S. competitors, or why the Big Three are losing ground to the Japanese at home.

Indeed, complaints about Japanese protectionism from American carmakers are notably short on specifics. Taking a cue from U.S. civil-rights law, the Big Three prefer simply to assume that any statistical disparity is due to unfair discrimination. They try to justify this assumption, if at all, by citing the improved quality of American cars. But these speeches are aimed at politicians and policy makers rather than consumers. And that, in a nutshell, is the problem. ■