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Two Cheers for the FDA

By ACSH Staff — November 27, 2006

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The recent decision to allow silicone breast implants was a sadly unusual victory of evidence over fear for the agency.

The FDA's decision Friday to allow the sale of silicone breast implants (SBIs) comes as a belated but welcome development to those of us who believe that regulatory decisions should be based on science, rather than activist hype. It is probably merely wishful thinking to believe that this decision represents a long-term reversal of course at the FDA. While our drug and device regulators are charged with adhering strictly to sound science, they have often bent over to accommodate political and media-driven pressures instead. This practice has actually accelerated since the Vioxx recall of September 2004, and the normally cautious agency has really been circling the wagons since then.

The FDA's 1992 decision to effectively ban SBIs from the marketplace was a direct consequence of then-Commissioner David Kessler's "moratorium," provoked by public and media pressure. A CBS News report by Connie Chung in 1990, highlighting one woman's experience ostensibly resulting from SBI toxicity, stirred multiple similar articles. These scare stories were especially prevalent in women's magazines, provoking intense fear, followed by litigation--a common pathway for such alarmism. However, Kessler's ban of silicone used in breast implants, rather than quieting the situation, provoked panic among women with implants, and a surge in lawsuits, promulgated by a consortium of lawyers, anti-corporate activists (especially Public Citizen's Sidney Wolfe) and the media. Doctors, unfortunately, helped to feed this firestorm by publishing studies that alleged to have found various markers of systemic disease in women--or their children--with SBIs.

Many of these physicians went on to lucrative side careers as expert witnesses for lawyers suing SBI makers. Faced with thousands of lawsuits, rather than depending on scientific data to defend their products in the courtroom, SBI makers decided to settle with the plaintiffs, contributing to a $4.2 billion fund to pay off those with allegedly silicone-induced illness. The major manufacturer, Dow Corning, was forced into bankruptcy, while the plaintiffs' attorneys rejoiced. The fact that SBIs had been safely used worldwide since 1963 got lost in the shuffle. While the majority of such use was for cosmetic breast augmentation, almost 40% was for reconstruction subsequent to breast cancer surgery. Women who desired the most natural feel and appearance--whatever their reasons--were barred from having the prosthesis of their choice by the FDA ruling, based on nothing more than media and political pressure.

For most of us involved in public health, the scientific debate on SBIs ended in 1995, when several large studies were published confirming the lack of association with systemic diseases, including

auto-immune disease and cancer. Finally, the Institute of Medicine of the National Academy of Sciences issued a definitive report in 1999, absolving silicone implants entirely.

So why has it taken the FDA seven more years to catch up with the rest of the scientific world? Women who chose to have implants, and those that need them reconstructively, should cheer the fact that the regulatory hand has finally been lifted. But for many women, too much time has passed. Likewise, the stockholders whose companies were forced into huge, unfounded settlements or bankruptcy will not recoup their investments.

Even now, anti-science voices have been raised condemning the FDA's decision. The National Organization of Women decried the lifting of the ban, putting a classic political spin on it: "Women should be outraged by this reckless decision. Bush-appointed FDA leaders are once again endangering the public health, this time to enrich manufacturers and cosmetic surgeons," said NOW President Kim Gandy.

And Public Citizen's Dr. Wolfe, who has rarely encountered a drug or device he admires, asserted: "In terms of adverse safety and health information known at the time of approval--such as high rates of rupture, the need for repeat surgery and clear evidence of lymph node infiltration and damage by leaked silicone--silicone gel breast implants are the most defective medical device ever approved by the FDA. "

Wolfe has apparently forgotten that one of the reasons he has been calling for the ban of SBIs since the late 1980s was his belief that they were a cause of cancer--an idea which has been thoroughly disproven. Of course, SBIs can and do leak, after a number of years. The FDA has taken the most unusual step of recommending that women getting the implants have MRIs every few years to detect silent leakage. As with any implanted medical device, such complications are a known occurrence. At last, the FDA has wisely decided to let the patient and her doctor decide on the best course to follow, in full cognizance of the risks. Dr. Daniel Schultz, director of the FDA's Center for Devices and Radiological Health, stated this succinctly: "Women should know that breast implants are not lifetime devices." Indeed, studies have shown that the majority of women with SBIs will need to have some sort of corrective surgery eventually to deal with a ruptured implant.

Over the past few years, several companies have repeatedly petitioned the FDA for re-assessment of this nonsensical ban, without success--until now. We in public health must pay careful attention to FDA activities. Scientists willing to speak out against such behavior must come forward, or the public will read only those who are against scientific progress. Such a black mark cannot be allowed to recur. The FDA must do a better job, and must be held to account when it does not.

Links
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