



# MISPLACED MANDATE: AN EXAMINATION OF FDA'S SILICONE BREAST IMPLANT POLICY

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MISPLACED MANDATE:  
AN EXAMINATION OF FDA'S SILICONE BREAST IMPLANT POLICY

Why did the Food and Drug Administration (FDA) suddenly call for a forty-five day moratorium on silicone gel breast implants in 1992 and then ban virtually all cosmetic breast implants' only months after an FDA advisory panel had recommended that silicone breast implants remain on the market for both reconstructive and cosmetic uses?<sup>2</sup> Is FDA's policy, which remains in force today, justified? What is FDA's mandate, and has FDA overstepped it in banning cosmetic breast implants?

This paper explores these questions. First, it traces the use of silicone breast implants in the United States; next, it examines the process that led to FDA's precipitous policy reversal; and finally~ it concludes with an assessment of current FDA policy.

SILICONE BREAST IMPLANTS

Medical Use of Silicone

Silicones are a family of inorganic silicon oxide polymers with elastomeric properties that have wide applicability in modern medicine. Medical silicone (polydimethylsiloxane) can be formulated

1 FDA, U.S. Department of Health and Human Services, Pub. No. P92-I (1992) (H.H.S. News).

2 FDA, U.S. Department of Health and Human Services, Pub. No. T91 -72 (1991) (Talk Paper).

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in varying ways. Depending on the additives with which it is combined, it can appear in liquid, gel, or solid form.<sup>3</sup>

Although developed in the 1930s, medical silicone initially was used clinically during World War II – as a lubricant for glass syringes to ensure reliable plunger functioning.<sup>4</sup> It was first employed in plastic surgery to waterproof wound dressings.<sup>5</sup> Today silicone is extensively used in a wide range of medical devices: as a coating for needles, catheters, and silk sutures; as antifoams for gastric bloating; as tubing for gastrointestinal, intravenous, and intra-arterial administration of nutrients and drugs; as implants for fingers, wrists, elbows, and shoulders; as pacemaker covers; and as breast, penile, and testicular implants—to name only a representative sample of uses.<sup>6</sup>

#### History of Silicone Breast Implants

Silicone breast implants are elasticized silicone rubber pouches filled with silicone gel.<sup>7</sup> Since 1962, when they first came on the market, silicone breast implants have been implanted in 3 Jack C. Fisher, *The Silicone Controversy—When Will Science Prevail?*, 326 *NEW ENG. J. MED.* 1696 (1992).

<sup>4</sup> *Id.*

<sup>5</sup> J.B. Brown et al., *Silicones in Plastic Surgery: Laboratory and Clinical Investigations, A Preliminary Report*, 12 *Plast. Reconstr. Surg.* 374-376 (1953).

<sup>6</sup> Ten Randall, *Medical News & Perspectives*, 268 *JAMA* 12 (1992); Council on Scientific Affairs, *Silicone Gel Breast Implants*, 21 *JAMA* 2602 (1993).

<sup>7</sup> Of all silicone medical devices, only silicone breast, chin, hiatal hernia, and testicular implants contain silicone gel. *Id.*

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between 1 and 2.2 million women in the United States and Canada alone.<sup>8</sup> According to FDA estimates, approximately 20 percent of all breast implants have been for reconstructive purposes (as a follow-up to a mastectomy) and 80 percent have been purely for cosmetic reasons.<sup>9</sup>

A number of medical concerns have been raised by silicone gel implants. These include silicone gel penetration or bleed (seepage of microdroplets of silicone gel through the semipermeable membrane of the silicone envelope); fibrous capsular contracture (painful hardening of the breast); rupture of the silicone envelope; interference with early tumor detection; and a variety of connective-tissue, autoimmune diseases such as scleroderma, rheumatoid arthritis, human adjuvant disease, and lupus.<sup>10</sup>

Since 1981, approximately 10,000 lawsuits have been filed against the manufacturers of silicone breast implants.<sup>11</sup> A number of large individual claims have been awarded in recent years.<sup>12</sup>

<sup>8</sup> Jorge Sanchez-Guerrero and Matthew H. Liang, *Silicone Breast Implants and Connective Tissue Diseases: No Association Has Been Convincingly Established*,

309 BRITISH MEDICAL JOURNAL 822 (1994).

<sup>9</sup> FDA, U.S. Department of Health and Human Services, Pub. No. T9 1-18 (1991) (Talk Paper).

<sup>10</sup> Rebecca Weisman, *Reforms in Medical Device Regulation: An Examination of the Silicone Gel Breast Implant Debacle*, 23 GOLDEN GATE U.L. REV. 973.

<sup>11</sup> Charlotte Allen, *Jurisprudence of Breasts*, 5 STAN. L. & POL'Y REV. 83 (1994).

<sup>12</sup> See, e.g., *Hopkins v. Dow Corning Corp.*, CA 9, No. 92-16132 (9th Cir.

1994)(upholding a \$7.3 million individual award, including \$6.5 million in punitive damages).

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There have also been a growing number of settlements, capped in the fall of 1994 by a nationwide class-action suit that was settled for over \$4 billion.<sup>13</sup>

## FDA REGULATION OF SILICONE BREAST IMPLANTS

In 1938, Congress passed the Federal Food, Drug, and Cosmetic Act, which authorizes FDA to regulate food, drugs, and cosmetics sold or transported in interstate commerce. In 1976 Congress passed the Medical Device Amendments, which substantially expanded FDA's regulatory powers vis a vis medical devices in order to assure their safety and effectiveness.

After the 1976 Amendments, all medical devices (that is, those devices marketed intentionally for medical purposes)<sup>14</sup> are subject to the general regulatory controls of the 1938 Act, including the provisions relating to adulteration, misbranding, and good manufacturing practices. In addition, the Amendments require FDA to classify all medical devices into one of three regulatory categories based on the need for proof of safety and effectiveness.

<sup>13</sup> In *Re Breast Implant Litigation*, DC NAIa, MDL No. 926 (1994).

<sup>14</sup> A device is any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. 21 U.S.C. § 321 (h) (1994).

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Class I devices are those for which the general regulatory controls of the 1938 Act are sufficient to assure safety and effectiveness. Classes II and III include devices for which general controls are not sufficient to assure safety and effectiveness; Class II devices are those for which sufficient information exists to establish a performance standard; Class III devices are those for which sufficient information to establish a performance standard does not as yet exist. In addition, Class III includes all new devices introduced after enactment of the 1976 Amendments that are not substantially equivalent to a pre-enactment device.<sup>15</sup>

Because silicone breast implants had been on the market prior to the passage of the 1976 Amendments, they were considered grandfathered in. It was not until 1988 that FDA classified them as a Class III device.<sup>16</sup> On April 10, 1991, FDA published a regulation requiring manufacturers of silicone breast implants to submit proof that the implants are safe and effective.<sup>17</sup> On November 15, 1991, an FDA advisory panel recommended virtually unanimously that, although there was insufficient information to warrant approval, silicone breast implants be kept on the market while additional safety and effectiveness information was collected and that no distinction be made between reconstructive and augmentation

<sup>15</sup> See Peter Barton Hutt and Richard A. Merrill, *FOOD AND DRUG LAW* at 745

(2nd ed. 1991).

<sup>16</sup> 55 Fed. Reg. 20,568 (1990).

<sup>17</sup> FDA, U.S. Department of Health and Human Services, Pub. No. T9 1-1 8

(1991) (Talk Paper).

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implantations.<sup>18</sup> After the multimillion dollar jury award in Hopkins v. Dow Corning Corp. (award to mastectomy implant recipient), a panel member wrote to FDA urging reconsideration of the panel's November recommendation. On January 6, 1992, David Kessler, FDA's Commissioner, appeared on national television and declared a forty-five day moratorium on the distribution and use of all breast implants.<sup>19</sup> This dramatic and highly publicized FDA policy reversal set off a media frenzy. When a reconvened advisory panel met in February to hold a new hearing, its finding seemed to be a foregone conclusion.<sup>20</sup> Although four of the five scientists on the panel voted against restricting implants solely to patients desiring reconstructive surgery, by a five-to-four vote the committee recommended the prohibition of purely cosmetic breast implants indefinitely. Of the five members voting to limit the availability of implants, only one had any scientific background and that person was not an expert in autoimmune diseases.<sup>21</sup> On April 16, 1992, FDA adopted the panel's recommendations, thereby effectively ending all cosmetic silicone breast implants in the United States.<sup>22</sup>

<sup>18</sup> Mark A. Heller, *Breast Implants: A Crisis Waiting to Happen* at 247 (1994);

FDA Talk Paper *supra*. fn. 1.

<sup>19</sup> Heller at 248; FDA *supra* fn. 2.

<sup>20</sup> Heller at 249.

<sup>21</sup> *Id.*

<sup>22</sup> FDA, U.S. Department of Health and Human Services, Pub. No. P-92-1 1 (1992) (H.H.S. News).

## ANALYSIS

FDA's current ban on silicone breast implants for strictly cosmetic purposes is troublesome in many key respects.

### Fallacy of FDA's Reconstructive/Cosmetic Distinction

In making a regulatory distinction between reconstructive and cosmetic breast implantation, FDA has created an artificial and arbitrary distinction that is not logically justifiable. There is no basic difference between the two types of implantations. Whether performed for reconstructive or for augmentation purposes, breast implantation is a totally discretionary procedure performed purely for psychological and social reasons. In that sense, it is always an elective cosmetic procedure. Indeed, it's important to note that even when done as a follow-up to a mastectomy, implantation is a totally separate surgical procedure, performed many months after the original cancer surgery.

The one genuine difference between reconstructive and augmentation implantation is the average age of the implant recipients. Because cancer tends to strike older women (typically, in their fifties and sixties), while women having augmentation surgery tend to be in their twenties and thirties, implantation devices inserted for augmentation purposes are likely to stay in the recipient's body for many more years and presumably need to be more durable. In addition, younger women may be more physically and sexually active than older women and hence their implants may be subjected to more stress. Finally, the need to be able to detect

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incipient breast cancer is greater for younger women who have never had breast cancer than for women who have already been diagnosed with it; thus, the difficulties that the presence of implants poses to the accurate reading of mammographies (because of tissue compression and visual blockage) can create additional risks for augmentation implant recipients.

There are a number of responses to these concerns. Considering that the projected lifespan of the average woman today is nearly eighty years, even women having implantations in their forties and fifties can anticipate the need for their implants to last thirty years or more. Thus, both categories of implant recipients share the same legitimate concerns about the durability of their implants. As for the purported age-related differences in physical activity, these are even more speculative; but even assuming that older women may be somewhat less active than younger women, most older women are still physically and sexually active, and thus, here too they share the same concerns of younger recipients. Finally, other methods of cancer detection that do not involve X-rays such as ultrasonography and MRI imaging can be used to supplement mammograms. Thus, in reality, the distinctions between older and younger implant recipients are really differences of degree rather than of kind. (Additionally, implant recipients in these two categories may overlap in age. Some women develop breast cancer in their early thirties and some women in their forties may wish to augment their breasts.)

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#### Trivializing of Cosmetic Concerns and Benefits

FDA seems to be equating cosmetic with frivolous or unimportant. This is an inappropriate and inaccurate value judgment. American society places a high value on being as physically attractive as possible. The literature of social psychology is filled with studies that show that physically attractive people have clear social, economic, and professional advantages in American society.<sup>23</sup> There is considerable evidence that people react more favorably toward individuals who are physically attractive; that they tend to overgeneralize from appearances, assuming that those who are attractive on the outside also have attractive personal characteristics; that physically attractive people are seen as being more socially competent, more intellectually competent, better adjusted, and more self-assertive than those who are less attractive.<sup>24</sup>

Therefore, wanting a cosmetic procedure to improve one's appearance isn't silly or trivial. It's an entirely rational and sensible motive—and one deserving of respect. We may deplore the pressures that women feel to conform to a stereotyped standard of

<sup>23</sup> See Sharon S. Brehm and Saul M. Kassin, SOCIAL PSYCHOLOGY at 211-215 (2nd ed. 1993).

<sup>24</sup> E. Hatfield and S. Sprecher, Mirror, Mirror... The Importance of Looks in Everyday Life (1986); K.K. Dion, et al., *What Is Beautiful Is Good*, 24 J. of PERS. AND SOC. PSYCH. 285; A.H. Eagly et al., *What Is Beautiful Is Good, But...: A*

*Meta-Analytic Review of Research on the Physical Attractiveness Stereotype*, 90 PSYCH. BULLETIN, 1.

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beauty, while at the same time defending their right to make their own decisions.<sup>25</sup>

#### Inappropriate Moral and Social Value Judgments

FDA is statutorily mandated to base its decisions concerning medical devices only on safety and effectiveness considerations. Nonetheless, in disallowing strictly cosmetic breast implantations, FDA seems to be basing its decision on a moral judgment that cosmetic breast implantation is improper and socially unworthy. As FDA Commissioner David Kessler notes in defending FDA's distinction between reconstructive and augmentation implantation, Certainly, as a society, we are far from according cosmetic interventions the same importance as a matter of public health that we accord to cancer treatments. ... It makes little sense for the FDA to consider breast augmentation of equivalent importance with an accepted component of cancer therapy.<sup>26</sup> Significantly, FDA's decision to prohibit cosmetic implants seems to be only minimally based on a belief that cosmetic implants entail higher risks than reconstructive implants (which might be more defensible).<sup>27</sup> Rather

<sup>25</sup> Marcia Angell, *Breast Implants—Protection or Paternalism?* 326 NEW ENG. J. MED. 1695,1696(1992).

<sup>26</sup> David A. Kessler, *The Basis of the FDA 's Decision on Breast Implants*, 326 NEWENG.J. MED. 1713,1715(1992).

<sup>27</sup> Kessler does offer the rationale that the complications created by implants in the use of mammography for detection of breast cancer raise the risks to cosmetic implant recipients, but it seems more to be an effort to show that FDA is not basing its decision on any moral judgments, coming as it does after the following sentences: These restrictions on the use of silicone-gel implants for breast augmentation are not based on any judgment about values. Rather,

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(and somewhat astoundingly), Kessler claims that FDA's decision is based on FDA's determination that the needs of reconstructive and cosmetic implant recipients differ. As Kessler states: Some argue, however, that it is inconsistent for the FDA to allow the use of a medical device in some situations and not in others. In their view, healthy women who have poor body images because they have small or asymmetrical breasts have as great a need for the device as women who have breast cancer. This contention has a superficial appeal. Although one can legitimately argue for a continuum of need, in the end the needs of the patient who desires reconstructive surgery differ from those of the patient who desires augmentation.<sup>28</sup>

Since this assessment is unrelated to the safety and effectiveness concerns upon which FDA is supposed to base its actions, a strong argument can be made that FDA's prohibition of cosmetic breast implants while allowing reconstructive ones is an abuse of FDA's enormous discretionary power. This kind of policy decision relating to how society wishes to use its resources is best left to Congress. It is simply not FDA's business to be making these kinds of broad social policy decisions.

It is also not FDA's business to be making private value judgments that are best left to the individual patient. The key to any risk/benefit analysis of a procedure of this sort—whose

the FDA has concluded that women who desire breast augmentation are at higher risk than patients with breast cancer who have had a mastectomy. *Id.* 28 *Id.*

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benefits are purely psychological and social—is to determine the value that this particular patient places on these benefits. And only the individual patient can make this determination. Some mastectomy patients may be completely uninterested in reconstructive implants, while some women may be desperate for augmentation surgery. In such circumstances, the benefits would be heavily weighted in favor of the augmentation implant recipient. FDA is simply not equipped to make this kind of benefit analysis—and it shouldn't be trying to do so.

Worth noting are the results of surveys of women with breast implants, which report a greater than 90 percent incidence of satisfaction with the procedure and the outcome.<sup>29</sup>

Finally, one must also ask whether FDA's precipitous policy reversal did not in itself contribute to diminishing the potential benefits of this procedure. By creating an atmosphere of panic and unwarranted fears out of proportion to what is known about the risks, it may have led some asymptomatic women with implants to opt for surgical removal of their implants because of an alarm induced by FDA and the media; and at the very least, FDA's actions have significantly impaired the peace of mind and quality of life of the million or so women with implants.

<sup>29</sup> J.C. Fisher and G.S. Brody, *Breast Implants Under Siege: An Historical*

*Commentary*, 1 J. LONG TERM EFF. MED. IMPLANTS 243; Silicone Implant Research Committee of the Plastic Surgery Educational Foundation, *Comments*

*From Plastic Surgery in Response to the FDA Proposed Rule and Request for Premarket Approval of Silicone Gel-Filled Breast Implants (1990).*

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## Paternalism

FDA's ban on cosmetic implants is paternalistic and profoundly disrespectful of the intelligence and judgment of patients in general and women in particular. In effect, FDA is saying that no matter how well-informed a patient may be, no matter how strongly and rationally motivated, and no matter how sound her doctor's advice, the patient simply can't be trusted to make a rational choice. The fact that the patients in question are all women only compounds this paternalism.

This disparaging attitude toward the patient's ability to make an informed choice permeates Commissioner's Kessler's comments:

It has become fashionable in some quarters to argue that women ought to be able to make such decisions on their own. If members of our society were empowered to make their own decisions about the entire range of products for which the FDA has responsibility, however, then the whole rationale for the agency would cease to exist.... To argue that people ought to be able to choose their own risks, that government should not intervene, even in the face of inadequate information, is to impose an unrealistic burden on people when they are most vulnerable to manufacturers' assertions: when they are desparately ill, when they are hoping against hope for a cure, or when they are seeking to enhance their physical appearance. These are precisely the situations in which the legal and ethical justification for the FDA's existence is greatest, however.<sup>30</sup> This rather grandiose view of the role of FDA is a kind of moral

<sup>30</sup> Kessler, *supra* note 1 2, at 171 5.

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overreaching that goes far beyond the statutory role delegated to it by Congress.

#### Current Scientific Studies

FDA's ban on cosmetic implants is not supported by the general scientific community. There is no solid scientific data showing a causal connection between silicone and immune-system disorders—only anecdotal evidence. And it was on the basis of this merely anecdotal evidence that FDA decided to ban cosmetic breast implants.

But, significantly, within the last seven months, important controlled studies have appeared in major journals that show no relationship between silicone breast implants and an increased risk of connective tissue and other forms of auto-immune disease. The most significant of these, Gabriel et al.'s Mayo Clinic Study<sup>31</sup> was an eight-year retrospective cohort study of all 749 women in Olmsted County, Minnesota, who had received a breast implant between 1964 and 1991.<sup>31</sup> There have also been other studies that indicate that women who undergo breast augmentation with silicone breast implants have a lower risk of breast cancer than the general population.<sup>32</sup>

These studies represent the best currently available scientific knowledge on the medical risks associated with silicone breast implants.

<sup>31</sup> Shenne E. Gabriel et al., *Risk of Connective-Tissue Diseases and Other Disorders After Breast Implantation*, 330 N. ENG. J. MED. 1967 (1994).

<sup>32</sup> Hans Berkel et al., *Breast Augmentation: A Risk Factor for Breast Cancer?* 326 N. ENG. J. MED. 1649 (1992)

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And they do not offer support for FDA's current policy banning cosmetic breast implants.

#### No Safer Alternatives

No safer alternatives to silicone gel implants are currently on the market. Saline-filled implants (which are encased in a silicone envelope) have elicited the same anecdotal reports and concerns as silicone gel implants (in addition to reports of sudden deflation), and all other substances currently being tested—for example, soy bean oil—still must undergo years of testing before their safety and effectiveness can be determined.

Thus, a blanket long-term ban on all cosmetic breast implants in the United States may lead disparate patients to take extreme measures. Many will go to other countries to have the surgery performed under considerably less safe and less controlled conditions.

#### Sufficient Protections

There are already protections in place to discourage rash or ill-considered decisions in regard to breast implants. After all, we are not talking about an over-the-counter drug a patient can pick up at her nearest pharmacy. This is a surgical procedure that must be performed by a qualified and knowledgeable physician, that requires the patient's written informed consent, and that necessitates considerable advance planning. The patient desiring this procedure must be willing to experience the pain and risks associated with any surgery; in addition, because cosmetic procedures are not covered by

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health insurance, the patient must be willing to bear the costs of this expensive procedure herself. In addition, according to current FDA regulations, all implant recipients must participate in a patient registry, clinical trials, and postmarket surveillance. Thus, any patient deciding to have this procedure is not likely to make it lightly.

In conclusion, then, yes, FDA must insist on full and complete disclosure to the patient of all possible risks early in the decision-making process to make certain that the patient is fully informed. But FDA should rest the ultimate decision where it belongs—with the patient herself. It's her life—it should be her choice.