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**Food and Drug Administration General and Plastic Surgery Devices Panel
of the Medical Devices Advisory Committee Meeting
On Breast Implants**

**Testimony of Sidney Wolfe, M.D.
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I have no conflicts of interest

A. Serious Deficiencies in the Medical Device Law

We have been involved in the overall issue of permanently implanted devices since 1973, three years before passage of the 1976 Medical Device Amendments.

On October 23, 1973, we testified before the U.S. House of Representatives' Subcommittee on Health and the Environment of the Committee on Interstate and Foreign Commerce, which was chaired by Congressman Paul Rogers, a sponsor of pending medical device legislation. Our urgent request was to greatly improve that legislation with the following mandatory language: "Premarket Testing. If a medical device meets one or more of the following criteria, premarket testing should be required: a. Implantable or prolonged bodily contact; b. Life-Supporting; c. Life-Sustaining; d. Emits ionizing radiation or other forms of energy; e. Potential hazard to good health." Because of the industry's history of many preventable serious device injuries caused by the absence of mandatory pre-market testing and by its strong, successful resistance to the above critically-needed legislative changes, we also stated that despite some progress in device technology, "the device industry operates much more like an unaccountable business than a part of a humanized health services system."¹

Permanently implanted devices raise issues of durability (rupture, breakage, gel leakage in the case of many devices, including breast implants), as well as effects on the immune system or on other bodily functions. The latter, sometimes described as foreign body reactions, broadly describes how the body reacts, especially with permanent implantation, to foreign, non-inert substances such as breast implants and, to cite another recent cause of serious problems, permanently implanted metal-on-metal hip joints.

¹ Testimony of Sidney M. Wolfe and Anita Johnson, Health Research Group (Public Citizen), Before House of Representatives Health Subcommittee on Medical Device Legislation. October 23, 1973.

B. Between 1976 and 1991

In January 1989, we testified before this committee on the topic of silicone breast implants and immune disorder. Our testimony included a review of the published literature, including a discussion of plausible biological hypotheses for silicone-induced immune disorders.

In addition to recommending implant and explant registries, we concluded that “There is enough evidence that significant immune derangement, with consequent connective tissue disease, occurs with exposure to the silicone in breast implants to warrant careful epidemiologic study. Until either a well-designed case control study or a cohort study with enough patients and lengthy follow-up proves otherwise, these implants are not safe for human use.”²

In November 1991, because of concerns about ruptured implants, other local problems, possible carcinogenicity, and autoimmune diseases, we petitioned Food and Drug Administration (FDA) Commissioner David Kessler to ban silicone gel implants. In partial support of this petition, we submitted the results of a then-recent a nationwide survey by the American Society of Plastic and Reconstructive Surgeons (ASPRS) intended to learn about satisfaction as well as patient-perceived complications related to breast implants.

The ASPRS had described this study, based a survey of 100,000 U.S. households, as “chosen to represent the nation’s consumer population.” From the data for the 592 women with breast implants who self-reported various problems, we projected the a lower limit of the number of the then-estimated 1.5 million American women with implants for augmentation who had each of these various problems. The survey results of the 592 women are below,³ based largely on women with implants for augmentation, but including the smaller number for reconstruction.

² Public Citizen. Dr. Douglas Teich’s statement on silicone breast implants and immune disorder. Hearing before the FDA’s General and Plastic Surgical Devices Committee. January 26, 1989.

³ Public Citizen. Petition to the Food and Drug Administration to ban silicone gel breast implants. November 7, 1991.

Nationwide Survey of Women with Breast Implants for Augmentation

Type of Complication	% in survey with problem	projected # of women with problem*
Complications such as rupture or infection	5% of women	75,000 women
Hard breasts	5% of women	75,000 women
Breast firmness: somewhat or very bothersome	11.4% of women	171,000 women
Scars somewhat or very visible	30% of women	449,000 women
Breasts somewhat or very unnatural/uncomfortable	7% of women	105,000 women
Bothersome changes in nipple sensation	12.4% of women	185,000 women
Pain and sensitivity complaints	5% of women	75,000 women

*Projected by Public Citizen Health Research Group to all U.S. women (1.495 million) with breast implants for augmentation. Based on a survey of 100,000 American households "chosen to represent the nation's consumer population", funded by the American Society of Plastic and Reconstructive Surgeons

Although there certainly is some overlap between women with various categories of complaints, the actual projected number of women was likely between at least 100,000 and 200,000, and rupture or infection complications alone including an estimated 75,000 women.

C. More recently

In 2011, just one week after the FDA announcement that there had been a growing number of published cases – then 34 – documenting an unusual kind of cancer (anaplastic large cell lymphoma (ALCL)) surrounding the breast in women with breast implants, the presidents of the two leading plastic surgery organizations, the American Society of Plastic Surgeons (ASPS) and the American Society for Aesthetic Plastic Surgery (ASAPS), in a webinar essentially urged the members of their societies to inaccurately downplay the significance of recent evidence about the risks of breast implant-related cancer when speaking to female patients. The transcript, provided to us by one of certainly a large number of members offended by this unethical betrayal of the truth, stated that “[Y]es it’s classically a malignant tumor, but it has such a benign course that when we were discussing ways to talk to the media, we decided that we would call this a condition when we talked to the media, not a tumor, not a disease, and certainly not a malignancy. Um, because, and I would recommend that you use the same terms with your patients rather than disturb them by saying this is a cancer, this is a malignancy. The best word is this is a condition.” A further falsehood was the statement that surgery is curative, also making mockery of informed consent. The full contents of our letter to the FDA that strongly objected to this degrading, patronizing, and unprofessional webinar can be found on our website.⁴

Finally, most recently, is the FDA’s statement in the briefing package for this meeting concerning the dilatory tactics of breast implant manufactures in conducting the required post-approval trials of their implants: “Breast implant post-approval studies designed at the time of device premarket approval to follow patients longitudinally and answer our long-term questions have been unreliable. Poor compliance and changes in surgical practice over time have produced results difficult to interpret in a generalized manner much less with the precision needed to deliver personalized patient care.”⁵

These post approval trials to obtain information that should have been derived before, not after approval, remind us why much more extensive mandatory pre-approval testing on such permanently implanted devices is necessary. Otherwise, women, in this case and both genders in too many other cases, are serving as guinea pigs.

⁴ Public Citizen. Letter to the Food and Drug Administration on inaccurate communications regarding risks of breast implant-related cancer. February 17, 2011. <https://www.citizen.org/our-work/health-and-safety/letter-inaccurate-communications-regarding-risks-breast-implant>. Accessed March 25, 2019.

⁵ Food and Drug Administration. FDA executive summary: Breast implant special topics prepared for the meeting of the General and Plastic Surgery Devices Panel. March 25-26, 2019. <https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/GeneralandPlasticSurgeryDevicesPanel/UCM634147.pdf>. Accessed March 25, 2019.