January 3, 2005

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

RE: PMA P030053/A6 Mentor Silicone Gel-Filled Breast Implants:
Amendment 6 – Benefits of Mentor's Silicone Gel-Filled Breast Implants

Mentor Corporation is submitting Amendment 6 of the above-referenced PMA in order to provide additional psychological and functional benefits data for Mentor's Silicone Gel-Filled Breast Implants. This information will be sent by e-mail under separate cover to Dr. Schultz and Ms. Linda Kahan for their review, since these policy issues were raised separately in prior discussions with them.

We consider the existence of this PMA application and its contents to be confidential and exempt from public disclosure.

If additional information is needed, please contact me at (805) 879-6168.

Sincerely,

Donna Free
Vice President, Regulatory Submissions

Enclosure

PSYCHOLOGICAL AND FUNCTIONAL BENEFITS OF MENTOR'S SILICONE GEL-FILLED BREAST IMPLANTS

As the Agency moves to make decisions on the latest round of review for Mentor Corporation's silicone gel-filled breast implant Premarket Approval Application ("PMA") (P030053), the benefits to health provided by these products will be part of its overall evaluation. In the past, the Agency has acknowledged that the potential psychological benefits offered by these devices "are an important part of the device's efficacy."[1] Because the literature supporting the clinical benefits of silicone gel-filled breast implants has further evolved since this Agency acknowledgement was made, Mentor summarizes below the recent literature as it relates to both reconstruction and augmentation patients.

As part of the effectiveness evaluation in Mentor's Core clinical study, "Global Patient Satisfaction" was assessed.[2] Results from this evaluation demonstrate that, in all cohorts, patients were highly satisfied with the benefits provided by silicone breast implants. At the three-year follow-up visit, overall 97% of all patients indicated they would have the surgery again. The results were similar for all three cohorts: 98%, 97%, and 96% for reconstruction, augmentation, and revision, respectively.

The medical literature, described below, offers further explanation as to how these patient satisfaction results correlate to meaningful functional and psychosocial benefits for both breast reconstruction and augmentation patients. Mentor respectfully requests that these important benefits factor significantly into any next step conclusions regarding the approvability of Mentor's PMA.

I. Breast Reconstruction

The many psychological and functional benefits of silicone gel-filled breast implants for women seeking reconstruction following mastectomy are well recognized in the literature. As described below, the literature consistently documents the benefits of feeling whole again; eliminating the need for an external prosthesis by restoring the breast mound; improved psychological health, self-esteem, sexuality, and body image; ability to move past their cancer experience; and reduced concerns about cancer recurrence. These psychological benefits are sufficiently notable that they have begun to be evaluated for their potential favorable impact on survival.[3] The functional benefits provided by silicone gel-filled breast implants for reconstruction patients are also important, because, other than reconstructive surgery involving autologous tissue, there currently are no other suitable device alternatives in many cases.[4]

Women who have undergone mastectomy to remove a cancerous breast experience a complex and wide-ranging spectrum of devastating physical and psychological effects. These effects include: disruption of body image; feelings of incompleteness due to the lost body part; loss of femininity; feelings of diminished self-worth; anxiety over being a cancer victim and, relatedly, fear that the cancer will return; and interpersonal, sexual, and marital dysfunction.[5] As noted by Harcourt and Rumsey (2001), "[t]he psychological ramifications of mastectomy can be especially substantial as these women face the distress and disfigurement caused by the loss of the breast in addition to the fear of a potentially life-threatening disease."[6]

Women who elect to undergo breast reconstruction following mastectomy seek both functional (i.e., physical) and psychological wholeness. Reaby (1998) emphasized that "it is important for women to comprehend that reconstructive surgery is . . . a legitimate means to restore a lost body part. The procedure should be seen as both a physiological and a psychological treatment for breast cancer in that it improves a woman's physical functioning, appearance, and sense of self."[7] This conclusion was echoed in a review of the literature by Harcourt and Rumsey (2001): "Motivation for breast reconstruction includes the perceived need to restore feelings of femininity and wholeness, to avoid disfigurement and deformity, to improve self-confidence, and to avoid the need for external prosthesis."[8]

As with Mentor's Core clinical study, both retrospective and prospective literature reports have found that the overwhelming majority of breast reconstruction patients (91% to 97%) are satisfied with the outcomes of their surgery.[9] Consistent with this high level of patient satisfaction, researchers have found that 88% of women consider the results of the surgery to meet or exceed expectations, and 90% of women consider the benefits of breast reconstruction to outweigh the risks.[10]

Considerable psychosocial benefits, which contribute to a patient's satisfaction, have been reported in breast cancer patients who have undergone reconstruction. Significant improvements in all psychosocial variables, including emotional well-being, vitality, general mental health, and body image were reported by Wilkins et al. (2000) in a large prospective, multicenter study that employed validated assessments (Medical Outcome Study Short Form-36 (SF-36); Functional Assessment of Cancer Therapy-Breast (FACT-B)) to measure these endpoints.[11] Similarly, improved quality of life, improved body image, increased self-esteem, feeling whole, less anxiety regarding cancer, less anxiety and depression, restored feelings of femininity, and improved social and emotional functioning were all significant findings in several other prospective and retrospective trials.[12]

Despite the commonly held belief that breast reconstruction may be an unnecessary risk in older patients (e.g., >65 years of age), the psychosocial benefits reported for mastectomy patients who have undergone breast reconstruction also extend to older women. Girotto et al. (2003) conducted a prospective study in which they found that older patients (i.e., >65 years of age) who elected breast reconstruction, had better outcomes than age-matched general population patients and previously reported mastectomy-only patients in all surveyed areas (i.e., physical and emotional well-being, social functioning, vitality, and general health).[13] Significantly improved body image also was seen in a recently published larger longitudinal cohort study that compared breast conservation surgery to mastectomy in women aged 67 years or greater. In this study conducted by Figueiredo et al. (2004),[14] body image was an important factor in treatment decisions for 31% of women. Additionally, women who chose breast conserving surgery had a better body image two years after treatment than women who had mastectomies ($p<0.0001$). Notably, body image predicted the two-year mental health scores in this cohort, and women who were concerned about their physical appearance, but underwent mastectomies (with no reconstruction), scored lowest on mental health scales, such as the SF-36.

A just published population-based, retrospective cohort study evaluated the effect of breast implants after mastectomy on long-term survival.[15] Patients were identified from the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) cancer registry in San Francisco-Oakland, CA, Seattle-Puget Sound, WA, and Iowa; a standardized questionnaire was completed; and medical records were examined. This study involved an unprecedented number of representative post-mastectomy patients (1,018 with breast implants and 3,950 without implants), and long-term follow-up (median duration of 12.4 years). The authors found that the risk of breast cancer mortality was approximately one-half of that for women without implants, after adjusting for multiple clinical and sociodemographic potential confounding factors. While contributing factors such as socioeconomic variables, comorbidity, smoking, or other lifestyle factors need to be examined in more detail, it can be concluded that, at a minimum, breast implants do not appear to have an adverse effect on survival in women who are younger than 65 years of age with early-stage breast cancer. The authors postulated several possible mechanisms to account for the increased survival in women with breast implants, including increased self-esteem.[16]

Studies thus confirm that the functional benefit of restoring the breast mound and replacing a missing body part, coupled with improved body image and mental health, are all important outcomes of breast reconstruction following mastectomy. Because these outcomes correlate to meaningful clinical benefits that are comparable to, and in some circumstances more significant than, other implanted prosthetic devices, silicone gel-filled breast implants for reconstruction should be afforded a risk/benefit evaluation that is at least consistent with these other products.

II. Breast Augmentation

A. Introduction

As with the breast reconstruction cohort, augmentation patients in Mentor's Core study have reported a high degree of satisfaction with the results of their surgery.[17] Results of several prospective and retrospective studies support Mentor's findings that women who undergo breast augmentation are overwhelmingly satisfied with the results.[18] Product satisfaction ratings in the literature range from 84% to 94%.[19] Relatedly, high response rates with regard to successful surgery (86%-88%) and meeting expectations (92%-96%) also have been reported.[20] In a recently published online survey conducted by the Aesthetic Surgery Education and Research Foundation (ASERF) of 2,273 women who underwent breast augmentation, 98% reported that the surgery met expectations, 92% reported that they were happy with their decision to get implants, and 93% said they would recommend the procedure to family or friends.[21]

The concept of satisfaction has been reviewed in the literature, and it consistently correlates to improved mental and physical well-being. For example, the interrelationship of patient satisfaction with improved mental and physical well-being was evaluated by Cash et al. (2002), in their multicenter, prospective, two-year study in 360 women who underwent breast augmentation. They found that overall surgical satisfaction was highly related to improved body image satisfaction ($p<0.001$), improved self-image ($p<0.001$), and improved sexual satisfaction ($p<0.001$).[22]

B. Motivation for Seeking Augmentation, and the Decision Making Process

Aesthetic procedures generally, and breast augmentation specifically, are an increasingly more popular means to optimize one's body image for improving well-being by a growing population of informed women.[23] As described below, self-improvement represents the driving reason for seeking aesthetic breast augmentation, and women today have highly personal and varied motives to do so, including: improved body image; improved psychosocial outcomes (which encompass mental health and well-being generally, and improved self-esteem, relationships, and sexuality, specifically); and functional/restorative benefits.

The motivations for women seeking breast augmentation have been widely studied over the years, and the goals of today's breast augmentation patient are best captured by Cash et al. (2002). In this study, it was demonstrated that the motivations for women who had breast augmentation were to improve body image (feelings about physical appearance in general (91.6%), improve body proportions (86.2%), improve breast size (88.2%)), improve self-esteem (81.2%), improve feelings of femininity (70.6%), and improve sexual attractiveness (65.0%).[24] These motivational factors are supported by the ASERF survey, in which the highest rated reasons for breast augmentation were related to improved physical appearance, improved self-esteem, and improved confidence.[25] Other investigators likewise have reported that the most common factors influencing the choice to undergo breast augmentation are: improved breast size and body proportions; increased self confidence; improved appearance in clothing; improved physical appearance overall; and enhanced feelings of sexuality and femininity.[26]

Studies also have identified a more restorative desire for augmentation as a motivational factor -- that is, to regain the breast size/shape women had prior to pregnancy and lactation, and to correct sagging breasts, caused, at least in part, by these events. For this class of women, augmentation serves a functional as well as psychological benefit, as discussed below.

Goin and Goin,[27] for example, identify women with postpartum breast involution as one major category of women seeking breast augmentation, because they considered their breasts to be adequate before pregnancy, but found them to have diminished as a result of pregnancy. These women have augmentation to restore their breasts to their earlier size and contour. Similarly, acquiring a better shape when firmness is lost as a result of childbirth

is one of the main reasons for seeking breast augmentation identified by Kaslow and Becker.[28] The recent ASERF survey also lists restoration of pre-childbirth shape and contour as an important reason for patients to undergo this procedure.[29]

Most women seeking aesthetic breast augmentation, do so with the background of education and life experience. It has been reported recently that almost 90% of aesthetic breast augmentation recipients have had some level of college education. In particular, the recent ASERF survey demonstrated that 11% have graduate/professional degrees, 5% have some graduate school, 26% have bachelor's degrees, and 40% have some college.[30] For most of these women, household income exceeds $50,000 per year; almost 50% over $75,000; and almost 30% over $100,000.[31] Because the cost of the surgery is not reimbursed, regardless of disposable income, the decision to seek augmentation is a significant one that comes only after informed deliberation.

C. Satisfaction Outcomes

Literature and survey findings demonstrate that the psychological and physical well-being benefits of aesthetic breast augmentation are three-fold: improved body image; improved psychosocial outcomes; and functional restoration of breast tissue.[32] These findings, and how they correlate to improved psychological and physical well-being, are discussed below.

1. Body Image

Response rates for several indices of body image are consistently high across several retrospective and prospective studies of breast augmentation patients. For example, in a retrospective study of 112 women by Young et al. (2004), 93% of the participants believed that they looked better following surgery and 95% believed that their appearance had been improved.[33] In Cash et al. (2002), 90%-92% of the women studied reported improvement in self-image through 24 months after surgery.[34] Appearance evaluation and satisfaction with specific body areas scores assessed using the Multidimensional Body-Self Relations Questionnaire likewise improved significantly at both three and six months post surgery as compared to the preoperative score ($p<0.001$), in a recently published study by Banbury et al. (2004).[35] In a study conducted by Kilman et al.,[36] women who had breast augmentation reported that the surgery had a significant positive effect on their attractiveness and their body and self-image. These results are supported by the ASERF online survey, which found that 92% of the respondents thought that breast augmentation improved their overall appearance.[37] Improvement in body image, and related improvements in well-being, thus, are important contributing factors to overall satisfaction.

2. Psychosocial Outcomes

Psychosocial outcomes encompass a wide range of indices, including mental health generally, and self-esteem, relationships, and sexuality, specifically. Women who undergo breast augmentation frequently report that the surgery made them feel better about themselves, increased their self-confidence, diminished feelings of self-consciousness, and improved their mental health.[38]

These psychosocial benefits are also reflected in a women's feelings about her sexuality and interpersonal relationships. For example, in Mentor's Core study, significant improvements were observed in the sexual attractiveness subscale of the Body Esteem Scale in both the Augmentation cohort ($p<0.0001$), and across all three cohorts ($p<0.0001$). Breast augmentation patients in a study conducted by Kilmann et al. (1987) reported that their sexual relationship was significantly enhanced.[39] Cash and colleagues (2002) likewise reported statistically significant increases in breast augmentation patients for sexual/social relationship improvements (51.1% at 12 months, $p=0.051$),[40] and 53% of the respondents in the ASERF survey reported improvement in their sex lives as well.[41] FDA previously has acknowledged the benefit of improved sexual relations as a clinical benefit to women and men alike, by approving numerous drugs and devices in this category, such as oral drugs (i.e., Viagra®, Cialis®, and Levitra®) and penile implants.[42]

3. Functional/Restorative Benefits

In addition to psychological benefits of breast augmentation, there are also functional (i.e., restorative) benefits to breast implants. To better understand these functional/restorative benefits, the population of cosmetic breast implant recipients must first be understood. Women seeking breast implants for cosmetic purposes are predominantly married (64%) and in their 20s, 30s, and 40s; 64% percent of the married women have children.[43] In this population, some level of breast involution and/or sagging can result from pregnancy, lactation, and/or significant weight change caused by these events. For these women, physiological replacement of the involuted/sagging breast -- that is, regaining the breast size/shape these women had before pregnancy, lactation, or weight changes -- also factors into decisions for seeking cosmetic breast augmentation.[44] Women who have augmentation for this reason report high levels of satisfaction with the results of their surgery.[45] Thus, there are clearly identifiable functional (i.e., restorative) as well as psychological benefits to these women.

III. Conclusions

As demonstrated by the literature, for women seeking both reconstruction and augmentation, satisfaction results are compellingly high and correlate consistently to psychological and physical well-being -- meaningful clinical benefits. These clinical benefits should be factored into the risk/benefit evaluation of Mentor's silicone gel-filled breast implant PMA.

1/ 64 Fed. Reg. 45155 at 45159 (Aug. 19, 1999) (final rule calling for PMA review of silicone gel-filled breast implants, emphasizing in particular, the potential psychological benefits offered by these devices).

2/ The study was designed and conducted in accordance with the FDA's guidance, and in consultation with experts from a variety of medical disciplines. The clinical indications being studied include reconstruction of the female breast, aesthetic augmentation of the female breast for cosmetic purposes, and revision of pre-existing implants. See FDA, Guidance for Saline, Silicone Gel, and Alternative Breast Implants; Guidance for Industry and FDA (Feb. 11, 2003). A total of 1007 women (252 in the reconstruction cohort, 551 in the augmentation cohort, and 204 in the revision cohort) were enrolled by 40 investigators. Three-year data have thus far been submitted to the Agency in support of Mentor's PMA.

3/ Le, G.M., et al 2005. Breast implants following mastectomy in women with early-stage breast cancer: prevalence and impact on survival. Breast Cancer Res. 7:R184-93. See, also, Georgiade, G.S., et al. 1985. Long-term clinical outcome of immediate reconstruction after mastectomy. Plast. Reconstr. Surg. 76:415-20; Petit, J.Y., et al. 1994. Can breast reconstruction with gel-filled silicone implants increase the risk of death and second primary cancer in patients treated by mastectomy for breast cancer? Plast. Reconstr. Surg. 94:115-9; Vandeweyer, E., et al. 2001. Immediate breast reconstruction with saline-filled implants: no interference with the oncologic outcome? Plast. Reconstr. Surg. 107:1409-12.

4/ Autologous tissue reconstruction generally is not an option for women who require reconstruction of both breasts; saline breast implants are an option for some, but not all, women.

5/ See, e.g., Reaby, L.L. 1998. Reasons why women who have mastectomy decide to have or not to have breast reconstruction. Plast. Reconstr. Surg. 101:1810-8; Wilkins, E.G., et al. 2000. Prospective analysis of psychosocial outcomes in breast reconstruction: one-year postoperative results from the Michigan breast reconstruction outcome study. Plast. Reconstr. Surg. 106:1014-25; Tykkä, E., et al. 2001. Patients' satisfaction with breast reconstruction and reduction mammaplasty. Scand. J. Plast. Reconstr. Hand Surg. 35:399-405; Harcourt, D., and Rumsey, N. 2001 Psychological aspects of breast reconstruction: a review of the literature. J. Advanced Nursing 35(4):477-87.

6/ Harcourt, D., and Rumsey, N. 2001. Psychological aspects of breast reconstruction: a review of the literature. J. Advanced Nursing 35(4):477-87.

7/ Reaby, L.L. 1998. Reasons why women who have mastectomy decide to have or not to have breast reconstruction. Plast. Reconstr. Surg. 101:1810-8.

8/ Harcourt, D., and Rumsey, N. 2001. Psychological aspects of breast reconstruction: a review of the literature. J. Advanced Nursing 35(4):477-87.

9/ Park, A.J., et al. 1996. Patient satisfaction following insertion of silicone breast implants. Br. J. Plast. Surg. 49:515-8; Tykkä, E., et al. 2001. Patients' satisfaction with breast reconstruction and reduction mammaplasty. Scand. J. Plast. Reconstr. Hand Surg. 35:399-405; Tykkä, E., et al. 2002. Patient satisfaction with delayed breast reconstruction: a prospective study. Ann. Plast. Surg. 49(3):258-63; Tykkä, E., et al. 2002. Patient satisfaction with delayed breast reconstruction: a prospective study. Ann Plast. Surg. 49(3):258-63.

10/ Id.

11/ Wilkins, E.G., et al. 2000. Prospective analysis of psychosocial outcomes in breast reconstruction: one-year postoperative results from the Michigan breast reconstruction outcome study. Plast. Reconstr. Surg. 106:1014-25.

12/ See, e.g., Tykkä, E., et al. 2001. Patients' satisfaction with breast reconstruction and reduction mammaplasty. Scand. J. Plast. Reconstr. Hand Surg. 35:399-405; Tykkä, E., et al. 2002. Patient satisfaction with delayed breast reconstruction: a prospective study. Ann. Plast. Surg. 49(3):258-63; Harcourt, D.M., et al. .2003 The psychological effect of mastectomy with or without breast reconstruction: a prospective multicenter study. Plast. Reconstr. Surg. 111:1060-8.

13/ Girotto, J.A., et al. 2003. Breast reconstruction in the elderly: preserving excellent quality of life Ann. Plast. Surg. 50:572-8.

14/ Figueiredo, M.I., et al. 2004. Breast cancer treatment in older women: Does getting what you want improve your long-term body image and mental health? J. Clin. Oncol. 22:4002-9.

15/ Le, G.M., et al. 2005. Breast implants following mastectomy in women with early-stage breast cancer: prevalence and impact on survival. Breast Cancer Res. 7:R184-93.

16/ Other possible mechanisms postulated by the authors, which warrant further study, included: stimulation of a local immune response that could destroy cancer cells; compression of breast tissue, which reduces the flow of blood and consequently, the rate of cell or tumor growth; and decreased breast tissue temperature, which would slow the growth of residual breast cancer cells (citing Hoshaw, S.J., et al. 2001. Breast implants and cancer: causation, delayed detection, and survival. Plast. Reconstr. Surg. 107:1393-1407; Deapen, D., et al.1997. Are breast implants anticarcinogenic? A 14-year follow-up of the Los Angeles Study. Plast. Reconstr. Surg. 99:1346-53; Brinton, L.A., et al. 1996. Breast enlargement and reduction: results from a breast cancer case-control study. Plast. Reconstr. Surg. 97:269-75; Dreyfuss, D.A., et al. 1987. Silicone implants as an anticarcinogen. Surg. Forum 38.587-8; Su, C.W., et al. 1995. Silicone implants and the inhibition of cancer. Plast. Reconstr. Surg. 96:513-8; Ramasastry, S.S., et al. 1991. Regression of local and distant tumor growth by tissue expansion: an experimental study of mammary carcinoma in 13,762 rats. Plast. Reconstr. Surg. 87:1-7.

17/ Relatedly, in Mentor's pivotal study supporting the approval of its saline breast implants, statistically significant improvements ($p<0.0001$) with regard to satisfaction with breast attributes and appearance were noted in the Breast Evaluation Questionnaire ("BEQ"), a validated instrument that consisted of a series of questions that was administered to augmentation patients (see P940039 and P950004). The BEQ was developed and validated for evaluation of breast satisfaction among augmentation patients in the Mentor Saline-filled Mammary Prosthesis pivotal study. The results indicated significant improvement in satisfaction with shape and firmness of the breasts in intimate/sexual, leisure/social, and professional/job related situations after augmentation surgery. Patients also reported a significant improvement in appearance fully dressed, in a bathing suit, and unclothed after undergoing augmentation mammaplasty.

18/ See, e.g., Beale, S., et al. 1984. Augmentation mammoplasty: the surgical and psychological effects of the operation and prediction of the results. Ann. Plast. Surg. 13.279-97; Goin, J M., and Goin, M.K. 1981. Changing the Body. Psychological Effects of Plastic Surgery. Baltimore, MD: Williams & Wilkins; Sarwer, D., et al 2003. Body image concerns of augmentation patients. Am. Soc. Plast. Surg. 112(1):83-90; Cash, T.F., et al. 2002. Women's psychosocial outcomes of breast augmentation with silicone gel-filled implants: a 2-year prospective study. Plast. Reconstr. Surg. 109(6).2112-23; Kj ller, K., et al. 2003. Characteristics of women with cosmetic breast implants compared with women with other types of cosmetic surgery and population based controls in

Denmark. Ann. Plast. Surg. 50(1):6-12; Schlebusch, L., and Mahrt, I. 1993. Long-term psychological sequelae of augmentation mammoplasty. S. Afr. Med. J. 83:267-71;

19/ See, e.g., Young, V.L., et al. 1994. The efficacy of breast augmentation: breast size increase, patient satisfaction, and psychological effects. Plast. Reconstr. Surg. 94(7):958-69; Park, A.J., et al. 1996. Patient satisfaction following insertion of silicone breast implants. Br. J. Plast. Surg. 49:515-8; Reaby, L.L.; Reaby, L.L. 1998. Reasons why women who have mastectomy decide to have or not to have breast reconstruction. Plast. Reconstr. Surg. 101:1810-8; Cash, T.F., et al. 2002. Women's psychosocial outcomes of breast augmentation with silicone gel-filled implants: a 2-year prospective study. Plast. Reconstr. Surg. 109(6):2112-23; Sarwer, D.B., et al. 2002. An investigation of changes in body image following cosmetic surgery. Plast. Reconstr. Surg. 109(1):363-9; Banbury, J., et al. 2004. Prospective analysis of the outcome of subpectoral breast augmentation: sensory changes, muscle function, and body image. Plast. Reconstr. Surg. 113(2):701-7; Young, V.L., et al. 2004. Initial results from an online breast augmentation survey. Aesthetic Surgery Journal 24(2):117-35.

20/ See, e.g., Kilmann, P.R., et al. 1987. The impact of augmentation mammaplasty, a follow-up study. Plast. Reconstr. Surg. 80(3):374-78; Young, V.L., et al. 1994. The efficacy of breast augmentation: breast size increase, patient satisfaction, and psychological effects. Plast. Reconstr. Surg. 94(7):958-69.

21/ Young, V.L., et al. 2004. Initial results from an online breast augmentation survey. Aesthetic Surgery Journal 24(2):117-35. This "Online Breast Augmentation Survey ("OBAS") was conducted to "collect data from a large-geographically diverse, and anonymous group of women in an attempt to answer questions raised by the U.S. Food and Drug Administration's General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee, the medical literature, and plastic surgeons and their patients." The OBAS consisted of 177 questions, and was posted on www.implantinfo.com for 6 months (August 2001-February 2002). There were a total of 4,011 respondents: 2,273 women who had received breast implants (saline and silicone) and 1,738 who were considering augmentation. The results were analyzed by a third party (Data Harbor).

22/ Cash, T.F., et al. 2002. Women's psychosocial outcomes of breast augmentation with silicone gel-filled implants: a 2-year prospective study. Plast. Reconstr. Surg. 109(6):2112-23.

23/ According to the latest American Society of Plastic Surgeons ("ASPS") statistics, more than 8.7 million cosmetic plastic surgery procedures and more than 1.7 million cosmetic surgical procedures were performed in 2003, which represents a 33% and 5% increase from 2002, respectively. ASPS also reported that breast augmentation was one of the five most popular cosmetic surgical procedures in 2003, with 254,140 breast augmentations performed, which is a 7% increase from 2002, a 20% increase from 2000, and a 657% increase from 1992. American Society of Plastic Surgeons. ASPS. 2004. National Plastic Surgery Statistics. www.plasticsurgery.org.

24/ Cash, T.F., et al. 2002. Women's psychosocial outcomes of breast augmentation with silicone gel-filled implants: A 2-year prospective study. Plast. Reconstr. Surg. 109(6):2112-23.

25/ Young, V.L., et al. 2004. Initial results from an online breast augmentation survey. Aesthetic Surgery Journal 24(2):117-35.

26/ Kaslow, F., and Becker, H. 1992. Breast augmentation: psychological and plastic surgery considerations. Psychotherapy 29:467-73; Anderson, R.C. 1996. Aesthetic surgery and psychosexual issues. Aesthet. Surg. Q. 16:227-9; Anderson, R.C. The Augmentation Mammaplasty Patient. Psychological Issues. In: Surgery of the Breast. LippincottWilliams * Wilkin. In Press.

27/ Goin, J.M., and Goin, M.K. 1981. Changing the Body: Psychological Effects of Plastic Surgery. Baltimore, MD: Williams & Wilkin.

28/ Kaslow, F., and Becker, H. 1992. Breast augmentation: psychological and plastic surgery considerations. Psychotherapy 29:467-73.

29/ Young et al. 2004. Initial results from an online breast augmentation survey. Aesthetic Surgery Journal 24(2):117-35.

30/ See, e.g., Young et al. 2004. Initial results from an online breast augmentation survey. Aesthetic Surgery Journal 24(2):117-35; Cosmetic Surgery News 2004. Breast implants very popular, but patients today seek a more natural result from breast augmentation surgery according to plastic surgeon in Raleigh, North Carolina Sept. 20, 2004.

31/ Young et al. 2004. Initial results from an online breast augmentation survey. Aesthetic Surgery Journal. 24(2):117-35.

32/ Given that the majority of psychological assessments used in the aesthetic surgery literature originated from the evaluation of disease states (see, e.g., Ching, S., et al. 2003. Measuring outcomes in aesthetic surgy: A comprehensive review of the literature. Plast. Reconstr. Surg. 111(1):469-80), they typically do not detect differences post-surgery if psychopathology is absent, as is the case for most aesthetic surgery patients. The significant improvements noted in the augmentation patients using these assessment tools may, therefore, be more clinically meaningful.

33/ Young, V.L., et al. 1994. The efficacy of breast augmentation. breast size increase, patient satisfaction, and psychological effects. Plast. Reconstr. Surg. 94(7):958-69.

34/ Cash, T.F , et al. 2002. Women's psychosocial outcomes of breast augmentation with silicone gel-filled implants. a 2-year prospective study. Plast. Reconstr. Surg. 109(6):2112-23.

35/ Banbury, J., et al. 2004. Prospective analysis of the outcome of subpectoral breast augmentation: sensory changes, muscle function, and body image. Plast. Reconstr. Surg. 113(2):701-7.

36/ Kilmann, P.R., et al. 1987. The impact of augmentation mammaplasty: a follow-up study. Plast. Reconstr. Surg. 80(3):374-78.

37/ Young et al. 2004. Initial results from an online breast augmentation survey. Aesthetic Surgery Journal 24(2):117-35.

38/ See, e.g., Young, V.L., et al. 1994. The efficacy of breast augmentation: breast size increase, patient satisfaction, and psychological effects. Plast. Reconstr. Surg. 94(7):958-69; Cash, T.F., et al. 2002. Women's psychosocial outcomes of breast augmentation with silicone gel-filled implants: A 2-year prospective study. Plast. Reconstr. Surg. 109(6):2112-23; Young, V.L., et al. 2004. Initial results from an online breast augmentation survey. Aesthetic Surgery Journal. 24(2):117-35; Sarwer, D.B., et al. 2000. Cosmetic breast augmentation surgery: a critical overview. J Women's Health Gend. Based Med. 9(8):843-56; Sarwer, D.B., et al. 2002. An investigation of changes in body image following cosmetic surgery. Plast. Reconstr. Surg. 109(1):363-9.

39/ Kilmann, P.R., et al 1987. The impact of augmentation mammaplasty: a follow-up study. Plast. Reconstr. Surg. 80(3):374-78.

40/ Cash, T.F., et al. 2002. Women's psychosocial outcomes of breast augmentation with silicone gel-filled implants: a 2-year prospective study. Plast. Reconstr. Surg. 109(6):2112-23.

41/ Young, V.L., et al. 2004. Initial results from an online breast augmentation survey Aesthetic Surgery Journal 24(2):117-35

42. Examples include: Viagra® (sildenafil citrate); Cialis® (tadalafil); Levitra® (vardenafil); Caverject® (alprostadil); and various prosthetic penile devices for use in men with erectile dysfunction; and devices for use in women with female sexual arousal disorder.

43. Young, V.L., et al. 2004. Initial results from an online breast augmentation survey Aesthetic Surgery Journal 24(2):117-35.

44/ See, e.g., Goin, J.M., and Goin, M.K. 1981. Changing the Body: Psychological Effects of Plastic Surgery. Baltimore, MD: Williams & Wilkin; Young, V.L., et al. 2004. Initial results from an online breast augmentation survey. Aesthetic Surgery Journal 24(2):117-35.

45/ Id.