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# WLF CHARGES FDA IMPROPRIETY IN MAKING NEW RULES FOR SILICONE BREAST IMPLANTS

The Washington Legal Foundation (WLF) this week charged that FDA is violating clearly established rules governing administrative procedure in its handling of premarket applications (PMAs) submitted by two companies seeking permission to market silicone gel-filled breast implants. In written comments filed with FDA's Medical Devices Advisory Committee, WLF stated that the Administrative Procedure Act (APA) prohibits FDA from imposing far stricter approval requirements on silicone breast implants than it has imposed on similar medical devices. WLF Chief Counsel Richard Samp will elaborate on WLF's charges during an oral presentation, scheduled for next Monday, April 11, before the Committee's General and Plastic Surgery Devices Panel.

The panel has been asked by FDA to advise the agency on whether the PMAs of Mentor Corp. and Inamed Corp. should be approved. A previous panel recommended in 2003 that Inamed's PMA be approved, but FDA overruled that recommendation and required further testing. A Draft Guidance issued by FDA in January 2004 indicates that FDA wants Mentor and Inamed to provide long-term data regarding the health consequences of breast implant failure (particularly rupture). Both PMAs include at least three years of post-implant data on the large number of women included in Mentor's and Inamed's studies. But because only a tiny fraction of breast implants rupture within seven years, gathering the breast implant failure information requested by FDA would require at least 10 years of post-implant clinical testing. Thus, if FDA stands by its request for long-term post-implant follow-up data, Mentor and Inamed would not be able to gain approval of their PMAs for many years to come.

WLF stated that the APA prohibits FDA from imposing long-term pre-approval data requirements on the silicone breast implant PMAs, given that FDA has never previously imposed such requirements on similar medical devices. "The courts have made clear that a federal agency must treat similar cases in a similar manner unless it can provide a legitimate reason for failing to do so," said WLF Chief Counsel Richard Samp after filing WLF's comments. "FDA has failed to explain why silicone breast implants present unique safety and efficacy concerns that warrant extending from two to ten years the duration of post-implant testing needed to obtain a PMA," Samp said.

WLF noted that in the vast majority of cases, FDA requires no more than two years of pre-approval long-term clinical follow-up before granting a PMA for an implantable or prosthesis, and FDA has *never* required such testing of a duration that even approaches the number of years it would require Mentor and Inamed to gather the data requested in the Draft Guidance. WLF stated that nothing about silicone breast implants justifies such disparate treatment. WLF noted that numerous other, approved devices contain the silicone elastomers present in silicone breast implants, and that devices with similar risk-benefit profiles (such as inflatable penile prostheses and testicular prostheses) were approved based on two years or less of post-implant clinical data.

WLF argued that the lengthy pre-approval clinical testing contemplated by the Draft Guidance also violates the standards for medical device approval set forth in the Federal Food, Drug, and Cosmetics Act (FDCA). The FDCA mandates that PMAs should be approved once the manufacturer has demonstrated a "reasonable assurance" that its device is both safe and effective. WLF argued that Mentor and Inamed have met that standard by providing three years of post-implant clinical data. WLF charged that the Draft Guidance appears to impose an "absolute assurance" standard, rather than the "reasonable assurance" standard contemplated by the FDCA. WLF noted that the manufacturers have pledged to continue to collect post-implant data from clinical study members for many years to come, even after their PMAs are approved, so the long-term data FDA seeks will be available eventually. If the data were to uncover potential health concerns, FDA could take appropriate action at that time, WLF said.

"We are very concerned that the breast implant PMAs have become entangled in political issues that have nothing to do with safety and effectiveness concerns," said WLF Chief Counsel Richard Samp. "If the manufacturers can meet the safety and effectiveness requirements normally applied by FDA to similar products, then they are entitled to product approval, regardless of the political objections some groups may have to breast implants used solely for cosmetic purposes," Samp said.

WLF is a public interest law and policy group with supporters in all 50 states. WLF regularly litigates in support of the public's right of access to innovative drugs and medical devices shown to be reasonably safe and effective for their intended uses.

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For further information, contact WLF Chief Counsel Richard Samp, 202-588-0302. A copy of WLF's written comments to the Advisory Committee are posted on its web site, www.wlf.org.