News Release

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WLF URGES FDA TO REJECT PUBLIC CITIZEN'S CHALLENGE TO SILICONE BREAST IMPLANTS

The Washington Legal Foundation (WLF) today urged the Food and Drug Administration to deny a Citizen Petition, filed by Public Citizen and others, seeking to block FDA approval of PMAs (marketing applications) for silicone gel-filled breast implants.

In comments filed with FDA, WLF argued that the Citizen Petition is based on a misreading of the Administrative Procedure Act (APA) and the Federal Food, Drug, and Cosmetic Act (FDCA). WLF argued that Mentor Corp. and Inamed Corp., the manufacturers seeking PMAs, have provided adequate assurances that their products are safe and effective and that (contrary Public Citizen's contention) a demonstration of *absolute* safety is neither possible nor required under federal law.

An FDA Advisory Panel heard extensive public testimony in April regarding the PMAs, including testimony from WLF urging approval. FDA issued an "approvable" letter to Mentor in July and an "approvable" letter to Inamed in September. Public Citizen's petition is a last-ditch effort to block final marketing approval for silicone breast implants manufactured by the two companies. Public Citizen has indicated that it may file suit if FDA grants final approval.

Public Citizen argues that granting the PMAs would violate the APA because it would constitute an unexplained, "180-degree departure from [FDA's] long-standing approach to silicone implants." WLF responded that Public Citizen is wrong both on the facts and the law. First, WLF pointed out that FDA's "long-standing approach" has been a general acceptance of silicone breast implants: prior to 1992, they had been widely marketed in this country for *decades* without objection from FDA, and after 1992, they continued to be available to certain patient groups. Second, WLF argued that the APA does not require FDA to explain any alleged "change" in FDA policy, because FDA has never taken any binding agency position regarding the health issues on which Public Citizen relies.

WLF also noted that 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. WLF stated that any effort by FDA to require the ten years of post-implant data demanded by Public Citizen would itself constitute a violation of the APA because 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. "Public Citizen 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 also argued that the FDCA requires that a manufacturer provide only "reasonable assurances" of safety and effectiveness for its product, not the *absolute* safety demanded by Public Citizen. WLF argued that the massive amounts of data supplied by Inamed and Mentor more than satisfy the "reasonable assurances" standard.

"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 response to the Citizen Petition, as well as its written comments to the Advisory Panel, are posted on its web site, www.wlf.org.