



## **MENTOR STATEMENT**

**SANTA BARBARA, Calif. – Jan. 27, 2011** – Mentor’s first priority has and always will be patient safety. We fully support the U.S. Food and Drug Administration’s (FDA) efforts to gather additional data and study ALCL (anaplastic large cell lymphoma) in patients with breast implants.

According to today’s FDA report, there are about “60 ALCL cases worldwide [though] that number is difficult to verify.” FDA also estimates that 5 to 10 million women worldwide have breast implants. Mentor has been monitoring very closely case reports of patients with ALCL, (a rare form of non-Hodgkins lymphoma) since reports first appeared in the medical literature regarding this condition. Mentor has provided and continues to provide information to FDA and other regulatory agencies about the safety of its products.

Mentor concurs with FDA’s position that, “because the risk of ALCL appears very small, FDA believes that the totality of evidence continues to support a reasonable assurance that FDA-approved breast implants are safe and effective when used as labeled.”