

Nation

FDA panel rejects silicone implants

Separate request gets review today

By Rita Rubin
USA TODAY

GAITHERSBURG, Md. — A Food and Drug Administration advisory panel Tuesday voted 5-4 against recommending approval of a manufacturer's request to sell silicone-gel breast implants to any woman who wants them.

Since 1992, when safety concerns led then-FDA commissioner David Kessler to pull silicone-gel breast implants off the market, they have been available only in clinical trials and then only to women who've had a mastectomy, were born with a deformity or needed to replace existing implants. Women wanting larger breasts can only get saline, or saltwater-filled, implants, considered cosmetically inferior.

Panelists who voted against Inamed's application to sell the implants to all comers Tuesday said the company had failed to provide adequate data about the products' long-term safety. "If you come back with five-year data that look as good as this, then unequivocally you've got my yes," said panelist Stephen Li, president of a Sarasota, Fla., company involved in medical device testing. Li had voted in favor of Inamed's application in October 2003, the first time it came before the advisory committee.

At that meeting, the vote was 9-6 in favor of Inamed's application. In January 2004, though, the FDA took the unusual step of going against an advisory committee's recommendation and rejected the application. Then the agency issued a "guidance" laying out



FDA scientist: Sahar Dawisha talks about the rupture of breast implants to an FDA advisory panel Tuesday in Gaithersburg, Md.

Photos by Kevin Wolf, AP



Panel member: Stephen Li questions Inamed executives about silicone-gel breast implants.

what it needs to know about how often silicone-gel implants tear and why. Some research suggests that leaking silicone might cause health problems. Inamed submitted an amended application in August.

At Tuesday's meeting, Inamed presented three-year rupture data from its "core" study of 940 women who received silicone-gel implants for reconstruction after breast cancer, replacement of previous implants or breast augmentation. Because the average yearly rupture rate over three years was 1.4%, the company concluded that the 10-year rate would be 14%.

But FDA scientist Sahar Dawisha said the actual 10-year rupture rate could be much higher if it rose over

time instead of staying constant. "Our approach was to say let's not make any assumptions," she said. "Let's look at the data we have."

After the meeting, Inamed executive Dan Cohen said, "We believe in the data." Cohen said that the company will continue the core study for a total of 10 years as planned.

Today, the advisory committee will consider the first application from Inamed competitor Mentor to market silicone-gel implants. When asked whether Mentor has longer-term data than Inamed, New York City plastic surgeon Scot Glasberg, a company consultant, said, "The length may not be different, but the data are different. Hopefully, the panelists will start fresh in their evaluation."

But Cynthia Pearson of the National Women's Health Network said she was not impressed with what she saw of Mentor's research data posted on the FDA's website. "Mentor's data looked weaker" than Inamed's, she said. Pearson had urged the advisory committee to vote against Inamed's application.

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By Jim Mone, AP

shooting: Red Lake students
ay. Only 90 students attended.

end class as school reopens

stayed away Tuesday as Red Lake
ned for the first time since a teen
en people at the Minnesota school.
300 students attended classes amid
Pat Mills, public safety director for
of Chippewa. Some people feared
ls said. "It's a fear that goes through
Mills said. Principal Chris Dunshee
dents that the school is safe. "There
lots of hugs," he said.
ff Weise, 16, went on a rampage
his grandfather and the man's girl-
g to his school and killing five stu-
d a security guard. He then commit-
said.
16, has been arrested as a possible
ne probe is continuing. FBI spokes-
declined to comment.

t arrested after manhunt

no collaborated with two professors
rison life was captured in Augusta,
of two slayings in South Carolina.
37, was arrested in a shopping cen-
y after a nationwide manhunt was
County police spokesman Andy
investigators had offered a \$10,000

Justices defend court's independence

Supreme Court budget hearing



officers to the court's current
squad of about 130. One new
officer would assess threats
made against the justices.