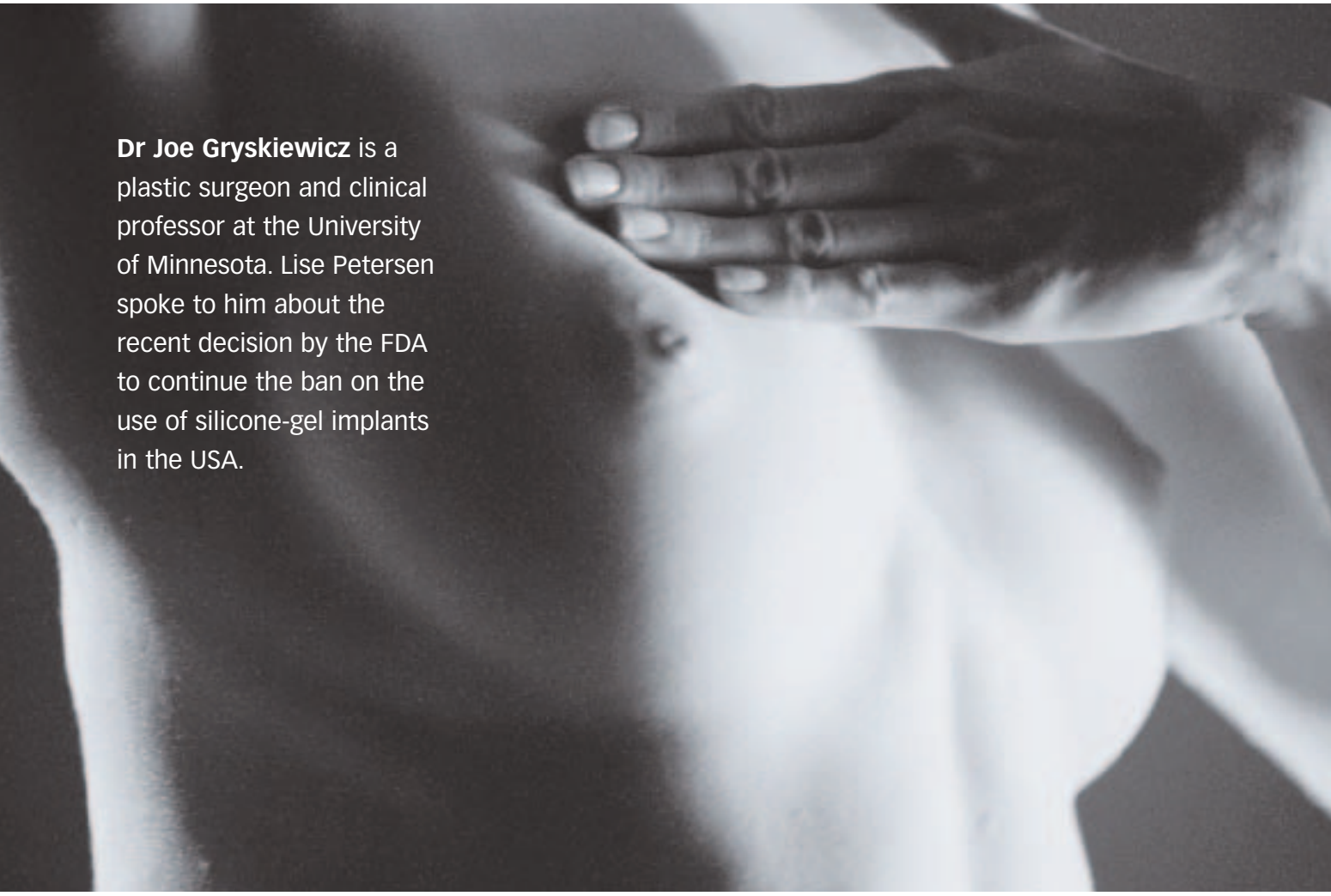
why did the FDA



Dr Joe Gryskiewicz is a plastic surgeon and clinical professor at the University of Minnesota. Lise Petersen spoke to him about the recent decision by the FDA to continue the ban on the use of silicone-gel implants in the USA.

Silicone-gel implants were available for many years. What led to them being banned?

There were reports that the silicone-gel implants might be causing undefined symptom complexes such as connective tissue diseases, joint aches and arthritis in women. These patients were seeking care from rheumatologists or immunologists. In addition, there were problems with silicone-gel implants in that they would rupture or become very firm. The FDA decided it would be politically correct to take the implants off the market. They then requested further long-term studies. Since then these long-term studies have shown there is no difference in large groups.

The problem is that the science involved in this is what we call 'junk science' and the FDA was evidently looking at this politically more than scientifically. For example, they allowed silicone-gel implants to be used on patients who had breast reconstruction after breast cancer. The problem with this is that if you have, let us say, two women who are

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ban silicone?

neighbours – one can have silicone-gel implants because she is having a reconstruction and the other, who wants a breast enlargement for cosmetic purposes, can't have silicone-gel implants. Women who wanted a reconstruction would therefore come into my office and say, 'What does the government think? Because I have had breast cancer I can have silicone-gel implants because I might die anyway?' So, in my opinion, the FDA's decision was unscientific and illogical.

Why didn't the majority of the Western world also ban these devices?

The FDA doesn't exist in the rest of the world – that's all I can say. If you look at the issue scientifically there is no reason whatsoever to ban silicone-gel implants in terms of them causing health problems. There were and there are many problems with silicone-gel implants – mainly from ruptures or firmness – but that is not a scientific reason to ban them.

There have been a number of authoritative studies done in the intervening 10 plus years since the FDA ban. What were the results?

The studies were very conclusive. They confirmed that silicone-gel implants do not cause disease. The best way to answer this question is to quote from an article titled 'Long-term follow-up of women with cosmetic breast implants: How long is long enough?' in the September 1 2004 issue (114.3) of the *Journal of the American Society of Plastic Surgeons*:

'On October 14 to 15, 2003, the General and Plastic Surgery Devices Panel convened by the US Food and Drug Administration met to evaluate the available clinical and epidemiologic data to determine whether there was sufficient assurance of the safety of silicone gel-filled breast implants for them to be considered for market approval. During those meetings, and subsequently in the media, a recurring allegation was that there is a dearth of long-term safety data related to silicone breast implants. Contrary to this contention, there are in fact more than 50 published articles in the peer-reviewed biomedical literature assessing the long-term effects of cosmetic breast implants.

'Concerns about a link between silicone breast implants and various adverse health outcomes were initially raised in the 1980s and early 1990s by anecdotal case reports. However, as unanimously concluded by several independent expert review committees by the late 1990s, these alleged health risks have not been supported by numerous analytic epidemiologic studies of cosmetic breast implant recipients.'

The FDA advisory panel recommended the approval of the devices in 2003. Why didn't the FDA approve this recommendation?

My understanding is that the panel is made up of 15 members who vote and a chairman who doesn't get a vote. The panel voted nine to six to allow silicone-gel breast implants to be put back on the general market for cosmetic purposes. After that vote, the chairman of the committee wrote a scathing two-page letter denouncing the decision of his own committee. I think this put the FDA in a real quandary. It appears they decided to take the safe way out and continue the ban for now.

There were also many patient advocacy groups at the hearings and they were very well organised. They had some sad stories to tell about patients who had silicone-gel implants. So there was some strong emotional evidence presented against silicone-gel implants by these advocacy

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groups. I actually think the groups had some good points to make but, again, I don't think that is a scientific reason for banning a medical device.

However, in terms of scientific evidence, there was some very compelling data that I personally saw that would make me be a little more sympathetic in the decision against the implants. The data that was presented was for saline

why did the FDA ban silicone?

implants. The re-operation rate was 20.6 per cent after three years. So out of every patient who received saline implants for cosmetic purposes or reconstruction 20.6 per cent needed an additional operation. That's a very scary number. Out of this 20.6 per cent, 30 per cent were removed because the patient 'chose' to have the implants removed.

In response to that we assembled a group of plastic surgeons. We have come up with algorithms, or protocols, to treat various postoperative issues with breast implants and try to decrease the re-operation rate from 20 per cent down to five per cent. This committee is called the Breast Augmentation Surgeons For Patients Initiative and we'll be publishing our algorithms in the *Journal of Plastic and Reconstructive Surgery* in the near future. I'm on that committee and an author on the paper.

What factors do you think were pivotal in the recent FDA decision?

Evidently more members on the FDA advisory panel thought silicone-gel implants weren't a problem (nine thought they weren't and six did). The thing that bothers me about the panel's decision to allow silicone-gel implants is that I don't understand why they didn't vote 15 to 0 in either direction – whether pro or con. I can't understand why they couldn't reach a consensus in deciding whether a medical device should either be on or not be on the market.

I think the FDA was responding to the committee's ambivalence and also the letter by the chairman (which was, I believe, totally inappropriate). The chairman of the committee in his letter claimed that plastic surgeons were greedy and that's why they wanted silicone-gel implants on the market. I don't understand this because we charge the same amount for a breast augmentation whether we use silicone or saline. It sounded like he just didn't like plastic surgeons.

'Basically most surgeons prefer silicone-gel implants because they look more natural and feel softer'

However there was quite a bit of data regarding deflation rates on saline breast implants. For the Inamed Corporation the five-year saline implant deflation rate in cosmetic breast augmentation patients was 6.8 per cent and after seven years it was 9.8 per cent. In breast reconstruction patients the five-year rupture rate of saline implants was 7.5 per cent and after seven years was 12.4 per cent.

Now for the Mentor Corporation, for cosmetic breast augmentation the five-year rate was 9.7 per cent and the seven-year rate was 16.4 per cent. For breast reconstruction patients the five-year rate was 18 per cent and the seven-year rate was 26.9 per cent. I can see why the panel may have been divided on the situation because there is a lot of negative scientific data.

We are working diligently to decrease the re-operation rate and the manufacturers are working diligently to decrease the rupture rate with saline implants. So when viewing the current situation, it still doesn't make sense to say some women in America can have silicone-gel implants but others can't. However there is a high re-operation rate whether patients have silicone-gel or saline implants and we as surgeons are working hard to decrease that re-operation rate.

What is your view of the current situation?

If it had been up to me I would have demanded that the manufacturers make safer implants – both silicone-gel and saline – and I would start an education program for all surgeons placing implants to be educated on the alternatives with breast implant problems to try to decrease the re-operation rate. I would also have required surgeons to attend a one- or two-day symposium outlining these issues before they could use the devices. With those conditions I would have allowed silicone implants to be placed back on the market just as the advisory panel recommended.

What now must be done to gain approval?

The FDA has now wrapped up its studies on silicone-gel implants. I have a release from Inamed that says it has submitted its formal response to the January 2004 non-approval letter it received from the FDA concerning its pre-market approval (PMA) application for its silicone-gel filled implants. It says: 'In this supplemental submission additional retrospective and prospective data have been included as requested by the FDA in its letter and in its revised guidance for information to be included in PMAs for breast implants.'

So the committee recommended approval of the PMA but the FDA issues a non-approval letter. Inamed is now working on its next generation of silicone-gel implants, which they say are overwhelmingly the preferred choice of implants for surgeons and patients. They have finished some of their studies on this and will be following patients over the years then resubmitting their results to the FDA.

Basically most surgeons prefer silicone-gel implants because they look more natural and feel softer than saline implants. There is much less of a problem of rippling in patients who are very thin and have a small amount of breast tissue. Personally, I find it is much easier to fine tune the size of one breast versus the other with saline implants. Also, I can place a saline implant through a much smaller incision compared to a silicone implant. **acsm**