

212
BURRELLE'S PI

Women's health concerns prompt condom makers to stop using talc

By Marie McCullough
Knight-Ridder Newspapers
Candace Sue Kasper believes "safe sex" should be as safe for women as for men.

So early this year, the Dallas skin pathologist began urging some would say badgering - condom makers and the federal Food and Drug Administration to stop the little-known practice of coating condoms with talc.

Talc, a powder made from the rocklike mineral magnesium silicate, is an excellent dry lubricant, but can scar soft tissues inside the body, where it does not dissolve. In women, body powders containing talc have been linked to infertility and ovarian cancer.

Kasper's campaign apparently worked.

"We've requested U.S. manufacturers to cease using (talc) and, in fact, all have agreed not to use it in manufacturing condoms," FDA spokesman Arthur Whitmore said in December.

Concern about talc as an ovarian carcinogen goes back 50 years in the medical literature. By the 1970s, evidence was mounting that talc particles might migrate into a woman's fallopian tubes where they could cause scarring and irritation of the ovaries. Scientists believed in some cases that the scarring led to infertility or cancer.

Carter-Wallace, which makes Trojans and claims 60 percent of the American condom market, said in a statement that "to allay any possible concern," it has "discontinued the use of talc in its condom manufacturing process."

'Why take the risk?'

Kasper, 46, feels vindicated, but not victorious. She said an FDA official told her the agency has not been proven to be harmful - because cornstarch is a cheap, safe alternative.

"We'll probably never know for sure" that condom talc is unsafe, he said. "But why take the risk? Cornstarch does just fine and doesn't pose risks. I think it's prudent for manufacturers' to switch."

Indeed it is, said Ansell Inc. of Eatontown, N.J., which makes LifeStyle condoms and has about a quarter of the American condom market. Ansell switched from talc to cornstarch in January 1994.

"We knew surgical glove talc was a problem, so we figured there might be a problem with condoms," said Milt Hinsch, Ansell's vice president of technical affairs. "Whether it's rational or scientific, you just have to say, 'Let's not argue about it. Let's just do it.'"

In 1990, the FDA asked manufacturers to voluntarily stop putting talc on surgical gloves amid mounting scientific evidence that it caused adhesions in surgical patients. At the same time, the agency evaluated talc on condoms, but concluded the amount was insignificant and did not pose problems, said FDA spokeswoman Sharon Snider.

Talc in breast tissue

Kasper's concern about condoms arose after she and a colleague, Dallas plastic surgeon Preston Chandler, discovered talc in the hardened tissue surrounding breast implants that had been removed from women.

In a 1994 journal article, the two physicians speculated that the talc might have contributed to the hardening and that it came from surgical gloves. They also speculated that talc might play a role in the autoimmune symptoms that are the subject of numerous breast-implant lawsuits.

Curious to see whether other products were dusted with talc, Kasper and Chandler bought condoms, pacifiers and baby-bottle nipples in 1994 at Dallas-area stores, then scrutinized them under a microscope. The nipples and pacifiers appeared clean, but all eight brands of American-made and foreign-made condoms had varying amounts of

talc, cornstarch and, in some cases, substances such as sand, silicone dioxide or club moss spores (an outmoded lubricant that also causes scarring in soft tissues).

Kasper and Chandler wrote to the condom manufacturers, several of which responded that they did not use talc in their production process. Carter-Wallace did not respond to them, Kasper said.

Only one manufacturer, Ansell, backed up its claim to be talc-free, Kasper said. She examined Ansell condoms made after January 1994 and found cornstarch, not talc.

She and Chandler also expressed their concern to the FDA, which thanked them for their information - but didn't say it would take any action.

"Largely, we've been ignored," said Kasper, who has a private pathology practice and is a staff physician at Baylor Medical Center. "Fortunately, my livelihood doesn't depend on this. I've done this on my own time and money."

Journal spurred action

What spurred the FDA to act was a letter to the editor from Kasper and Chandler, published in the March 15 Journal of the American Medical Association, warning about talc on condoms. The FDA's office of device evaluation wrote to four American condom makers, enclosing a copy of the JAMA letter.

"Please let us know if you are using talc in your condom manufacturing process," said the FDA's letter - which did not specifically say to stop using it.

The FDA's Snider said the FDA inspects condoms for holes, but not contaminants, so talc compliance is voluntary.

What's to stop condom makers from returning to talc?

"Right at the moment, legally, nothing," Snider said.

Several manufacturers' spokesmen asserted they did not use talc.

David Mayer, president of the company that distributes Japanese-made Sagami condoms, said the product was lubricated with silicone oil.

"But there is no scientific evidence that talc on condoms does any harm," he said.

Carter-Wallace spokesman Steven Curtis would not say what lubricant the company had substituted for talc.

Neither would Leanne Hand, spokeswoman for Lofdon International U.S. Holdings Inc., which distributes Japanese-made condoms including Ramses.

The company "did use talc until about 1989," she said.

