Drug maker urges group to lobby FDA on testosterone for women

Ray Moynihan *Washington, DC*

The major household products manufacturer Procter & Gamble recently sought support from an international medical society, which it sponsors, asking the group to get involved in a regulatory hearing assessing the company's experimental testosterone patch.

No peer reviewed data on the testosterone patch have been published, but it has been granted a fast track review by the US Food and Drug Administration and will be publicly debated by an advisory panel next week. The patch is the first drug to be assessed for a controversial condition called hypoactive sexual desire disorder.

Procter & Gamble wrote to the International Society for the Study of Women's Sexual Health, whose recent conference it sponsored, urging the society to "participate" in next week's meeting by sending someone to testify or writing a letter.

"I think a letter would be appropriate in this case," wrote Procter & Gamble's global programme manager for the patch, Andrea Klemes. "Please note the time sensitivity of this matter as the FDA closes agenda registration on November 17."

Key office holders of the medical society have financial ties to Procter & Gamble, and the company was a "gold level" sponsor of the society's recent annual conference in Atlanta, where the patch was enthusiastically endorsed in some presentations.

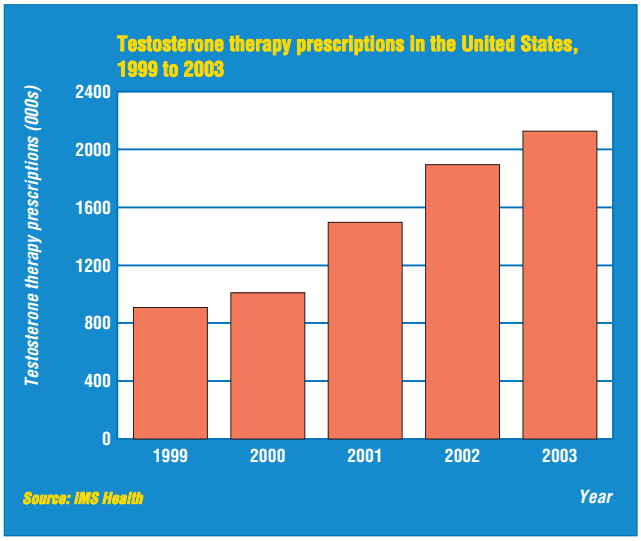
Seen by some in the field as standard marketing practice, the company's approach was seen by others as an attempt to seek product endorsement. Procter & Gamble, whose market worth is $138bn (£74bn; €106bn), declined requests for an interview.

Procter & Gamble has initiated a worldwide public relations campaign to promote awareness of the testosterone patch, while seeking approval for its use among surgically menopausal women (see Review section, p 1294).

Company press releases, prepared with the media advisers Hill & Knowlton, have claimed that the patch can increase sexual activity by 74% and have generated enthusiastic media coverage. But the marketing has caused concern among some sex researchers by failing to state that in absolute terms the patch may increase sexual activity by only one "episode," or less, per month.

"I doubt whether this is really a big difference," says University of Amsterdam associate professor Ellen Laan, a specialist in women's sexual problems.

"If that one episode saves a relationship that can be worthwhile," argues University of Melbourne professor Lorraine Dennerstein, a paid adviser to Procter & Gamble, "and there is tremendous resistance to change, inherent in behaviour."



More than two million men in the United States take testoterone. Now Procter & Gamble want to market it to women

Leonore Tiefer, a clinical associate professor at New York University, agrees that an increase of one sexual episode a month may be of value clinically to some women but says that this is overshadowed by serious doubts about the long term safety of testosterone. "To me it's an insufficient increase to outweigh the negatives: the dangers, the harms, the uncertainties."

One of the leading authorities in the field of women's sexual difficulties, the University of British Columbia's professor of obstetrics and gynaecology, Rosemary Basson, says much caution is needed in prescribing testosterone to women, because of uncertainty about how to measure testoterone activity in women.

Also, doubt continues as to when common sexual difficulties should be categorised as medical disorders or dysfunctions. Procter & Gamble claims that the women in their trials had hypoactive sexual desire disorder. Yet a recent journal article published by Professor Basson, Professor Laan, and colleagues raised serious questions about the disorder and described it as "problematic," because with age and length of relationships a lowering of sexual desire is widespread and normal (*Journal of Sexual Medicine* 2004;1:40-8). □

Public interest group accuses FDA of trying to discredit whistleblower

Jeanne Lenzer *New York*

A public interest group that aims to protect whistleblowers claimed last week that an attempt had been made by a member of staff at the Food and Drug Administration to discredit Dr David Graham, the FDA executive who testified to the US Senate committee on 18 November.

Dr Graham, associate director in the FDA's Office of Drug Safety, had carried out a study with Kaiser Permanente of northern California that looked at the cardiovascular risks in patients taking rofecoxib (Vioxx). He had submitted the results of the study to the *Lancet*. Dr Graham withdrew the study, however, after getting a warning from his supervisor.

The FDA issued a statement after the Senate hearing last week, claiming that Dr Graham had failed to adhere to agency protocol when he submitted his data to the *Lancet*.

When the *BMJ* inquired about the FDA's statement and the possible publication of the rofecoxib study in the *Lancet*, Dr Graham referred the *BMJ* to his attorney, Tom Devine, for comment.

Mr Devine, legal director of the Government Accountability Project—a public interest group based in Washington, DC, that helps whistleblowers in order to promote governmental and corporate accountability—said Dr Graham, fearing for his job, had sought the group's help in connection with the rofecoxib study about a month ago.

The group's decision on whether to provide legal counsel for Dr Graham was delayed after it received another request for aid from someone claiming to be an anonymous whistleblower at the FDA who was being "bullied" by Dr Graham. The anonymous caller also said that Dr Graham's study could reflect scientific misconduct.

After some investigation the project found out that the "anonymous" charges actually came from FDA management, which, according to Mr Devine, had "full control" over Dr Graham.

"We made demands to call whichever side was bluffing," said Mr Devine. "The FDA flunked every test of credibility, while Dr Graham passed all of them. The FDA was employing a classic law of whistleblower reprisal—the smokescreen syndrome—which shifts the spotlight from the message to the messenger.

"The agency attempted to discredit Dr Graham rather than provide any scientific evidence contradicting his conclusions." □