

## FDA panel rejects testosterone patch for women on safety grounds

Ray Moynihan *Washington, DC*

A panel of advisers to the US Food and Drug Administration last week unanimously rejected an experimental testosterone patch as a treatment for women with sexual difficulties.

Procter & Gamble, global manufacturer of household products, wants to market the patch to women who have become menopausal after ovarian surgery, are currently taking oestrogen, and are said to have a controversial condition—"hypoactive sexual desire disorder."

The FDA had granted Procter & Gamble a fast track review of the testosterone patch, but the committee's unanimous rejection

makes approval by the FDA unlikely until more data on the drug are available.

At a meeting last Thursday, near Washington, DC, panel members strongly criticised the company funded clinical trials as "inadequate" to assess issues of long term safety. Panel members also raised serious concerns about the risks of cardiovascular disease and breast cancer associated with a drug that appeared to offer women, on average, little more than one extra episode of sexual activity a month, compared with placebo.

Panel member Steve Nissen from the Cleveland Clinic said that the testosterone patch's

potential to increase cardiovascular risk was substantial: "I don't want to expose several million American women to the risk of myocardial infarction and stroke, with their devastating consequences, in order that they can have one more sexual episode a month," he said.

None of the data from Procter & Gamble's 24 week randomised controlled trials of the patch have been published yet in peer reviewed journals. Abstracts presented at conferences have claimed repeatedly that the drug is safe and effective and has side effects similar to those of placebo. Yet data presented at last week's FDA meeting showed that women using testosterone were more likely to experience hair growth, acne, and weight gain.

During the course of the highly charged day long meeting,

FDA advisers repeatedly questioned Procter & Gamble's officials and the company's paid academic consultants about the clinical meaningfulness of the drug's small benefits, the lack of long term data, and the scientific uncertainties that surround the link between testosterone concentrations and sexual difficulties.

In a 14 to three vote, most of the FDA advisory committee agreed that, although the benefits of the patch appeared to be small, they could be described as "clinically meaningful." But the committee then voted unanimously to recommend against approving the drug because of the lack of data about its long term safety.

Acknowledging its disappointment, Procter & Gamble says it will work with the FDA and try to provide additional safety data. □

## Can medical students learn empathy at the movies?

Roger Dobson *Abergavenny*

Doctors are often portrayed in films as materialistic and arrogant, but some films could be a useful addition to the medical school curriculum, an analysis of 150 films shows.

The report, in *Archives of Disease in Childhood* (2004;89:1084-8), says, "Materialism and a love of money have pervaded

cinematic portrayals of doctors dating back to the 1920s, and continue to be prominent in recent movies."

It cites as an example the materialistic approach to medicine shown by Dr Jim Nooke, a character in *Carry on Again Doctor* (1969). The character sums up his philosophy by saying, "Specialise, that's what I'd like to do—specialise. The whole Harley Street bit with bags of lovely filthy rich women patients."

Compiled by Glenn Flores, a paediatrician at the Medical College of Wisconsin, the report looks at how doctors are portrayed and names the top 10 most useful films for medical

### Best portrayal of doctors in films

- 1 *Red Beard* (1965)
- 2 *The Hospital* (1971)
- 3 *Article 99* (1991)
- 4 *State of Emergency* (1993)
- 5 *Miss Evers' Boys* (1997)
- 6 *The Elephant Man* (1980)
- 7 *Panic in the Streets* (1950)
- 8 *Spellbound* (1945)
- 9 *Death and the Maiden* (1994)
- 10 *Guess Who's Coming to Dinner* (1967)

### Most useful films for medical education

- 1 *The Doctor* (1991)
- 2 *Arrowsmith* (1932)
- 3 *The Citadel* (1938)
- 4 *Not as a Stranger* (1955)
- 5 *Pressure Point* (1962)
- 6 *Whose Life is it Anyway?* (1981)
- 7 *Miss Evers' Boys* (1997)
- 8 *The Interns* (1962)
- 9 *Critical Care* (1997)
- 10 *And the Band Played On* (1993)

education. The medical specialties most favoured by doctors in films are surgery (33%), psychiatry (26%), and family or general practice (18%).

Paediatrics accounts for a modest 2%, and not all references to it are positive: "Paediatrics can't just dump their overload on us. Tell them to cut down on their lunchtime and tennis. Maybe they'll have more time to practise medicine" (*Sunchaser*, 1996).

The report names the best medical film as *Red Beard* (1965), from Japan, in which an arrogant young man learns the true meaning of being a doctor from a mentor who cares for the poor. Runner-up was *The Hospital* (1971).

The top 10 most useful films for medical education are headed by *The Doctor* (1991), which stars William Hurt as a "hotshot

surgeon with a detached demeanour" who learns about empathy and compassion when he contracts cancer.

In second place was *Arrowsmith* (1932), which "definitely explores a doctor's motivations and struggles with a clinical versus research career and is thus inspirational and enlightening for medical students." In third place was *The Citadel* (1938). Best humorous films were *M\*A\*S\*H* (1970), *Body Parts* (1991), and *High Anxiety* (1977).

"Doctor movies continue to fascinate because they can be humorous, thought provoking, informative of the public's perception of doctors, and they never cease to entertain. Movie doctors provide insightful and realistic portraits of the challenges, rewards, and excitement of being a doctor," concludes the report. □



Surgeon William Hurt learns empathy when he becomes a patient in *The Doctor*, a film that could be useful for teaching medical students