



Premature Ejaculation: Marketing the Condition Before the Drug

By **Jonathan D. Rockoff**

Folks from Sciele Pharma stopped by Health Blog HQ recently to talk about the company's potential treatment for premature ejaculation. They were making the rounds at newspapers and magazines in an effort to raise awareness of the condition and their product, even though the company hasn't asked regulators for approval yet.

The visit was a reminder about how drug makers can try to lay the groundwork for sales well before a new therapy hits the market. That is especially true when the product will be aimed at treating a condition that carries a stigma. Hence, the effort for Sciele's treatment, a spray that goes by the moniker PSD502 for the time being.

Sciele, which is a unit of Japanese pharma Shionogi, has been pursuing two tracks to raise awareness. For months, it has sought to educate physicians about premature ejaculation, making presentations at medical meetings. Last month, after [Phase 3 studies](#) finished, the company launched a [Web site for bloggers](#) with information about the condition and scientific milestones in their product's development.

While the Web site is intended for blogger types, anyone searching for [information about premature ejaculation](#) can find the material. Once Sciele asks the FDA to approve the product — it expects to file by the end of March — the company plans on launching a Web site dedicated to explaining the condition. "It's not well recognized. It's not well understood. We know we have to spend a tremendous amount of time and effort," said Donna Gibson Dell, a Sciele official.

All this effort begs the question whether Sciele is acting prematurely. Analysts say the FDA has taken a tougher line on so-called lifestyle drugs. In 2005, [the FDA rejected](#) Johnson & Johnson's request for approval of a premature ejaculation drug called dapoxetine.

Sciele officials expressed optimism about the prospects for PSD502, while allowing that they can't predict what the FDA will do. The experimental treatment combines two local anesthetics, lidocaine and prilocaine. Sciele officials emphasized that it has an entirely different mechanism of action than dapoxetine, which was made from the ingredient in an antidepressant that attracted regulatory scrutiny.

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