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Drug makers have a treatment. But is it a disorder?

The creators of medicines such as Viagra and Priligy, which is aimed at premature ejaculators, are keen to turn quality-of-life issues into medical problems for which they hold the solutions

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Tablets of Pfizer's erectile dysfunction drug Viagra. PHOTO: BLOOMBERG

Viagra and its pitchman, Bob Dole, turned erectile dysfunction into a modern man's malady.

Out went impotence, an unfashionable condition that nobody wanted to discuss with his doctor or lover, and in came ED, an in-the-know abbreviation for erectile dysfunction that neatly dovetailed with other pop-cultural acronyms like OMG and LOL.

Now brace yourselves for PE — shorthand for premature ejaculation.

Johnson & Johnson has developed Priligy, a pill aimed at men who ejaculate before copulating or within seconds of beginning. Priligy, which is intended to help prolong latency time before orgasm, went on sale earlier this year in nine countries, but it has not been approved for sale in the US by the Food and Drug Administration.

Meanwhile, Sciele Pharma, based in Atlanta, plans to seek approval from the agency next year to market a prescription drug in the form of a metered-dose aerosol sprayed on the skin that is intended to increase latency time. Company representatives have been making the rounds of medical conferences and meeting journalists, trying to drum up sympathy and attention for premature ejaculation as a widespread medical problem in need of a drug intervention.

"PE is more prevalent than ED," Joseph Schepers, the company's director of investor relations and corporate communications, told me when his team came to the office this week as part of a press tour in Manhattan. "One in three men actually have the condition."

Donna Gibson Dell, Sciele's senior product manager for the drug, concurred: "It's a huge unmet need."

Pharmaceutical companies dream of developing the next Viagra, a product that had worldwide sales last year of about US\$1.93 billion.

"Viagra, and I think ED along with it, have become part of the cultural fabric," said Jim Maffezzoli, a senior director in marketing at Pfizer, which introduced the drug in 1998. "The brand, everybody knows it."

Maffezzoli credited Viagra's success to its status as the first prescription pill approved to treat a man's inability to develop or maintain an erection.

But creating a blockbuster quality-of-life drug like Viagra involves more than just being innovative or being first.

Sometimes it requires a drug maker to create and market a whole new category of disease.

The template goes something like this: Start with a legitimate quality-of-life issue — like fitful sleep or shyness — that does not yet have its own prescription medication and is debilitating to a few people a lot of the time.

Next, position the quality-of-life issue as a medical condition with symptoms so common it covers vast numbers of people who had previously not identified themselves as having a health problem, or who thought they were just experiencing an occasional and normal annoyance.

Articles in medical journals with high estimates on the prevalence of the issue help convince doctors and journalists of its scope. FDA approval of the new drug legitimizes the condition as a problem with a medical solution.

The uncertainty for drug makers as this kind of script plays

out is whether doctors and the public will buy into a hitherto unrecognized disease, said Alan Cassels, a pharmaceutical policy researcher at the University of Victoria in British Columbia.

"Marketers know you don't sell the steak, you sell the sizzle," said Cassels, the co-author of *Selling Sickness: How the World's Biggest Pharmaceutical Companies Are Turning Us All Into Patients*.

With premature ejaculation drugs, he said, "It will come down to convincing physicians that this is a serious disease and convincing most men that, if they have unsatisfactory intercourse and they don't last up to a minute, they have a medical problem."

Premature ejaculation can be extremely distressing for men, said Wayne Hellstrom, a professor of urology at the Tulane University School of Medicine in New Orleans.

"They don't usually last in their relationships," said Hellstrom, who has consulted for Johnson & Johnson.

The International Society for Sexual Medicine, a professional association, has developed a definition for premature ejaculation. It is a condition "characterized by ejaculation which always or nearly always occurs prior to or within about one minute of vaginal penetration," and which is accompanied by feelings of distress and lack of control.

Sciele's spray-on drug contains lidocaine and prilocaine, which act on sensory nerve endings in the penis, said Mike Wiley, director of urology for Sciele.

The company studied the product on several hundred men who had a typical ejaculation time of about 36 seconds, Wiley said. After using the product, the typical time from penetration to ejaculation was about 2.6 minutes — about a two-minute increase.

While there is no doubt that some men are distressed about their inability to control their orgasms, there is little concrete evidence to suggest that there is an epidemic of premature ejaculation.

In response to a query from this reporter, a public relations representative for Sciele sent material to back up the claim that one in three American men suffer from this affliction. One study, a 1999 report on sexual dysfunction in the US, has been disputed by some sexologists because it was based on a sociology survey from 1992 that included questions about issues like fidelity — but was not created by epidemiologists to answer sexual health questions. Hellstrom at Tulane said perhaps 20 to 30 percent of men experience premature ejaculation at some point in their lifetimes.

But Leonore Tiefer, a clinical associate professor in the psychiatry department at the New York University School of Medicine, said drug makers were increasingly trying to medicalize parts of daily life — whether it be mood, sleep or sexual function — in which there is a healthy and wide variation of normal.

"Rapid ejaculation as opposed to slow ejaculation is common, but there is slow and fast everything in the world: slow and fast walkers, slow and fast eaters, slow and fast breathers," said Tiefer, a psychologist specializing in sexual problems. "When you tell someone they are a fast ejaculator, it makes it sound like there is a right time to ejaculate and, if you ejaculate before, it's a medical problem."

She added: "It is going to become a problem once enough publicity is given to it."