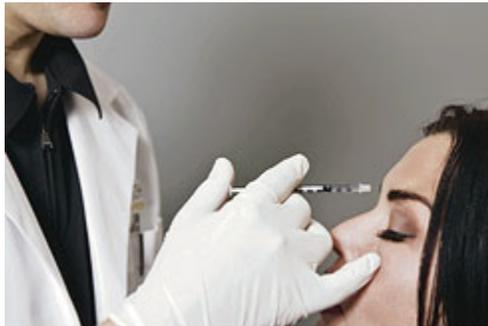


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## Botox Faces Worry Lines In Smooth Skin Game

By RHONDA L. RUNDLE  
December 6, 2007; Page B1

Botox, which hit \$1 billion in world-wide sales last year, is the only drug of its kind that the Food and Drug Administration has approved as an antiwrinkle therapy. But Botox maker **Allergan Inc.**'s U.S. monopoly could end late next year, putting pressure on the California company to defend its franchise.



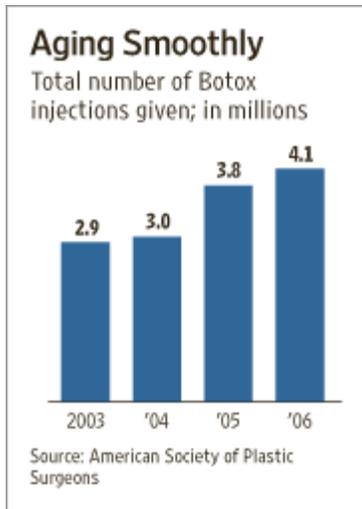
Dermatologist prepares to inject patient with Botox.

**Medicis Pharmaceutical Corp.** of Scottsdale, Ariz., is set to announce that it has submitted an application to the FDA for approval to sell a rival botulinum toxin, Reloxin, for cosmetic use. Barring a snag in the regulatory process, Reloxin could start showing up in dermatologists' offices a year from now.

Botox shots are the most-frequently performed cosmetic procedure in the U.S., with four million injections in 2006, up 6.5% from a year before, according to the American Society of Plastic Surgeons. Last year Botox accounted for nearly a third of Allergan's revenue, split almost evenly between cosmetic and medical uses.

While Botox and Reloxin aren't identical, many physicians who have tested them say the similarities far outweigh the small differences. Competition will be waged largely on price, consumer marketing and professional loyalties that tie companies to their doctor customers. Currently, Allergan and Medicis compete in the arena for so-called injectable dermal fillers that treat wrinkles using a different mechanism than drugs. Medicis sells the market leader, Restylane, while Allergan came on strong this year with Juvéderm, which was introduced with a splashy campaign in January.

Physicians and patients are hoping that Reloxin will be cheaper than Botox, whose price has risen steadily. "Many dermatologists and cosmetic surgeons are excited about the possibilities for a lower-priced form of botulinum toxin," says Joel Schlessinger, an Omaha, Neb., dermatologist who participated in the Reloxin tests submitted to the FDA. Patients typically pay at least \$500 for Botox injections, which



wear off after four months or so.

At a cosmetic dermatology meeting in Las Vegas on Saturday, Dr. Schlessinger discussed his Reloxin trial of 300 patients who were randomly assigned to receive either the drug or a placebo. The most common side effect was headaches, which occurred in about 11% of the Reloxin patients and 9% of the placebo group, a finding that Dr. Schlessinger called insignificant. The average duration of Reloxin's antiwrinkle effect was 117 days, about the same as Botox, he said. Several patients who first used Botox and then had Reloxin thought the new drug might have "a little quicker time for onset," he added.

However, the test wasn't designed to compare the two drugs, so such impressions aren't reliable indicators of how the drugs would perform head to head. Allergan points to Botox's dominance in Europe, where other botulinum toxins are sold, as evidence of its strength. The Irvine, Calif., company claims an 85% cosmetic share in five European markets where Reloxin is sold by Paris-based Ipsen under the brand name Dysport.

Ipsen disputes Allergan's figures and says that Europe isn't a level playing field because Ipsen doesn't have regulatory authorization there to promote Dysport as a cosmetic treatment. Dysport was originally launched in the U.K. in 1991 and is marketed for various motor disorders and forms of muscular spasticity. A week ago, Ipsen filed an FDA petition to sell Dysport in the U.S. for cervical dystonia, a chronic condition in which the neck is twisted or deviated. Cosmetic marketing rights in the U.S. were acquired by Medicis from Ipsen two years ago.

Nick Lowe, a dermatologist at the Cranley Clinic in London, says that both Botox and Dysport are effective, but Botox accounted for about 90% of the cosmetic treatments delivered by his clinic over the past two years. Dr. Lowe says that Botox doesn't spread under the skin as readily as Dysport so it's easier for physicians to control. Dysport's diffusion characteristics can be an advantage in some patients, such as men with heavy forehead muscles, he adds. Dr. Lowe says he is "pro-Botox" but has consulted for Allergan and Medicis.

Securities analysts look to the ongoing U.S. battle between Medicis's Restylane and Allergan's Juvéderm for clues to what might happen once there's an alternative to Botox. They estimate that Juvéderm has grabbed as much as 35% of the filler market despite the strong reputation of Restylane. Juvéderm sales were helped by an early physician giveaway program and some modest volume discounting, they say. More importantly, however, Allergan's consumer advertising has spurred expansion of the overall filler market, benefiting both companies.

"Botox is more of a household name than Restylane, but why wouldn't the same thing happen" once there is competition for Botox, says David Steinberg, an analyst at Deutsche Bank AG. "We're in the middle of a vanity boom so all of the companies involved should win." Patients waiting for sharp price cuts could be disappointed, he adds. The market will become a duopoly, and it will be five to 10 years before there are a lot of competitors.

Still, the arrival of Reloxin could slow -- or even end -- Allergan's annual Botox price increases, says Peter Bye, an analyst at Jefferies & Co. This would help to appease dermatologists and plastic surgeons who have complained vehemently about Allergan's Botox pricing. Allergan is viewed as "historically arrogant" by some of these high-volume users, who are thought to be ready to "stick it to Allergan" once there's an alternative available, Mr. Bye says. Reloxin could take 20% of the botulinum toxin market in the U.S. in the second year after its launch, the analyst calculates.

Of course, the timing of the FDA's approval for Reloxin is uncertain. Medicis says it submitted data for 3,250 patients treated at 83 sites and expects an FDA response within 10 months. But approval could be delayed if the agency requests additional data. Analysts say that agency officials may be reassured by the drug's track record in scores of other countries.

At least two other injectable botulinum toxins are in the pipeline a year or more behind Reloxin. Germany's Merz Group is developing its NT-201 drug for cosmetic use, and PurTox is in pivotal human tests sponsored by breast-implant maker **Mentor Corp.** of Santa Barbara, Calif. Further down the road is a topical form of botulinum toxin that is being developed by Revance Therapeutics Inc, a small venture in Mountain View, Calif.

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