

"All the News
That's Fit to Print"

The New York Times

Late Edition

New York: Today, cloudy with a period of rain, high 43. Tonight, clear and breezy, low 34. Tomorrow, all sunshine, high 48. Yesterday, high low 30. Weather map is on Page 7

VOL. CLI . . No. 52,022

Copyright © 2002 The New York Times

NEW YORK, THURSDAY, FEBRUARY 7, 2002

\$1 beyond the greater New York metropolitan area.

75 CENTS

In Quest for Wrinkle-Free Future, Frown Becomes Thing of the Past

By ALEX KUCZYNSKI

It is a staple for affluent professionals, television talking heads, ladies who lunch and actors who refuse to age. Without a peep of promotion, it has become the most popular cosmetic medical procedure in the country, despite the fact that it involves injecting the neurotoxin that causes botulism directly into muscles in the face, paralyzing them and thus erasing wrinkles.

Now, the injectable drug known as Botox, in use since 1991, is on the verge of achieving what it never has before: approval by the Food and Drug Administration for cosmetic use, which could allow it to burst into the mainstream.

The toxin is already approved for treating spastic disorders of the eye muscles, but the F.D.A. approval for its use as a cosmetic would allow the manufacturer, Allergan Inc. of Irvine, Calif., to promote Botox — the commercial name for botulinum toxin A — with a multimillion-dollar blitz of television commercials and print advertising that could rival that of other drugs like Viagra or Claritin, analysts said. They predicted that Botox use could grow from the 1.1 million Americans who tried it in 2000 by 30 percent or even 50 percent in the next year.

According to an F.D.A. official, the agency plans to approve Botox for cosmetic use. After reviewing two clinical trials Allergan submitted to the F.D.A. last year, a spokeswoman for Allergan said that the company expected the agency's approval next



Photographs by Dr. Debra Jallman

month at the very latest.

Botox has already worked its numbing magic on the face of America. Hollywood directors like Martin Scorsese and Baz Luhrmann have complained that Botox is so popular among actors that it is playing havoc with facial expression. In a variation on "The Stepford Wives," it is now rare in certain social enclaves to see a woman over the age of 35 with the ability to look angry.

And as the wrinkle-smoother rides a wave of popularity with aging boomers, a Botox Nation of citizens with unnaturally placid expressions may find itself abandoning some old beliefs. The wisdom that a person's

Continued on Page A26

FOR HOME DELIVERY CALL 1-800-NYTIMES



0 354613 9 06402

F.D.A. Plans to Approve a Drug Long Endorsed by the Vainers Set

Continued From Page A1

character can be etched on his face, or Coco Chanel's observation that at 20 you have the face nature gave you, and at 50 you have the face you merit, may no longer apply.

"We will look at wrinkles the way we look at cracked or discolored teeth — remnants of the past, just something to be fixed," said Dr. Nancy Etcoff, a psychologist at the Harvard Medical School and the author of "Survival of the Prettiest: The Science of Beauty" (Doubleday). "You still see young women smoking and sitting in the sun, and they can just get rid of the wrinkles.

"It's very much about having your cake and eating it too," Dr. Etcoff said. "It is as though we have given up on authenticity."

Last week, Greta Van Susteren, an anchor for the Fox News Channel, caused headlines after unveiling the effects of surgery to remove bags under her eyes. But Ms. Van Susteren said eye tucks were not the reason viewers expected a 47-year-old woman like herself to have the countenance of a 25-year-old: Botox was.

"I can't get through the day without someone mentioning it to me," she said. "I'm not going to out anyone, but every person on television has had it done."

Despite the fact that the television industry depends on Botox as much as it does on pancake makeup and forgiving lighting, Ms. Van Susteren said she had not yet tried it. "But I am not closing the door on the possibility," she said.

In a Botox treatment, a doctor injects a diluted form of the drug into a patient's facial muscles. Over the next four days, the toxin paralyzes the muscles that control facial wrinkling, not only stopping more wrinkles, but eradicating existing ones. The skin does not feel numb to the patient, nor does it change in texture.

Nor is there a risk of becoming infected with botulism — which causes respiratory failure in advanced cases — from Botox because the treatment is in so diluted a form.

Still, there are complications. For example, patients are advised not to lie down or lean over or even tie their shoes for six hours after treatment, lest the toxin seep and inadvertently paralyze other muscles.

And while a treatment lasts for three to four months, patients must get more injections, which can cost from \$300 to more than \$1,000, to maintain the effect.

Though Botox has not yet been approved for cosmetic applications, its use for such purposes has grown since 1991, when the F.D.A. approved it as a treatment for eye muscle spasms. Soon after, doctors noticed reduced wrinkles in the treatment areas. Dermatologists and plastic surgeons caught on, using it on the forehead, around the eyes, even the neck. And revenues leaped: from \$19.5 million in 1992 to \$310



While Botox differs from other popular prescription drugs in its requirement that a doctor administer injections, some analysts compared the treatment's market potential to Viagra and predicted that it would be the next blockbuster drug.

"America is aging," said Gregg Gilbert, an analyst at Merrill Lynch & Company. "There is an openness about these procedures now. And it's going to be fun for the media, who get to pick on how vain everybody is."

With F.D.A. approval, Mr. Gilbert predicted that within two years Botox revenues would quadruple from those reported for 2001.

Other analysts had more modest

Injections of Botox, a drug originally approved for eye muscle spasms, have been used to paralyze facial muscles that cause wrinkles. The treatment is expected to win F.D.A. approval shortly for cosmetic use.

Making worry lines disappear by paralyzing muscles.

expectations. Thomas DesChamps of Mehta Partners said Allergan could double its revenue in four years, putting Botox close to a billion-dollar earner by 2006, a milestone reached only by blockbuster drugs like Viagra, Prilosec and Vioxx.

Botox injections made up 19.1 percent of all cosmetic procedures practiced by surgeons in the United States in 2000, compared with 3.5 percent for breast augmentations, according to the American Society for Aesthetic and Plastic Surgeons.

The popularity of Botox reflects the growing national mania for cosmetic surgery and the array of related procedures that try to slow time's winged chariot. Plastic surgical procedures are on a sharp rise, up 173 percent from 1997 to 2000, according to the society, at a cost of approximately \$7.4 billion to consumers.

The available assortment of prescribed treatments used by doctors to fill or plump wrinkles and pits alone is dizzying: Alloderm, Autologous, Cymetra, Dermoplast, Fascian,

Goretex, Isolagen, Plasmagel, Softform Zyderm, Zyplast.

Dr. Arnold Klein, a dermatologist in Beverly Hills, Calif., who counts numerous Hollywood actors and actresses among his patients, said: "You hear horror stories about doctors and nurses who fly into Miami and check into hotel rooms, so that patients can see them for injections of an untested form of silicone."

Silicone is recognized as a wrinkle remover, but because it is permanent, it can harden into golf-ball sized nodules after a few years and "literally slip off the cheeks, down into the jawline," said Dr. Peter Kopelson, another Beverly Hills dermatologist. Such nodules require extensive surgery for removal.

Dr. Malcolm Paul, president of the American Society for Aesthetic and Plastic Surgery, said he expected a steep uptick in the use of Botox after the treatment wins F.D.A. approval.

"You're not going to see the 1,600 percent increases we saw from 1997 to 2000, but I expect that it will grow by 30 or 40 percent for a while," Dr. Paul said. "Once consumers see broadcast ads, as they do now for drugs like Ambien, for example, it ought to happen pretty quickly."

Tim Chiang, an analyst at Banc of America Securities in New York, said it would not be unreasonable for Allergan to spend \$140 million to \$230 million in marketing the drug the first year.

By comparison, AstraZeneca, the

manufacturers of Prilosec, a prescription drug for ulcers, spent \$100 million marketing that drug in 2000, the same year it became the best-selling medication in the country.

Allergan executives would not comment on how much they planned to spend on marketing, but doctors and surgeons said company sales representatives had said the amount would be at least \$100 million the first year.

Christine Cassiano, a spokeswoman for Allergan, said that Allergan's regulatory group is in contact with the F.D.A., discussing the approval and even issues like the packaging of the cosmetic Botox. Advertisements are planned for broadcast, print and even on buses; the F.D.A., company executives said, was requesting that those advertisements not feature any models younger than 40.

Vanity has its price. Because Botox paralyzes muscles that create wrinkles, doctors said it should not be applied on muscles that move as a part of everyday facial expression. Otherwise, they said, it could cause a person's face to look immobilized, and render it waxy-looking.

The line between increased youth and facial emotive power, however, is not always clear. Mr. Luhrmann, the director of "Moulin Rouge," said last week that many actresses abuse Botox. "Their faces can't really move properly," he said, assuming a blank stare meant to mimic overuse.

Ms. Cassiano said that the compa-

ny expected the drug to be approved for use in treating "brow furrow" — the double indentation between the eyebrows caused by the constricting labellar muscles. "In its proper use, it will not cause a frozen facial expression," she said.

But Dr. Debra Jaliman, a plastic surgeon in New York, said that in the hands of an unskilled doctor, Botox — which requires multiple pinprick injections with each treatment — could produce unsightly results.

"Sometimes, one eyebrow is up here and the other is down here," Dr. Jaliman said.

"We had one patient who told us that she had to spend three weeks in the hospital on an IV because the doctor who injected her put the needle too deeply into her neck and she lost the ability to swallow," she said. "We had a soap opera actress who lost the ability to speak properly and had to go into hiding for three months."

There is also the potential for what some doctors call the Dorian Gray effect. Because Botox wears off more injections are required to maintain its effects or the patient's face will return to its wrinkly state.

"You could marry a woman with a flawlessly even face," one doctor said, "and wind up with someone who four months later looked like a Shar-Pei."

Despite the aesthetic risks, Mr. Gilbert of Merrill Lynch said that doctors would clamor for the drug, because it was both time-efficient and produced reliable income.

"You buy a vial for \$400, and that generates revenue of up to \$1,000," he said. "You can do a patient in 10 minutes, and you can run people in all day long. There is probably not another treatment that is so profitable for doctors."

Botox already has competition from Elan Pharmaceuticals, which is also marketing a form of the toxin, Myobloc, botulinum toxin b. Myobloc has one distinct advantage over Botox: it works within hours, whereas Botox usually takes several days to take full effect.

But several doctors said that Myobloc shots and its effects — at the current dosages — did not last as long as those of Botox.

Dr. Michelle Copeland, a plastic surgeon in New York, said Botox use was already so prevalent among her patients that she has to ask them their ages.

"I look at their faces and say, 'Remind me, are you 70? 50?' I can't really tell anymore," she said.

Botox's market potential may tap into a public more open to holding onto youth. "Plastic surgery is not something restricted to a small group of people who are seen as merely vain," Dr. Etcoff, of Harvard, said. "Because, really, we are all vain now."

Ting-Li Wang/The New York Times