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A drug to straighten clenched fingers

By Andrew Pollack 36/11

It took half a century. But a tiny US drug maker on has finally found a potentially lucrative use for its only medicine: straightening clenched fingers. And, if research proves successful, treating a condition that causes bent penises.

The Food and Drug Administration approved the drug, known as Xiaflex, last month as a nonsurgical treatment for Dupuytren's contracture, a condition in which one or more fingers cannot be straightened.

Hundreds of thousands of Americans have Dupuytren's, which can make it difficult to type, shake hands, wear gloves, reach into a pocket or perform numerous other tasks. The afflicted have included Ronald Reagan, Margaret Thatcher, Samuel Beckett and the classical pianist Misha Dichter.

Xiaflex, an injectable drug that goes on sale later this month, will not be cheap, at an estimated average cost per course of treatment of $5,400. But analysts expect sales to reach hundreds of millions of dollars a year.

And that total could go higher, if Xiaflex eventually wins approval for a related condition known as Peyronie's disease, in which a bent penis makes intercourse painful or even impossible.

Quite common

About one in 20 men is estimated to have Peyronie's, but figures are not precise because people with the condition tend not to discuss it publicly.

Although the company selling Xiaflex will be Auxilium Pharmaceuticals of Malvern, the FDA approval was a belated triumph for the drug's original developer, BioSpecifics Technologies of Lynbrook on Long Island. Founded in 1957, it struggled for decades to find uses for the product, almost going out of business before licensing the drug to Auxilium in 2004.

"It sort of proves to people that if you really believe in a drug you should never give up," said Matthew Geller, a biotechnology investment banker who

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Shares of BioSpecifics closed Monday at $27.61, up from $1 as recently as late 2006.

Some people treated with Xiaflex in clinical trials for the Dupuytren's hand condition said it had made a big difference in their lives, and had allowed them to avoid painful surgery.

"When I looked down and saw my finger straightened out, I cried," said Kenneth Nelson, 65, of Indianapolis. "It was to me just like a miracle."

Xiaflex is an enzyme produced by a gangrene-causing bacterium, Clostridium histolyticum, which uses it to eat away the tissues of its victims. The enzyme, called collagenase, breaks down collagen, a major component of the body's connective tissue that is found in skin, tendons, cartilage and other organs.

But collagenase by itself does not cause gangrene. And there are times doctors need to break down collagen, such as when an excess builds up in the hand or penis, causing Dupuytren's and Peyronie's. The ailments are named for French surgeons who described the conditions in the 18th and 19th centuries.

The enzyme was first extracted from the bacteria around 1950 by Ines Mandl, a young biochemist at Columbia University. Edwin H Wegman, a Long Island entrepreneur, learned about Dr Mandl's work and set up a company called Advance Biofactures, which later became BioSpecifics, to turn collagenase into a drug.

In 1965, the company won approval of an ointment containing collagenase for use in removing dead tissue from skin ulcers and burns. The ointment, sold by licensees under the name Santyl, was a modest success, but the company never truly prospered.

So in the 1970s the company began developing what it thought would be a bigger money-maker, an injectable collagenase. It tested that drug for numerous uses, including herniated disks. Finally, in the early 1990s, two professors of orthopedics at the nearby State University of New York at Stony Brook suggested using the drug