to men; the rest are "unexplained.")

In her study of more than 100 couples from 1975 to 1979, Mazor has identified three phases surrounding infertility:

- Development of narcissistic injury. "Acknowledgement of an infertility problem, whether it is after six months, one year or several years of attempting to achieve a pregnancy, is a tremendous blow," Mazor says. During this period, the person may become preoccupied with his or her body and may feel "damaged" or defective; the feeling may spread to aspects of life outside of the sexual sphere.
- Halting the infertility investigation and acknowledging the finality of the condition. "During this phase, the couple reexamine their own feelings about parenthood and go through a period of grieving for the loss of their reproductive function, of mourning for the biological children they could not have together," says the psychiatrist. Despite the modern-day lessening of pressures to have children, she says, "for most people, parenthood remains an integral part of their development as adults."
- Deciding about alternative routes. Those couples that decide not to go childless have basically two choices: adoption or, in the case of male infertility, artificial insemination by donor.

But those couples that opt for artificial insemination may face a whole new series of emotional obstacles, according to Elisabeth Chan Small and R. Nuran Turksoy of Tufts University Medical School in Boston. Citing what they call "an alarming increase in infertility" — a Florida study recently noted a marked decrease in sperm count among college students sampled in 1979, compared with those sampled in 1929 — the researchers estimate "conservatively" that as many as 250,000 births result from artificial insemination in the United States each year.

Many of the problems appear to revolve around the husband's feelings of inadequacy; when finally told they have no choice in reproduction, it is the men who "suffer a sense of profound loss [of their own biological child]," say the scientists. In addition to feelings of vulnerability, inadequacy and anger (often at the wife's fertility), the husband must deal with the prospect of the wife's artificial insemination by another male. "Consciously, while he accepts the idea of insemination, he [the husband] may unconsciously remain angry and this anger may be expressed in ways to affect the marriage which sometimes results in divorce," they note. With the help of proper counseling, however, Small and Turksoy report that "marriages usually do not deteriorate, the couples are happy, grateful and feel close to the children whom they consider their own and when queried whether they would consider having another child by the same method, the response is predominantly in the affirmative and many couples do return for further insemination." □

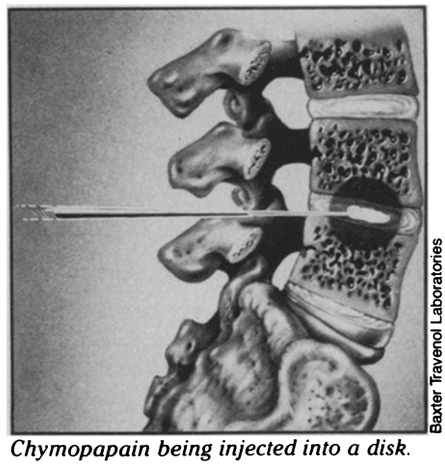
An enzyme may treat slipped disks

If a drug can be found that is safe and effective in alleviating the problems associated with slipped disks, many low back pain sufferers would be spared the trauma and costs of corrective surgery. But such a drug, some researchers feel, may have been discovered already. It has not been approved by the U.S. Food and Drug Administration because the results of clinical studies have been confusing. Now, with the help of a pending triple-blind clinical trial and data from long-term clinical observations, the FDA should be able to make a firm ruling.

The drug in question is an enzyme called chymopapain. In 1956, it was found to break down cartilagenous tissues (it made rabbit ears hang down like a spaniel's), suggesting that it might be able to dissolve cartilagenous disks that normally separate the spinal vertebrae but that sometimes slip out of place and cause excruciating low back pain. During the 1950s and early 1960s scientists at Travenol Laboratories in Deerfield, Ill., purified chymopapain, conducted safety studies in animals and then obtained FDA approval for the drug to be injected into patients' slipped disks. From 1964 to 1975, 75 orthopedic surgeons and neurosurgeons around the United Sates and Canada injected chymopapain into the slipped disks of some 17,000 patients. They found that the injections helped many patients and concluded that chymopapain might be a useful alternative to disk surgery for a number of slipped disk cases.

The FDA was reluctant to approve chymopapain on the basis of those findings since none of them had been obtained through a double-blind trial in which chymopapain was compared with an inert placebo and neither investigators nor patients knew what patient was getting the drug and what patient was getting a placebo. So such a double-blind study was set up, but the results, reported in 1975, were confounding. Chymopapain was found to have a 58 percent success rate (comparable to that reported in previous, uncontrolled studies), but the placebo (comprised of chemicals called cysteine, edetate and iothalamate) was found to have a 50 percent success rate — close enough to the success rate of chymopapain to render the results statistically nonsignificant and thus to suggest that chymopapain was no better than a placebo in helping slipped disk patients. The FDA decided, on the basis of these results, not to approve chymopapain for marketing.

But the chymopapain story was far from over. There was, subsequently, reason to believe that the placebo used in the trial really had not been a placebo (inert substance), but that two of the three chemicals in it were enzyme activators. This discovery suggested that chymopapain had not been compared with a placebo at all, but rather with a drug having physiological effects that could have helped slipped disk patients. Travenol asked the FDA if it could restudy chymopapain and resolve the questions raised by the double-blind study. In 1978 the FDA agreed, and a new, more rigorous trial got underway, the results of which are expected in July 1981. This is a triple-blind study in which chymopapain is being compared not only to cysteine, edetate and iothalamate but to saline (a substance often used as a placebo in double-blind trials and one generally accepted to be inert). If the results show that chymopapain is significantly better at helping slipped disk patients than is saline, Travenol will ask the FDA to approve chymopapain for marketing. Whether the FDA will do so, however, remains to be seen.


Baxter Travenol Laboratories

Chymopapain being injected into a disk.

Still other study results, which have just been published in the May 23/30 JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION by Manucher J. Javid of the University of Wisconsin Clinical Sciences Center in Madison, also might influence the FDA to approve chymopapain. Javid was one of the 75 investigators who initially studied chymopapain in slipped disk patients between 1964 and 1975. But he has done something that the other investigators have not. He has followed up the patients he treated between 1972 and 1975 for three to six years to see exactly what chymopapain's long-term effects are, and as he reports, chymopapain appears to have been capable of alleviating slipped disk in 73 percent of patients over that time span. These results, he concludes, "indicate that chymopapain should be considered an advantageous alternative to surgery in appropriately selected cases."

Chymopapain is already commercially available in Canada, Britain and Switzerland and is expected to be approved by still more countries in the next few months. It is also part of a new scientific frontier — the use of enzymes as pharmaceuticals and for other medical purposes (SN: 7/22/78, p. 58). □