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Smokers sticking to nicotine patch

By Karen Zagor and Clive Cookson

Federal health experts in the US estimate that 1,000 Americans die each day of smoking-related diseases. According to a former surgeon general, the nation's 50m regular cigarette smokers are caught in the grip of an addiction more powerful than heroin. Nicotine patches attached to the upper arm are the latest candidate for a miracle cure.

Unaided, fewer than 4 per cent of smokers kick the habit, according to some estimates. The advent of hypnotism, nicotine-impregnated chewing gum, acupuncture and behaviour-modification therapy have improved the odds, but most would-be ex-smokers still fail.

Nicotine patches, which have been on the market for less than four months, are selling almost as quickly as they can be made. Alza, which markets the Nicoderm patch, said its plant has been operating 24 hours-a-day, seven days-a-week since January to meet demand. In only two and a half months Nicoderm chalked up \$60m (£35m) in sales. "We knew that there would be a strong reaction," a company spokeswoman said, "but we did not expect such amazing demand for the product."

The technology behind patches is young, but not new. A patch for motion sickness has been available in the US since 1981. The product looks like an ordinary sticking plaster. It usually has a reservoir to hold the drug, which enters the bloodstream by permeating the skin at a regulated rate.

With traditional tablet medications the drug quickly passes from the intestine to the liver, where enzymes often digest most of the medication before it has had a chance to work. As a result, tablets often contain high concentrations of medicine. Drugs administered through a patch reach the liver at a slower rate after they have already started to work. Consequently, lower doses can be administered, generally with fewer side-effects.

While nicotine is the addictive ingredient in cigarettes, the biggest risks are associated with the nitrosamines, tars and other particulates unleashed when a cigarette is lit.

By providing smokers with nicotine in a less toxic form the patches give smokers time to change their behaviour and give up cigarettes without suffering the irritability, lack of concentration and other symptoms of nicotine withdrawal.

The overriding advantage of patches over nicotine-impregnated chewing gum is that they are easier to use. While gum allows patients to regulate the nicotine intake, in practice many people trying to give up tend to chew gum maniacally, releasing too much nicotine too quickly and making themselves ill.

The Food & Drug Administration has approved three nicotine patches for prescription sales - Habitrol marketed by Ciba Geigy, Nicoderm by Marion Merrill Dow and ProStep marketed by American Cyanamid's Lederle unit. A fourth patch, to be marketed by Warner Lambert, is waiting for approval.

The main difference between the competing patches is the mechanism for controlling entry into the bloodstream. Some, like Nicoderm, have a special membrane which controls the flow of nicotine. Others use the skin itself to control the drug's flow into the bloodstream. The doses also differ; ProStep comes in one strength only, while Nicoderm and Habitrol offer patches with increasingly reduced doses.

The patches seem to be effective. A study of Nicoderm's product, presented last December in the Journal of the American Medical Association, showed that it had a six-week success rate of 61 per cent compared with 27 per cent for the placebo.

After six months, 25 per cent of the patients originally treated with patches were still not smoking compared with 11 per cent of the placebo group. The patches work best for heavy smokers and are not recommended for those who smoke less than one pack a day.

They are also most effective in conjunction with behaviour-modification therapy. ProStep offers free phone therapy from smoking-cessation experts; Lederle has offered to reimburse pharmacists for time spent educating patients.

Stephen Rennard, one of the chief investigators in the transdermal nicotine study group, is enthusiastic about patches as a means of nicotine replacement, but cautions that "this won't cure everybody".

DynaGen, a Massachusetts biotechnology company, is starting clinical trials of an injectable non-nicotine material called NicErase, which it claims will do the same job as the patches. It "eliminates the need for the harmful and addictive nicotine," says Indu Muni, DynaGen president.

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