

Nicotine Patch: University of California, Los Angeles

When Jed Rose, Ph.D., gave his brother a ride to their family reunion back in 1981, the topic of work came up in their conversation. Little did Rose know that their discussion would lead to a major medical discovery that would save thousands of lives.

At the time, Jed Rose was a faculty member of the University of California, Los Angeles (UCLA), School of Medicine and founder of UCLA's nicotine research program, and his brother, Dr. Daniel Rose, was a physician with a successful private practice in Healdsburg, California.

"I remember talking to Dan about my research on separating nicotine from sensory factors like taste or inhaling tobacco smoke into your lungs," Jed Rose said. In discussing the issue of satisfying nicotine cravings, Dan wondered whether some sort of skin patch could be developed—similar to the transdermal scopolamine patch used for the prevention and treatment of motion sickness.

The nicotine patch could potentially be used to reduce people's cravings for cigarettes, cigars, and other tobacco products containing nicotine. "So we hatched a plan to develop the patch," Jed Rose said. And the rest, as they say, is history.

DEVELOPING THE PATCH

Working together with his brother and Murray Jarvik, Ph.D., then head of UCLA's psychopharmacology laboratory, Jed Rose initiated the research and development of the nicotine patch. Using himself as the first research subject, Jed Rose determined that

nicotine could indeed reach his bloodstream when applied to his skin using a polyethylene patch. The team's first published study on the subject in 1984 demonstrated that the transdermal, or through the skin, transfer of nicotine into the bloodstream had the desired effect of reducing nicotine cravings.

After years of experimentation on hundreds of test subjects, the team, with assistance from the Swiss pharmaceutical company Ciba-Geigy, developed a skin patch that would transmit low doses of nicotine into the bloodstream through a subject's skin at a rate corresponding to that of smoking. The patch could be used also in combination with a nicotine aerosol spray, being developed at the time, that would mimic some of the sensations associated with inhaling tobacco smoke. The trio of researchers obtained the first of three patents on the technology in May 1990.

Ciba-Geigy licensed the new nicotine patch technology from the University of California Office of Technology Transfer, and, after gaining approval from the U.S. Food and Drug Administration (FDA), the company launched the Habitrol® patch as a prescription drug in 1991. It wasn't long before other prescription-based transdermal nicotine patches entered the marketplace. In 1991 and 1992 other pharmaceutical companies began marketing their own nicotine patch products based on technologies licensed from other research institutions.

It was the FDA's approval of over-the-counter nicotine-replacement therapies in the mid-1990s that marked the next significant step in the nicotine patch

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success story. Through much wider over-the-counter accessibility, use of nicotine patches increased by as much as 92 percent compared with prior prescription use. By 1999, an over-the-counter version of Habitrol was introduced to the marketplace by Novartis, a pharmaceutical giant formed from the 1996 merger of Ciba-Geigy and Sandoz. Because 70 percent of all smokers express a desire to quit smoking, the widespread over-the-counter availability of nicotine-replacement therapies has presented even greater opportunities to kick the tobacco habit.

TREMENDOUS BENEFITS TO SOCIETY

To say that nicotine patches have benefited society is like saying breathing oxygen is good for your health. Ample scientific and medical data show that nicotine patches have helped reduce the toll of smoking on society.

And it has been a heavy toll indeed. In the United States alone, one out of five adults—44.5 million people—were smokers in 2004. Nearly one out of every five deaths is related to tobacco use, 438,000 people annually in the United States. Cigarette smoking is the primary cause of death and disease in the United States, taking more lives than alcohol, car accidents, suicide, AIDS, homicide, and illegal drugs combined.

The U.S. Centers for Disease Control estimates that adult male smokers lose, on average, 13.2 years of life, while female smokers lose 14.5 years of life, because of smoking. According to one estimate, each year in the United States, smoking is responsible for 1.1 million years of potential life lost, with respect to people under 65.

Besides these tremendous human costs, the economic costs of smoking are staggering as well. In 1993, an estimated \$50 billion in the United States was spent on smoking-related medical care. Lost productivity

and earnings from smoking-related disabilities were estimated to cost an additional \$47 billion.

Yet nicotine-replacement therapies, and the nicotine patch in particular, have gone far in reversing the devastating trends. Numerous studies indicate that nicotine patches roughly double the rate of successful quit attempts. Successful quit rates for those using nicotine patches range from nine percent to as much as 20 percent. According to one estimate, the annual number of successful quits achieved in the United States using over-the-counter patches alone was 13,566.

By helping thousands of smokers every year to quit, nicotine patches generate significant benefits—an estimated \$1.17 billion to \$1.39 billion in net social benefits. What's more, the nicotine patch is considered highly cost-effective. Use of the patch produces a lifetime quitter at an estimated cost of \$7,332, a tremendous bargain in light of the tremendous cost to society posed by tobacco use, which amounts to \$3,391 per smoker per year. It comes as no surprise that nicotine patches and other nicotine-replacement therapies are more cost-effective than other common disease-prevention approaches, such as the treatment of hypertension or high blood cholesterol.

Today Jed Rose continues to lead nicotine research as director of the Duke Center for Nicotine and Smoking Cessation Research at Duke University in Durham, North Carolina, working alongside his wife, Frederique Behm, who was involved in his initial nicotine patch experiments years ago. Looking back, he notes a humble feeling of satisfaction when reflecting on the groundbreaking research that he, his brother, and Murray Jarvik initiated.

“It is very exciting and gratifying to know that our work has made a difference in people's lives,” Jed Rose says. “This shows the potential impact that clinical research can have on society.” ■