The Marketing of Smoking Cessation Drugs

By Wanda Hamilton

Publication date: August 17, 2001

“Within the [North American] region, central nervous system products, currently growing at 18 percent constitute the largest class, with a value of $14.5 billion. The growth leaders in this class currently are anti-epilepsy and anti-smoking products.”


“Public health authorities, including the World Health Organization, have called for an increased focus on the treatment of tobacco dependence…”


“In 1996, sales of nicotine medications increased by 11% over average sales during the 4-week national GASO [the American Cancer Society’s Great American Smokeout] promotion; sales during the specific week of GASO increased 30%.”


It would be a marketer’s dream for the U.S. Surgeon General, the Centers for Disease Control, the World Health Organization, and the American Cancer Society to be actively involved in pushing a line of products. This dream has become a reality for several multinational pharmaceutical companies and their patented smoking cessation drugs.

Not only did the 1988 Surgeon General’s report prepare the way by declaring for the first time that tobacco use was “addiction” needing “treatment,” but subsequent reports focused specifically on smoking cessation treatment, including pharmacologic treatment. The Centers for Disease Control (CDC) has also increasingly emphasized smoking cessation and treatment for tobacco “addiction.” The federal agency even included two cessation drug marketing reports in its Morbidity and Mortality Weekly Report series and encouraged states to spend millions in tobacco settlement money on smoking cessation and treatment.

The World Health Organization and the American Cancer Society (ACS) made smoking cessation and treatment primary themes for World No-Smoking Day and the Great American Smokeout, both of which the drug companies were more than happy to fund. The WHO and the ACS also formed highly publicized “partnerships” with the drug companies. In addition, the ACS signed a multi-million-dollar contract with SmithKline Beecham for use of the organization’s name and logo in Nicoderm ads, and the American Lung Association signed a similar agreement with Johnson & Johnson subsidiary McNeill for Nicotrol.

Marketing interests of the drug companies are so intertwined with the public policy strategies of the anti-tobacco movement that it’s difficult to see where one leaves off and the other begins. The companies provide funding and commission studies to support anti-tobacco efforts, and the public health community lobbies for legislation that will
increase sales of the companies’ drugs and give them a competitive advantage over the tobacco companies’ products. As two articles in the *Bulletin of the World Health Organization* 2000 put it:

> “Products and services that have been proved effective in smoking cessation should be widely available and should have marketplace advantages (price, promotion, distribution outlets, package sizes, etc.) compared with tobacco products.” Sweanor D, “Is it the nicotine or the tobacco?” 78(7), p. 943.

> “Dealing with nicotine addiction involves many of the established tools of tobacco control: price increases, advertising bans, communications programmes, restrictions on smoking at work and in public places, and access to good treatment for dependence.” Bates C, “Taking the nicotine out of cigarettes—why it is a bad idea,” 78(7), p. 944.

These same policies are echoed by Nancy Kaufman, Vice President of the Robert Wood Johnson Foundation:

> “We have 2 focal points for our work: (1) preventing the use of tobacco by youth and young adults through the application of state and federal tobacco control policies (e.g. increases in tobacco taxes, indoor air policies, advertising restrictions, access measures) and (2) helping addicted users quit.” Philippe Boucher, Rendez-vous with Nancy J. Kaufman, Feb. 26, 2001.

And by Thomas Houston of the American Medical Association, along with Nancy Kaufman:

> “Worldwide, governments are taking steps toward comprehensive tobacco control plans that include increased taxes, restrictions on tobacco advertising and promotion, more informative warning labels on tobacco products, restrictions on smoking in public places, and increased availability of smoking cessation therapy.” Houston T, Kaufman NJ, “Tobacco Control in the 21st Century,” Editorial, JAMA, 284(6), Aug. 9, 2000.

And by David Satcher, U.S. Surgeon General:

> “Research shows that tobacco use can be reduced through a comprehensive approach including education, community and media-based activities, pharmacological treatment of nicotine addiction, regulation of advertising and promotion, clean air regulations, restriction of tobacco sales to minors, and taxation of tobacco products.” Satcher, D, “International Tobacco Control: An Update,” JAMA, 286(3), July 18, 2001.

Whether or not these policies would affect smoking rates is debatable; what is not debatable is that they would give a decided market advantage to the pharmaceutical companies over the tobacco companies with regard to cost, advertising and promotion, availability, and convenience of their products.
Cost Differential

“Potential barriers to use of tobacco treatment medications include concerns about the safety and cost of the treatments.... Treatment guidelines recommend that treatment of tobacco use be an insured medical benefit. A recent study in a health plan demonstrated that decreasing the costs of treatment increased use of treatment....”


“The common man will not be inclined to take these drugs if they cost more than a bundle of bidis [commercially produced hand-rolled cigarettes].” Unidentified smoker quoted in Aparna Krishnan, “Price wars in anti-smoking drugs?” Hindu Business Line, June 24, 2001.

Smoking cessation drugs are generally more expensive than tobacco products. For example, a six-week supply of cartridges for Johnson & Johnson’s Nicotrol Inhaler runs about $250.00, while a six-week supply of cigarettes for a pack-a-day smoker would cost roughly $180.00 for premium brands in those states with moderate tobacco taxes (less in states with low tobacco taxes). In states with the highest tobacco taxes, the cost of cigarettes is about the same as for the nicotine cartridges. Thus, one of the major goals of the pharmaceutical companies and their anti-tobacco allies is to push for ever-higher state and federal taxes on tobacco products.

Promoting state lawsuits against the tobacco companies was another strategy that caused massive tobacco consumer price increases, and The Robert Wood Johnson Foundation funded a number of legal studies to advance these lawsuits, including several hefty grants to the Tobacco Products Liability Project.

Rather than simply lowering the artificially high prices of their cessation drugs to levels more competitive with tobacco products, the pharmaceutical interests preferred to maximize their profits. Therefore, while promoting strategies to increase the price of cigarettes, they also promote insurance coverage of their own products as a financial incentive to consumers.

“The [U.S Public Health Service] guidelines also urged health insurance companies and government health programs to pay for tobacco cessation treatments and counseling. Only about half of all insurers currently do so; Medicare, the federal health program for seniors, doesn’t cover anti-smoking treatments and only 22 states provided Medicaid coverage for tobacco dependence treatments.” Karen Gullo, “Surgeon general calls on doctors, insurers to beef up anti-smoking efforts,” AP, June 27, 2000. Michael Fiore, head of the panel which drew up the PHS Clinical Guidelines, has received extensive funding from the pharmaceutical companies marketing cessation drugs.

“Late in 1997 a group of experts in the science of tobacco control was convened by the Center for the Advancement of Health to develop recommendations regarding the use of federal funds for treating tobacco dependence.” Pinney J, Ahluwalia J, Arkin E, Fiore M, Glynn T, Gruman J, Henningfield J, Hughes J, Maule C, Neff R, Ockene J, Orleans T, Shiffman, S, Slade J, “Realignment of the nation’s tobacco agenda: the need to treat tobacco dependence,” Preventive Medicine, 32(2): 95-100, Feb 2001. Pinney,
Henningfield and Fiore have served as consultants to the pharmaceutical companies marketing cessation drugs. Most of the others also have received significant funding from these companies, and Orleans is an employee of the Robert Wood Johnson Foundation. The Center for the Advancement of Health is an organization with heavy pharmaceutical company membership and heavy pharmaceutical funding.

To convince private and public health insurers to cover the cost of their cessation drugs, pharmaceutical companies and the Robert Wood Johnson Foundation have funded numerous “cost benefit” analyses. These analyses invariably show that it is cheaper for the insurers to pay for the cost of cessation drugs and counseling than it is to pay for healthcare for sick smokers. In other words, the pharmaceutical companies selling the drugs finance studies to bolster their argument that the insurers, including federal and state governments, will save money by paying for their products.

Some national governments have been convinced by the arguments of the drug companies and their allies to cover the cost of cessation drugs. In the U.K., for example, the National Health Service pays for nicotine replacement therapy. Thus the taxpayers subsidize the drug companies’ nicotine products, and the multinational pharmaceutical companies make a tidy profit.

Advertising

At the same time as the public health community demonizes the tobacco companies in paid and public service advertisements, they also promote legislation to prevent the tobacco industry from being able to commercially advertise their products in any and all venues.

By law, tobacco companies have not been permitted to advertise their products on U.S. television and radio for the past thirty years, which has meant they could only advertise on billboards, in the print media, and in private business establishments. In recent years, the anti-tobacco organizations have attempted to prohibit tobacco ads in even these remaining outlets. Virtually every large study has shown that tobacco advertising has little or no effect on whether or not people begin smoking, but that hasn’t deterred the anti-tobacco campaigners from repeatedly attempting to stamp out all tobacco advertising, even on the internet and in convenience stores.


The drug companies, on the other hand, have few limits on advertising their products, and no one is funding proposals suggesting additional regulations on their commercial speech.
“For the ad industry, the [smoking-cessation] products have become one of the biggest growth engines: Ad spending for smoking-cessation aids jumped to $220 million last year [1996] from $13 million the year before, according to Interpublic Group’s McCann-Erickson.” “Tobacco deal heats up nicotine-patch war: Settlement includes money for treatment of smoking habit; marketers looking for windfall,” The Wall St. Journal, July 5, 1997.

On the contrary, restrictions on pharmaceutical advertising have been eased. In 1997, under the leadership of David Kessler, the FDA loosened television advertising restrictions for prescription drugs, the same year it approved Glaxo Wellcome’s Zyban as a prescription drug for smoking cessation. Thus, the company was able to launch its product with a massive direct-to-consumer, prime-time television ad campaign.

**Availability**

“It makes very little sense for (nicotine) patches to be available under prescription when cigarettes are freely available over the counter. Either patches should be made freely available, or cigarettes should be only under prescription.” Gregory Hartl, WHO spokesman, quoted in Richard Hannaford, “Put cigarettes on prescription,” BBC News, April 27, 1999.

“On the wider political stage, doctors should demand a level playing field. The industry that promotes nicotine addiction should be regulated and the therapies that treat it not disadvantaged in relation to smoking.” Britton J, McNeill A, Editorial, BMJ, 322, 1077-1078, May 5, 2001. Both Britton and McNeill have received funding from companies which make cessation drugs.

To date, cigarettes are more widely available than are cessation drugs, but if the pharmaceutical and anti-tobacco industries have their way, that will change.

There are sporadic attempts by those in tobacco control to ban the sale of cigarettes in vending machines, on the internet and in certain venues such as pharmacies, but these measures have not significantly cut down consumer access to tobacco products. A far bigger threat to availability is regulation of tobacco products by the U.S. Food and Drug Administration.

Under the leadership of David Kessler, the FDA attempted to add tobacco to the list of products the agency regulates. Kessler was heavily assisted in his efforts by the tobacco control community, including the Robert Wood Johnson Foundation. However, the tobacco companies brought suit against the FDA, and in March 2000, the Supreme Court found that Congress had not given the FDA authority to regulate tobacco products.

Now, those in tobacco control are beginning to push for the U.S. Congress to pass legislation giving the FDA authority to regulate cigarettes and other tobacco products. Given the federal agency’s sweeping power and its close alliance with major pharmaceutical companies, availability of and consumer access to tobacco products could be severely curtailed. For example, the FDA would have the power to change the very composition of tobacco products by limiting the amount of nicotine they contain, or the agency could require that they be sold by prescription only, or not be sold at all. Any of
these measures would tilt product availability and ease of consumer access in favor of the pharmaceuticals’ products.

Meanwhile, the FDA has made the pharmaceutical companies’ nicotine products far more easily available to consumers than they once were. In 1984 when Nicorette gum was approved and in 1991 when the Nicotrol and Nicoderm patches were approved, the FDA mandated that they could be marketed only as prescription smoking-cessation drugs. This meant, of course, that anyone wishing to purchase them would first have to go to the trouble and expense of making an appointment with a physician.

To overcome this impediment to easy consumer access to their nicotine products, the pharmaceutical companies funded numerous studies designed to demonstrate not only that their products were safe enough for consumers to use without doctor supervision, but that they worked even better for smoking cessation when they were directly available to the public through over-the-counter (OTC) sales. In 1996, David Kessler’s FDA obliged the drug companies by approving first the gum and then the patches for OTC sale.

Johnson & Johnson was apparently confident that the FDA would approve OTC sales for its Nicotrol patch, because the pharmaceutical giant “set a record for quickly getting an Rx-to-OTC switch to market. Nicotrol patches were being shipped to stores within two weeks of gaining FDA approval for OTC sale” (“Smoke Cessation on Fire,” Information ACCESS Co., Thompson Corp., Medical Economic Publishing, Drug Topics, July 7, 1997).

And indeed OTC availability radically boosted nicotine drug sales:

“\textit{In an article published last winter in the journal Tobacco Control, psychologist Saul Shiffman of the University of Pittsburgh’s Smoking Research Group found that over-the-counter availability of the gum and the patch accounted for a 152 percent increase in the sales of these products}” Sandra Boodman, “Feeding the Nicotine Habit: Finding Safer Substitutes for Cigarettes,” The Washington Post, June 30, 1998. Shiffman, in fact, conducted one of the studies indicating OTC sales increased smoking cessation rates. His work was funded by SmithKline Beecham and Hoechst Marrion Roussel, marketers of Nicoderm.

Of course, not all the sales increases were due to smokers wanting to quit. Many of those who had no intention of quitting bought the patch or the gum to use on those occasions when they were prohibited from smoking because of bans. OTC availability clearly increased sales of the drug companies’ nicotine products to these continuing smokers, as the pharmaceutical companies knew they would.

\textbf{Increasing Bans, Increasing Sales}

\textit{“Last year [1997], SmithKline says, sales of its NicoDermCQ patch and Nicorette gum swelled 30\% to $448 million, partly because more smokers were using the products to avoid nicotine cravings in nonsmoking places…” To be crass about it, virtually every pharmaceutical company sees a tremendous market here,’ says David Sachs, director of the Palo Alto Center for Pulmonary Disease Prevention in California, which conducts clinical studies on smoking-cessation products.”} Suein Hwang, “Cigarette

The more places smoking is banned, the more smokers will purchase “nicotine replacement” products such as the gum and the patch, either in an attempt to quit smoking or merely to have an alternate source of nicotine. Smoking bans are very, very good for the pharmaceutical business.

Because the FDA has not approved nicotine replacement drugs for any use except smoking cessation therapy, the pharmaceutical companies are prohibited from directly marketing their nicotine products as substitutes for tobacco. Obviously, the companies are aware that smokers use their products as substitutes for smoking, and they would like to advertise their products for this purpose. As early as 1997, one year after the patch was approved for OTC sale, SmithKline Beecham suggested that nicotine replacement products could be used for harm reduction:

> “Beyond the 34 million smokers who say they want to quit, there is even more opportunity to reduce smoking. The tobacco settlement should also address ways to help smokers who can’t quit but who may benefit from drastically cutting down the number of cigarettes smoked…. “ Statement from SmithKline Beecham Consumer Healthcare About Stop Smoking Treatment Resources Included in the Tobacco Settlement,” PR Newswire, June 20, 1997.

The pharmaceutical companies are currently funding clinical tests to demonstrate that using their nicotine products for “harm reduction” is both safe for use in continuing smokers and that it helps them cut down on the number of cigarettes they smoke. If the clinical trials demonstrate safety and efficacy for harm reduction, it is likely that the FDA would approve the gum and the patch for this use. Then the drug companies would be free to market their nicotine products to smokers who would like to continue smoking, but who would like to cut down. This would be a marketing boon as great or greater than approval for OTC sales.

The drug companies’ allies in the medical and public health fields are already beating the drum for regulatory agencies such as the FDA to permit nicotine replacement products to be used for harm reduction and as substitutes for tobacco.

> “…there should be a huge market for alternative nicotine delivery systems. A move toward risk reduction could significantly benefit public health, provide consumer choice and allow free market forces to combat the leading cause of preventable death [tobacco]. However, market forces are currently prevented from providing consumers with the risk reducing products they want because of existing regulatory systems. Tobacco products have been exempted from consumer protection laws, but there are no such exemptions for other nicotine delivery products, e.g. NRT. This has resulted in an exceedingly uneven playing field for nicotine products…. “ Sweanor D. “Regulatory imbalance between medicinal and non-medicinal nicotine,” *Addiction*, 95 Suppl 1:S25-8, Jan 2000.
“Coordinating the efforts of the pharmaceutical industry, clinicians and researchers will probably be important in moving regulatory authorities further in the direction of accepting NRT for widespread use in smoking reduction.” West R, “Addressing regulatory barriers to licensing nicotine products for smoking reduction,” *Addiction*, 95, Suppl 1:S29-34, Jan 2000.

But the tobacco industry is fighting back by trying to produce reduced harm products of its own. At least three cigarette companies have developed “safer” cigarettes. Brown and Williamson is prepared to market a mint-flavored nicotine lozenge that smokers can suck on when they are unable to smoke, Swedish Match has developed a nicotine gum, and UST is marketing Revel, new mint-flavored snuff packets which will be advertised as a “fresh” way for smokers to enjoy tobacco when they can’t have a cigarette (Gordon Fairclough, “UST Pushes Mint-Flavored Tobacco With New Look, Marketing Campaign,” *The Wall St. Journal*, Aug 1, 2001).

The drug companies and their anti-tobacco allies are not at all happy about this new competition from the tobacco companies, and their spin-doctors and supporters are busy demanding FDA regulation of tobacco products. Ken Warner, who was an advisor to an Institute of Medicine panel to investigate “harm reduction” in reduced-risk tobacco products as well as pharmaceutical nicotine products, attacked the tobacco products:

> “All of the products that have been proposed to date from the tobacco industry represent risky products. You are still getting nicotine, you are still inhaling a chemical soup compared to not smoking at all.”

And defended the pharmaceutical companies:

> “It is ironic and tragic that we subject the manufacturers of the safest nicotine delivery products ever developed to this hugely expansive process to establish safety and efficacy, and we impose absolutely no regulatory marketing restrictions on the most deadly form of nicotine ever developed.” Both quotes are in Glenn Howatt, “Panel: Patches, gums, reduced-smoke cigarettes may be no safer,” Minneapolis Star Tribune, Feb 23, 2001. Warner has been a particular funding favorite of The Robert Wood Johnson Foundation.

Panel member Dorothy Hatsukami, another recipient of Robert Wood Johnson funding, called for Congress to enact legislation to give the FDA regulatory authority over the reduced-risk cigarettes. And drug giant Pharmacia was very pleased that the Institute of Medicine report advocated that the tobacco companies be held to the same standards as the pharmaceutical companies, no doubt by FDA regulation.

Anti-tobacco activist Clive Bates of ASH was outraged that the media didn’t report the findings of the panel more favorably for the drug companies:

> “Missing from the coverage was any sense that there are practical harm reducing measures that can be taken without giving away the entire field to Philip Morris. It is possible to authorize NRT products for harm reduction application, and it is possible to allow nicotine gum to compete with cigarettes….” Bates C, “Clearing the smoke or muddying the water?” Editorial, *Tobacco Control*, June 12, 2001.
Given the sheer power and wealth of the international pharmaceutical conglomerates and given the political power and “respectability” of their governmental and non-governmental “partners,” it may very well come to pass that TV viewers will be subjected to a whole new wrinkle in nicotine marketing:

“Honey, I forgot to go to the doctor to refill our prescription for cigarettes.” Husband responds: “Well, luckily for us, there’s a patch vending machine just around the corner.” Hugging her husband, the wife replies: “You know, maybe we ought to forget about cigarettes. The patch is so much more convenient and so much less expensive—and we don’t even have to go outside to use it.”