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Forum

Cancer Risk?

Nicotine Replacement Therapy May Do Smokers More Harm Than Good

By Norman E. Kjono

Does the principle of liability for promotion of products with potentially dangerous properties apply to pharmaceutical nicotine products used for smoking cessation or substitution purposes? Millions of consumers use pharmaceutical nicotine products to avoid cancer from tobacco use without knowing that those very products may themselves cause cancer. Recent research by the National Cancer Institute and the Stanford University School of Medicine raises serious questions regarding nicotine replacement therapy and its link to cancer.

Historically, promoting the use of pharmaceutical nicotine products has been a principal element of tobacco-control advocacy.

For example, on Feb. 15, 1998, United Press International published "Koop Predicts Nicotine Inhalers, Sprays," by Michael Smith, which presented former Surgeon General C. Everett Koop's views: "Within the next five years, America's nicotine addicts will increasingly get their fix without the dangers of smoking cigarettes," former surgeon-general C. Everett Koop said.

"Speaking at a major science meeting in Philadelphia, Koop said that he foresees nicotine nasal sprays and inhalers joining the currently available nicotine chewing gum and nicotine patch products. Said Koop: 'Nicotine is not the dangerous part of a cigarette.'

"Within the next five or 10 years, Koop said, 'we will still have a tremendous

number of nicotine addicts, but we will have smoking nicotine addicts and nonsmoking nicotine addicts.'"

On Feb. 27, 1998, The Wall Street Journal published a similar article by Suein L. Hwang, "Drug Makers See A Risky New Role For Nicotine." That article presented the views of a technical editor to Koop's 1988 report that declared nicotine to be addictive.

Dr. Neal Benowitz of University of California, San Francisco, said, "I'd rather see people dependent on nicotine than on tobacco."

Hwang also quoted Karl Fagerstrom, a former director of scientific information for Pharmacia & Upjohn (now part of Pfizer): "If it's the nicotine people want, why not give it to them?"

Pharmacia manufactures products such as Nicorette gum for GlaxoSmithKline.

The Wall Street Journal also quoted J. Andrew Johnson, head of psychiatry research at Glaxo Wellcome (now GlaxoSmithKline).

"I would support long term nicotine use through some administration other than cigarettes," Johnson said.

The Wall Street Journal's article discussed using nicotine replacement products while continuing to smoke, reporting that pharmaceutical nicotine distributors applied to the Food and Drug Administration to extend the recommended period for which nicotine patches and gums could be used. (The extension later was granted.)

Hwang's report stated that drug companies were talking with federal

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regulators about promoting their nicotine products to smokers who merely want to cut down on smoking. The Wall Street Journal presented opinions to the effect that nicotine is so addictive that smokers may need to use nicotine replacement products for life and that nicotine is relatively benign compared to tar.

In stark contrast with the above opinions about nicotine, on June 30, 2001, The Associated Press published an article about research by Dr. John Cooke, director of vascular medicine at Stanford University School of Medicine.

That article, "Questions Raised About Nicotine Patches," by Randolph E. Schmid, reported that Cooke concluded that nonsmoked nicotine (in gums, patches and inhalers) stimulates the growth of blood vessels, which in turn can increase the growth of tumors.

Cooke described his surprise at finding that nonsmoked nicotine increased blood flow.

Cooke was quoted as saying, "This [increased blood flow to tumors] was totally a shock to us. We expected just the opposite."

With tobacco nicotine, the effects appear to be the opposite; it reduces circulation.

Furthermore, on Jan. 2, "CBS Evening News" broadcast a report about conclusions of the National Cancer Institute diametrically opposed to the conclusions of the pharmaceutical industry. According to the institute, nicotine is not benign; there can be significant medical risks from long-term use of nicotine replacement products.

CBS reported the opinion of the institute's Dr. Phillip Dennis: "The take-home point is that nicotine is clearly not harmless."

Dennis explained that people who use nicotine replacement products should do so only for a short period and should not use the products for the long term.

The institute's research compared the effects of tars and nicotine on damaged cell behavior. The conclusion was that both tars and nicotine have a similar effect that can lead to cancer: DNA in damaged cells causes them to eliminate themselves; tar and nicotine stops that process. Consequently, more damaged cells remain in the body.

The institute's research characterized that phenomenon as "an important early event in the formation of cancer."

CBS reported that GlaxoSmithKline said, "There is no clinical evidence to prove that nicotine delivered by our products causes cancer."

National Cancer Institute and Stanford University School of Medicine research presents a potential double jeopardy cancer risk that appears to be unique to pharmaceutical nicotine. This research should be of interest to attorneys who represent cancer victims.

Principal among the questions that this research raises is, To what extent does using pharmaceutical nicotine products influence the development of cancer or accelerate the growth of tumors independent of tobacco

use or other causes?

Research suggests that smokers who used pharmaceutical nicotine products in several attempts to quit smoking or to avoid smoking in smoke-free work environments may unwittingly add to their cancer risk. Such inquiry could open the door to new sources of economic recovery.

As illustrated by the new research, tobacco-control public policy has the perverse effect of aggressively promoting products that appear to be linked to increased risks of cancer. Powerful pharmaceutical special interests may have willfully crafted a market for nicotine products that may present undisclosed additional risks of cancer.

Moreover, for at least the past 15 years, since Koop's 1988 report that declared nicotine to be addictive, tobacco consumers have been informed by tobacco-control advocates that they are addicted to the substance in most recommended smoking cessation products, nicotine. New consumer beliefs about their addiction to nicotine ironically tend to support the market for smoking cessation products.

Through tobacco-control advocacy, smokers have been juxtaposed between an addiction rock and a cancer hard place: One is allegedly addicted to nicotine and must use replacement therapy to quit smoking, yet the products that deliver nonsmoked nicotine apparently can lead to cancer, like tobacco.

The theme that nicotine is highly addictive has been created by tobacco-control advocacy. Aggressively promoting consumer choice of pharmaceutical nicotine replacement therapy products is also part of tobacco-control advocacy. Such recommendations are part of most smoking cessation programs.

Although smoking can be habit-forming and human biology becomes used to

regular intake of nicotine (thereby creating a mild addiction), the promotion of a public perception that nicotine is highly addictive is used to promote consumption of pharmaceutical nicotine products over alternative methods for smokers to stop smoking.

In addition, that perception is being used to promote pharmaceutical nicotine products as a continuing-use substance for the "addicted" smoker instead of a temporary smoking cessation method.

We need to develop a broader and more effective means of addressing the issues. Financial and civil accountability through our judicial process could be more effective. That is, after all, what worked with tobacco companies.

Earnest and public-spirited lawyers can comprehend and seize the opportunity that such policy has created. The good news is that both tobacco-control policy and its financial support money trails are clearly defined. Those trails lead directly to an expanded market for pharmaceutical nicotine products that has been socially engineered through promoting new public beliefs about nicotine.

Now that many of those beliefs are being proved false, indeed medically dangerous, their tragic consequences to consumers should be reviewed vigorously under the disciplined light of judicial discovery.

Perhaps in the end, we will find that unrestrained greed expressed through selling addiction beliefs to consumers and socially engineering markets for medically dangerous products is the true Achilles Heel of tobacco-control advocacy.

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