



Big Drug's

Nicotine War

By Wanda Hamilton

Overview

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“...a series of technological, economic, political, regulatory and social developments augurs a strange bedfellows competition in which these industries [tobacco and pharmaceutical] will vie for shares of a new multibillion dollar long-term nicotine-maintenance market.”

- Kenneth Warner, John Slade and David Sweanor, “The emerging market for long-term nicotine maintenance,” *Journal of the American Medical Assn.*, Oct. 1, 1997.

“I am pleased to announce a new partnership here today. We have just set up a Partnership Project in our European Region, with the objective of reducing tobacco-related death and disease among smokers.... Three major pharmaceutical companies have joined this partnership: Glaxo Wellcome, Novartis, and Pharmacia & Upjohn. They all manufacture treatment products against tobacco dependence.”

- Gro Harlem Brundtland, Director-General of the World Health Organization, Speech delivered at The World Economic Forum, Davos, Switzerland, Jan. 30, 1999.

“The support provided by Pharmacia and other committed [pharmaceutical] companies is invaluable in helping us achieve our goals. Their combined resources enable us to strengthen and expand our global leadership to increase the number of organizations and individuals engaged in the fight against tobacco. Collectively, we can promote the societal, political, and economic changes necessary to reduce tobacco exposure and use worldwide.”

Thomas Houston, M.D., Director, Science and Public Health Advocacy, American Medical Association; Co-director of The Robert Wood Johnson Foundation’s SmokeLess States Program; Co-chair, Executive Committee, World Conference on Tobacco OR Health, Aug 6 – 10, 2000. Quoted in Pharmacia press release, Aug. 7, 2000.

The air was decidedly un-smoky at the 11th World Conference on Tobacco and Health in Chicago in early August 2000. Thousands of leading tobacco control advocates from all over the world had assembled to discuss how they might drive Demon Tobacco from the face of the earth.

The American Medical Association, the American Cancer Society, and the Robert Wood Johnson Foundation co-hosted the conference, which was billed as “the world’s largest gathering of tobacco-control experts.” Co-sponsors were the American Heart Association, the American Lung Association, the U.S. Centers for Disease Control and Prevention, and the National Cancer Institute. The World Health Organization (WHO) and the United Nations Foundation served as “honorary hosts.” Gro Harlem Brundtland, Director of the WHO, was even on hand to give a spirited keynote address.

Chipping in for a good portion of the funding for the conference as “primary patrons” were four major pharmaceutical multinationals: Glaxo Wellcome, Novartis, Pharmacia and SmithKline Beecham, all of whom make and/or market “nicotine replacement” or other smoking cessation products. Johnson & Johnson’s McNeil Consumer Products, marketers of Nicotrol, was well represented by the Robert Wood Johnson Foundation, which receives almost all its roughly \$8 billion from shares of J&J stock.

So strong was the presence of the pharmaceuticals that the conference appears to have been more a drug trade show than a legitimate global public health meeting.

In addition to putting out numerous self-promoting press releases, the pharmaceutical companies also sponsored symposia, paper presentations, scholarships, a poster session, presentation of a Public Service Announcement ad campaign, sessions on research, and trade booths. They also sponsored a session on a “cessation treatment” database, funded by the drug companies for the Society for Research on Nicotine and Tobacco. The WHO, the Centers for Disease Control, the World Bank, and the Cochrane Tobacco Addiction Group provided “expert technical support” for the treatment database.

One of the most popular sessions of the entire conference, with more than 4,000 attendees, was “Nicotine Plenary: The Greatest Science Show on Earth,” sponsored by SmithKline Beecham [SKB], marketers of the Nicoderm patch and Nicorette gum. According to an SKB press release of Aug 9, the session “examined a case study on the introduction of ‘light’ and ‘reduced risk’ cigarettes to the consumer market.”

Another SKB-supported session, led by Judith Wilkenfeld of the Campaign for Tobacco-Free Kids and Karen Gerlach of the Robert Wood Johnson Foundation, “‘Light’ Cigarettes: Problems and Possible Solutions,” covered such topics as “science and public health-based approaches to countering tobacco industry tactics,” according to an SKB press release.

SmithKline Beecham and Glaxo Wellcome (which have merged since the conference), jointly sponsored a session entitled, “Does Treatment Support Prevention?” and Pharmacia sponsored a session on “Progress in Treatment with NRT [Nicotine Replacement Therapy].”

All in all, the 11th World Conference on Tobacco and Health was a highly successful marketing opportunity for the pharmaceutical industry. It strengthened their already close relationship with the global anti-tobacco organizations, the medical establishment, the WHO, and agencies of the U.S. federal government. It also ensured that the global public health community would enthusiastically continue promoting the companies’ cessation drugs. Even more than that, it assured the drug companies that their campaign to wrest control of nicotine from the tobacco companies was right on track.

In The Beginning

The 11th World Conference was the culmination of years of planning and work on the part of the pharmaceutical companies. When Pharmacia’s scientists began trying to develop “alternative” nicotine products back in 1962--two years before the first Surgeon General’s report on the health effects of smoking--the company was no doubt aware of the growing body of research linking lung cancer to smoking. Presumably Pharmacia thought it could capitalize on what it believed would be a growing market for smoking cessation products. However, if that was Pharmacia’s intent, it means they were already aware that nicotine was the substance in tobacco that was “habituating.”

Pharmacia was indeed the first pharmaceutical company to manufacture a product for nicotine replacement therapy [NRT]. It developed nicotine gum in 1971, and in 1978 SmithKline Beecham began marketing the gum as “Nicorette” in Switzerland.

In the early 1980s Duke University researcher Jed Rose invented and patented the transdermal nicotine patch which became the basis for SmithKline’s Nicoderm and for Johnson & Johnson subsidiary McNeil Consumer Products’ Nicotrol. The FDA first approved these products for marketing as prescription smoking cessation drugs in the U.S. in 1991. Both patches, as well as Nicorette gum, are actually manufactured by Pharmacia.

But the key event which turned these relatively ineffectual smoking cessation products into pure gold was Surgeon General C. Everett Koop’s report of 1988, “The Health Consequences of Smoking: Nicotine Addiction.” Prior to this report, all the previous reports of the Surgeon General had characterized the nicotine in tobacco as “habituating,” but the 1988 report effectively changed the definition of addiction to include the nicotine in tobacco products. Thus was a smoking “habit” turned into an “addiction” which needed to be “*treated*” by behavioral therapists and pharmaceutical cessation aids.

Therapeutic Nicotine

Meanwhile, researchers were discovering that nicotine had possible therapeutic applications for the treatment of certain diseases. They already knew that nicotine improved concentration and motor control, that it increased the pain threshold in some individuals, that it helped ward off hunger. For all these reasons, cigarettes were readily and copiously supplied to soldiers during World Wars I and II. But research was also

indicating that nicotine could be used in the treatment of such debilitating conditions as Alzheimer's and Parkinson's diseases.

Since then, many more therapeutic uses of nicotine and tobacco have been discovered, but the problem for the pharmaceutical companies was that nicotine itself cannot be patented because it occurs naturally in tobacco, tomatoes, potatoes and other plants. What *can* be patented are “nicotinic” compounds and nicotine delivery devices. Thus the pharmaceutical companies became increasingly interested in developing new nicotine compounds and new nicotine delivery devices that they could then patent, not only for smoking cessation but eventually for additional therapeutic uses.

Co-opting Public Health

Given that by the 1980s the public health establishment was already ramping up for a full assault on smoking as a public health issue, the pharmaceutical companies saw a golden opportunity for advancing their own nicotine products as smoking cessation aids. What could be better than having such revered entities as the Surgeon General, the AMA, the American Cancer Society, the American Lung Association, the American Heart Association, the Centers for Disease Control, the National Cancer Institute, other U.S. government agencies (and, later, the WHO) actually help market smoking cessation drugs as part of their smoking eradication programs?

And so, by the early 1990s the pharmaceutical companies began building partnerships with the public health establishment. In 1991 the Robert Wood Johnson Foundation, the largest single shareholder in Johnson & Johnson, initiated its anti-tobacco grant program, funding anti-tobacco programs and nicotine addiction research. By 1995 a RWJF representative sat on the U.S. Interagency Committee on Smoking and Health, helping coordinate the national tobacco control program. By 1996 the CDC listed the RWJF as a “partner” in tobacco control. Also in 1996, the RWJF funded the establishment of the Tobacco-Free Kids Coalition along with its “partners,” the American Cancer Society, the American Lung Association, and the American Heart Association. In 1999 the RWJF, the National Cancer Institute and the National Institute on Drug Abuse announced a jointly funded and jointly created “Transdisciplinary Tobacco Use Research Centers” to be established at seven academic institutions.

The other major pharmaceutical companies were also increasingly funding tobacco control in the U.S. and abroad. In January 1999 Gro Harlem Brundtland announced that Glaxo Wellcome, Novartis, and Pharmacia had become “partners” with the WHO in its anti-tobacco work.

The global public health establishment now dances to the tunes the pharmaceuticals play:

1. Increase tobacco taxes to make the price of the pharmaceutical products more competitive with tobacco products.
2. Demonize the tobacco industry and prohibit the advertising of their products.
3. Enact smoking bans to force smokers either to attempt to give up smoking using the pharmaceuticals' products or to use “nicotine replacement” products as substitutes for when they cannot smoke.
4. Promote smoking cessation and “treatment” for nicotine addiction.
5. Promote full coverage for treatment of nicotine addiction by public and private health insurers.

All these strategies are guaranteed to increase the pharmaceuticals' profits. And this is why they could afford to throw a big, tax-deductible, celebratory party for the global tobacco control establishment in Chicago in August of 2000, the 11th World Conference on Tobacco and Health. The pharmaceutical companies felt they were well on their way to winning the nicotine war.

I - The Nicotine War: A Chronology

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(From the CDC's "Chronology Significant Developments Related to Smoking and Health, 1964-1996" and other sources)

- **1962** – Pharmacia's scientists begin researching nicotine replacement therapy.
- **1971** – Pharmacia develops nicotine gum.
- **1978** – SmithKline Beecham launches Nicorette gum in Switzerland.
- **Early 1980s** – Jed Rose invents the nicotine patch.
- **1984** - FDA approves nicotine polacrilex gum as a "new drug" (Nicorette)
- **1984** - Interagency Committee on Smoking and Health established and empowered by the Comprehensive Tobacco Education Act to coordinate research, special projects, data gathering and education efforts on cigarettes both within the federal government and with private organizations. The committee will work with the Surgeon General's Office and the Office on Smoking and Health at the CDC. S.G chairs the committee.
- **1988** – Report of the S.G. concentrating exclusively on nicotine addiction.
- **1990** – S.G. report focuses on the health benefits of smoking cessation
- **1990** - David Kessler appointed to head FDA.
- **1991** - RWJF initiates its anti-tobacco grant program.
- **1991** – FDA approves a nicotine patch as a prescription drug.
- **1992** – Transdermal nicotine patch introduced.
- **1993** - FDA prohibits over-the-counter smoking-deterrent products because they have not been shown to be effective
- **1994** – FDA Commissioner Kessler testifies that cigarettes may qualify as drug delivery systems, bringing them within the jurisdiction of the FDA.
- **1994** – RWJF and AMA launch the "SmokeLess States" grant program to fund local initiatives for tobacco use prevention.
- **1995** - RWJF Vice President Nancy Kaufman officially becomes a member of the federal Interagency Committee on Smoking and Health. As of 2000, she is still a member.
- **1995** - FDA Commissioner Kessler declares tobacco use a "pediatric disease."
- **1996** – RWJF grants St. Peter's Medical Center \$27,883 for a meeting "to explore public health implications of alternative nicotine delivery devices."
- **1996**- RWJF grant to the American Society of Addiction Medicine, Inc., Chevy Chase, MD, \$197,884 for "Workshop and policy panel on alternative nicotine delivery systems." (1 year)
- **1996** – National Center for Tobacco-Free Kids established with primary funding from RWJF.
- **1996** – RWJF gives the National Foundation for the Centers for Disease Control and Prevention, Atlanta, GA, \$451,185 for "Research on racial and gender differences in teen smoking" (for 1 year).
- **1996** - February (gum); July (patch). FDA approves nicotine gum and two nicotine patches for over-the-counter sale.
- **1996** – August , 1996, Publication of a final rule on tobacco in the Federal Register to enable the FDA to regulate the sale and distribution of cigarettes and smokeless tobacco to children and adolescents.
- **1996** – September. First inhaled dosage form of nicotine, Nicotrol NS, launched.
- **1997** – FDA relaxes restrictions on TV ads for prescription drugs.
- **1997** – J. Michael McGinnis, former Dept. of Health and Human Services, Disease Prevention and Health Promotion deputy assistant secretary for health and assistant surgeon general, is hired as a consultant by the RWJF. He is also a consultant to the WHO and the National Academy of Sciences.
- **1997** – May. FDA approves a prescription-only oral inhalation system (Nicotrol Inhaler) for nicotine replacement therapy.
- **1997** – David Kessler resigns from FDA.

- **1997** – U.S. District Court Judge William Osteen, Sr. upholds FDA power to regulate access to tobacco products, but invalidates the proposed advertising restrictions. Both sides appeal.
- **1998** – July 27. At a conference on nicotine addiction sponsored jointly by the National Institute on Drug Abuse, the National Institutes of Health, and the Robert Wood Johnson Foundation, VP Gore announces the National Cancer Institute's plans to allocate \$38 million for additional research into tobacco prevention and cessation programs.
- **1998** – August. U.S. Court of Appeals for the 4th Circuit overturns Osteen's ruling, saying the FDA lacks authority over tobacco.
- **1999** – October 18. The National Institute on Drug Abuse, the National Cancer Institute, and the Robert Wood Johnson Foundation announce the jointly funded and jointly created Transdisciplinary Tobacco Use Research Centers at seven academic institutions.
- **1999** – FDA approves combined use of bupropion (Zyban) and the patch for treating the symptoms of smoking cessation.
- **2000** – March. The Supreme Court rules that the FDA lacks the authority to regulate tobacco.
- **2000** – Surgeon General report on "Reducing Tobacco Use," which also emphasizes smoking cessation therapy.
- **2001** – May 29. Jed Rose and Eric Westmann announce they have developed nicotine drops for smoking cessation. Their research was funded by the U.S. Department of Veterans Affairs.

W. Hamilton 6/8/01

II - Pharmaceutical Players: Drug Companies Involved With “Cessation” Products

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Johnson & Johnson – Under the banner of its subsidiary, McNeil Consumer Products, J&J markets the Nicotrol nicotine patch and nicotine inhaler. The Robert Wood Johnson Foundation is the biggest single shareholder in J&J and began its massive funding of tobacco control in the U.S. in 1991, the same year the FDA approved the nicotine patch as a prescription drug. **Pharmacia** reacquired the rights to market the Nicotrol Inhaler in North America from J&J's McNeil in July 2000.

GlaxoSmithKline – Pharmaceutical giants Glaxo Wellcome and SmithKline Beecham merged on December 27, 2000, making the new company the world's biggest drugs group by sales. Glaxo Wellcome markets **Zyban** (bupropion) and SKB markets **Nicoderm CQ** nicotine patch and **Nicorette** gum. One of the major holdups in getting FTC approval for the merger was that both companies sold smoking cessation products, but even though these cessation products accounted for less than 4% of SK's sales, neither company was willing for them to be sold to another pharmaceutical company to facilitate the merger. SK was also investigated by a congressional committee for overpricing of cancer treatments. SK infuriated the committee by refusing to hand over information about Kytril, its anti-nausea drug for chemotherapy patients. [“Federal smoke delays merger,” Andrew Clark, *The Guardian*, 10/10/2000].

In 1999, SmithKline Beecham Consumer Healthcare's combined U.S. sales of Nicorette and NicoDerm CQ reached \$570 million. The company also markets its nicotine patch under the trade name “**NiQuitin CQ**” in Belgium, France, Denmark, Mexico and Brazil and under “**Nicabate**” in Australia and New Zealand, where it was the number one smoking cessation product in 1999 [Philippe Boucher's *Rendez-vous* with Leslie A. Ashburn, Communications Supervisor for GlaxoSmithKline, 1/29/01].

During the interview, Ashburn sketches GSK's involvement with tobacco control:

“Treatment marketers, both individually and collaboratively, have continued to pursue involvement with the broader tobacco control community. Their involvement has ranged from establishing and supporting tobacco control programs, to conducting and disseminating primary research. Most recently at the 11th World Conference on Tobacco OR Health in Chicago, several major pharmaceutical companies, including GSK, united to support a variety of initiatives in the hopes of advancing the important role of smoking cessation treatment in the U.S. and international tobacco control policy. These initiatives include a scholarship program to support training in tobacco control, the WHO European Partnership on Tobacco Dependence, a public service announcement campaign and a treatment database, which will house a comprehensive library of tobacco-related resources.

“In the United States, GSK has formed a partnership with the American Cancer Society to educate the public about the dangers of tobacco use.... Among the collaborative efforts undertaken by GSK and the American Cancer Society is the Great American Smokeout....[SK also paid ACS \$1 million a year for use of the ACS logo in its ads for Nicoderm CQ].

“Additionally, GSK is a founding member of The Coalition for World No Tobacco Day, a non-profit organization dedicated to raising awareness about World No Tobacco Day in the United States. Established by the World Health Organization in 1988 and observed annually on May 31st, World No Tobacco Day is the only event that gives smokers around the world the opportunity to unite and halt tobacco use.”

Glaxo Wellcome signed on as a partner in the WHO's global tobacco control program in late 1998.

“For [Glaxo India] Zyban comes at a time when it has had a lackluster financial performance with not many product launches to prop up the bottom line.

“Zyban, which is in the top 10 list of new products for parent firm GlaxoSmithKline in 2000, is seen by Glaxo to be a potential ‘blockbuster’ in India, which has about 37 million smokers.” [“Glaxo brings Zyban to smoke out addiction,” Gauri Kamath, *The Economic Times*, 3/14/01].

Glaxo Wellcome sues IMPAX Laboratories, Inc., over generic versions of bupropion (Zyban and Wellbutrin). According to IMPAX Co-CEO Barry Edwards, the suit is a tactic to extend the exclusive marketing of the product by Glaxo. “It has been estimated that in the next few years branded pharmaceutical companies will lose patent protection on drugs with over \$25 billion in annual sales.... The filing of patent-infringement lawsuits is just one of the tactics these companies use in an attempt to extend marketing exclusivity of a product. Therefore, although we believe this suit is without merit, we are not surprised by its filing.” [“IMPAX Comments On Lawsuit Filed by Glaxo Wellcome Related to Generic Versions of Wellbutrin SR and Zyban,” Company Press Release, 10/10/2000].

Pharmacia - (Also Pharmacia & Upjohn). Makes **Nicorette** and **Nicotrol**, “a family of tobacco dependence therapies.” [“About Pharmacia & Upjohn,” company website, as of 1/15/00]. Pharmacia & Upjohn Consumer Healthcare “develops, manufactures and sells safe and efficacious OTC (Over the Counter) products.... A number of products are also sold globally. Among the company’s largest and most well-known brands is a line of nicotine replacement products, including nicotine gum, transdermal patch, and nasal spray and inhaler.”

Pharmacia & Upjohn are one of three pharmaceutical “partners” in the WHO global anti-tobacco project. “Pharmacia & Upjohn announced a 17 percent increase in first-quarter earnings Thursday, as U.S. drug sales soared for its top three medicines.... Sales climbed 12 percent to \$1.77 billion from \$1.59 billion a year ago. Pharmacia, which makes Xanax anti-anxiety medication and Nicorette smoking cessation products, has completed a massive turnaround in the past two years” [“Pharmacia & Upjohn Profits Rise, AP, 4/29/99].

“Pharmacia & Upjohn Inc.’s Japanese unit saw sales of its Nicorette antismoking gum rise 50% in 1998 over a year earlier” [“Sales of Nicorette Gum Make Gains in Japan,” *Wall St. Journal*, 5/14/99].

“Pharmacia Canada, Inc. and **Aventis Pharma, Inc.** today announced the closing of a transaction whereby Pharmacia acquires the Canadian Nicotine Replacement Therapy business of Aventis Pharma. Under the terms of the agreement, Pharmacia is acquiring the Nicoderm brand transdermal nicotine patch and re-acquiring the sales and marketing rights to its Nicorette brand gum.” Pharmacia Corporation is a global pharmaceutical company created through the merger of **Pharmacia & Upjohn with Monsanto Company and its G.D. Searle unit.** [“Pharmacia Consumer Healthcare acquires Nicotine Replacement Therapy (NRT) business of Aventis Pharma Inc,” Company Press Release, 1/26/01]

“ATP [**Advanced Tobacco Products, Inc./Advanced Therapeutic Products**] sold their patented nicotine technology, which forms the basis of the Nicorette/Nicotrol Inhaler, to what is now Pharmacia Corporation, in exchange for product payments of 3% of Pharmacia’s net sales. In July, Pharmacia announced it had reacquired the rights to market the Nicotrol Inhaler in North America from McNeil PPC, Inc., a unit of Johnson & Johnson. As a result of the Nicotrol takeback, Pharmacia said it has a renewed interest in consumer advertising as well as the professional detailing of doctors and healthcare providers.” [“ATP Announces Fiscal Year Results, Dividend Payments & British Medical Study of the Nicotine Inhaler,” Company Press Release, 11/28/2000]

Hoechst Marion Roussel (the pharmaceutical company of Hoechst) – Manufactures and markets Nicorette gum and Nicoderm patches in Canada. “NRT products have been available in Canada since 1979, and were cleared for non-prescription sale by Health Canada in 1993 (2mg Nicorette), 1997 (4mg Nicorette) and 1998 (Nicoderm and other patches....’When these products became more easily available in the U.S. three years

ago, the number of quit attempts doubled in one year,” says Tony Ruta, Hoechst Marion Roussel spokesman. [“Nicotine therapies critical piece in Ontario tobacco strategy,” Company Press Release, 4/23/99].

Novartis – Maker of the Habitrol patch in Canada. Novartis Consumer Health Canada, Inc. [“Habitrol nicotine patch now available in Ontario without a prescription, Canada Newswire, 4/23/99].

Novartis is one of the three major pharmaceutical partners with WHO in the WHO global tobacco control program.

“Novartis Pharma To Launch Nicotine Patches in Japan, “ NewsEdge, 5/11/99. “Although the patches are available over-the-counter in 29 countries, they will require a doctor’s prescription in Japan and will not be covered by insurance.”

Pfizer – Discovers, develops, manufactures and markets leading prescription medicines for humans and animals, and many of the world’s best known consumer products. Pfizer had global revenues of \$29.6 billion in 2000. In 2000 Pfizer took over **Warner-Lambert**. Pfizer is developing a new agent for smoking cessation, currently known as CP-526,555, “that relieves both cravings and withdrawal symptoms and blocks the reinforcing effect of smoking.” [“Pfizer to Advance Industry Leadership Through the Best People, Products And Pipeline, Steere Tells Shareholders,” Company Press Release, 4/26/01].

III - Gold In Nicotine

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“It helps digestion, the gout, the toothache, prevents infection by scents; it heats the cold, and cools them that sweat, feedeth the hungry, spent spirits restoreth, purgeth the stomach, killeth nits and lice; the juice of the green leaf healeth green wounds, although poisoned; the syrup for many diseases; the smoke for the phthisic, cough of the lungs, distillations of rheum, and all diseases of a cold and moist cause; good for all bodies cold and moist taken upon an empty stomach; taken upon a full stomach it precipitates digestion.”

John Josselyn on the medicinal uses of tobacco, 1675 (quoted in C.A. Weslager, *Magic Medicines of the Indians*, Signet, NY: 1974)

“Nicotine is an amazing chemical.”

Jack Henningfield, 1998 (quoted in “Smoking Aside, Nicotine Remains an Amazing Chemical,” Scott Shane, *The Seattle Times*, 1/11/98, p. A10). Henningfield, a pharmacologist at Johns Hopkins and former National Institute of Drug Abuse scientist, is also a consultant to SmithKline Beecham.

Tobacco was used medicinally by the indigenous populations in the Americas long before the arrival of European settlers. After the Europeans began to colonize the New World, they too used it to treat numerous physical diseases and complaints, a practice which continued in American folk remedies until well into the 20th century.

However, as the anti-tobacco movement gained strength and momentum in the 1980s, both tobacco and the nicotine it contained were excoriated by public health officials. And in 1988 the U.S. Surgeon General’s report for the first time asserted that nicotine was an addictive drug, chaining smokers to their cigarettes. This claim has become a favored weapon not only of the anti-tobacco establishment but also of trial attorneys attempting to win huge sums of money in lawsuits against the tobacco industry.

Pharmacologists and other scientists, who had been investigating the physiological effects of nicotine since at least the 1950s, began to find that nicotine could have significant therapeutic applications, both as a stop-smoking aid and as a medicine for treating various diseases. Their interest in nicotine increased as new discoveries about the substance emerged.

A time-specific online search of the National Library of Medicine’s PubMed database demonstrates quite well the pattern of increasing scientific interest in nicotine. Between 1963 (the earliest publication year PubMed indexes) and 1970, 1092 articles on nicotine are listed; between 1971 and 1980, 2346 articles are listed; between 1981 and 1990, 3771 articles are listed; and between 1991 and 2000, 6919 articles are listed. In other words, in thirty-seven years, published research involving nicotine multiplied by more than a factor of six.

The pharmaceutical industry had seen for some time the potential profits in developing nicotine-based smoking-cessation drugs. In 1962, Pharmacia’s scientists began working on such nicotine delivery devices, and by 1971 they had perfected nicotine-laden gum, which was later marketed by SmithKline Beecham as Nicorette. As the anti-tobacco movement grew, other pharmaceutical companies became interested in the potentially huge market for smoking-cessation products. When researcher Jed Rose developed the transdermal nicotine patch in the early 1980s, the pharmaceutical industry was quick to begin steps to bring it to market.

It wasn’t just the smoking-cessation applications of alternate nicotine delivery systems that interested the drug companies, of course, but a multitude of other pharmacological applications as well.

As Jed Rose, developer of the transdermal nicotine patch said, “There is a tremendous growth of interest in the nicotine field. There’s been a virtual explosion of new findings on every level,” (“A Cigarette Chemical Packed with Helpful Effects?” John Schwartz, *The Washington Post*, 11/9/98, p. A10).

Nicotine: The Wonder Drug

“The importance of nicotine’s safety, especially its long-term safety, is related not only to its role in the cessation of smoking but also to its potential role in the treatment of many clinical conditions.”

Alexander Glassman, M.D., Book Review of *Nicotine Safety and Toxicity*, Ed. by Neal L. Benowitz, NY, Oxford Univ. Press, 1998, in *The New England Journal of Medicine*, 2/18/99.

Some of the already established pharmacologic applications of nicotine include: pain relief, relief of anxiety and depression; improvement in concentration and performance in those with attention deficit hyperactivity disorders; relief of some of the symptoms of acute schizophrenia; relief of some of the symptoms of Tourette’s syndrome; relief of some of the symptoms of Parkinson’s disease; and relief of some of the symptoms of Alzheimer’s disease.

New, cutting-edge research indicates even greater medical applications for nicotine:

- **“This study demonstrates that nicotine stimulates recovery from brain damage and the results are discussed in relation to neural mechanism and potential applications.”** (Brown RW, Gonzalez CL, Whishaw IQ, Kolb B, “Nicotine improvement of Morris water task performance after fimbria-fornix lesion is blocked by mecamylamine,” *Behav Brain Research*, Mar 15, 2001.)
- **“The research, involving animal studies, showed that the nicotine agent created more new blood vessels in blocked arteries than any other known growth factor. The new agent could be used to treat failing hearts and limbs with poor circulation. It holds the potential for non-surgical heart by-pass procedures.”** (Company Press Release, “Research Indicating That Nicotine Holds Potential for Non-Surgical Heart By-Pass Procedures Honored by the American College of Cardiology,” 3/17/00)
- **“Nicotine might be a surprising alternative someday for treating stubborn forms of tuberculosis....’The compound stopped the growth of tuberculosis in laboratory tests, even when used in small quantities,’ said Saleh Naser, an associate professor of microbiology and molecular biology at UCF.... Naser said nicotine worked better than about 10 other substances also tested.”** (“Shocker: ‘Villain’ nicotine slays TB,” Robyn Suriano, Orlando Sentinel, 5/22/01).
- **“In addition, nicotine can exert a neuroprotective effect by attenuation of AA-induced upregulation of nNOS metabolism. These data may have therapeutic implication for the treatment of acute spinal cord trauma.”** (Toborek M, Garrido R, Malecki A, Kaiser S, et al, “Nicotine Attenuates Arachidonic Acid-Induced Overexpression of Nitric Oxide Synthase in Cultured Spinal Cord Neurons,” *Experimental Neurology*, 161(2), Feb 2000).
- **“According to a new study, nicotine may reduce cramping and other symptoms of colitis, a painful intestinal disease that affects hundreds of thousands of people in the U.S. and millions around the world. The study, published in the Annals of Internal Medicine (Mar 1, 1997), could lead to better treatment for the estimated 320,000 people who suffer from ulcerative colitis in the US.”** (AP, Mar 1, 1997).
- **Possible use of nicotine in the prevention of classical Kaposi’s sarcoma with KS herpes virus infection.** (Goedert J, Vitale F, Lorenzo G, Romano N, National Cancer Institute, “Classical Kaposi’s Sarcoma With KS Herpes Virus Infection: Reduced Risk with Cigarette Smoking,” *Proceedings of the American Association for Cancer Research*, Vol 42, March 2001).
- **Treatment of clinical depression. “That could mean a whole new arena for new antidepressant drugs. It’s quite possible you could make derivatives of nicotine that wouldn’t have the medical complications of nicotine but could prove very useful in the treatment of clinical depression.”** Dr. Alexander Glassman, chief of clinical psychopharmacology at Columbia University’s New

York State Psychiatric Institute (quoted in “Kicking Habit Kicks Up Depression,” Neil Sherman, HealthScout, 6/19/01).

Given studies such as these, in addition to the wealth of studies on the established therapeutic applications of nicotine, it's not difficult to understand the drug industry's interest in the substance. Though the pharmaceutical companies cannot patent nicotine per se, they *can* patent nicotine delivery devices and new therapeutic compounds containing nicotine as a primary ingredient. In fact, they have already accomplished a portion of this task by patenting nicotine delivery devices as smoking cessation aids and receiving FDA approval for their efficacy and safety. The pharmaceutical industry would of course be delighted if the tobacco companies and their “nicotine delivery devices” (i.e. cigarettes) were eradicated entirely. Then Big Drugs would be the sole provider of nicotine to the world.

Tobacco Companies and Therapeutic Nicotine

Despite Big Drugs' efforts to wrest control of nicotine from the proprietary hands of the tobacco industry, some of the tobacco companies are fighting back by starting pharmaceutical companies of their own.

In 1997 R J Reynolds formed Targacept, Inc., a pharmaceutical division focusing on developing “compounds” to treat such disorders as Alzheimer's, Parkinson's, depression, pain, ulcerative colitis, Tourette's Syndrome, attention deficit disorder and schizophrenia--all of which had been shown to respond to treatment with nicotine. On August 24, 2000, RJR announced that it had spun off Targacept after completing a \$30.4 million equity financing with lead investor EuclidSR Partners and other venture investors. RJR will own 43 percent of the new company, which has “more than 60 issued patents and pending applications, as well as hundreds of compounds that may have the potential to treat disease,” (PR Newswire, company press release, 8/25/2000).

On February 8, 1999, Rhone-Poulenc Rorer, a global pharmaceutical company, announced an alliance with Targacept for a “collaborative research, development and commercialization agreement...to develop new drugs to treat Alzheimer's and Parkinson's diseases” (Company Press Release, 2/9/99).

Japan Tobacco, now the world's third largest tobacco company, also has a pharmaceutical arm. On Oct. 26, 1997 Johnson & Johnson, marketers of Nicotrol, announced it had signed a licensing agreement with Japan Tobacco for the rights to a novel class of compounds for the treatment of pain and inflammation. J&J would have exclusive rights to develop and market the “compounds” worldwide except in Japan and South Korea. J&J ended the licensing agreement in July 2000, but Japan Tobacco said it would continue trials of the drug in Japan and consider other options for its development and marketing overseas.

In May 2001 Brown & Williamson, a division of British American Tobacco, announced the release of Ariva, a mint hard candy containing as much nicotine as a cigarette. B&W did not claim therapeutic uses for the candy, but said it was for smokers to use in venues where they cannot smoke.

Also in May 2001, chewing tobacco and snuff giant Swedish Match announced the development of a nicotine gum which would be launched in Europe later in the year. As with the mint candy, no therapeutic applications are claimed. Swedish Match is simply billing it as an alternative chew.

Nicotine is indeed a wondrous substance. It can be used as a pesticide and is toxic in sufficient quantities at sufficient strength, but it can also heal and soothe man's body and soul. The Indians revered the tobacco plant, the greatest natural source of nicotine, as a gift from the gods. Now it appears that multinational corporations are battling over golden nicotine just as European countries battled over control of the New World's gold more than four centuries ago.

IV - The Demonization of the Tobacco Industry

Publication date: July 13, 2001

“We can also report that there has been a significant reduction in the tar yield of American cigarettes, a reduction which we hope will continue; that the tumorigenic activity of tobacco as measured in animal studies, has decreased; and that as a consequence of the above, the risk of lung cancer and other tobacco-related cancers among smokers of these cigarettes is lower than in years past. It is unlikely that man will ever be able to inhale smoke components as harmless as unpolluted air, but as long as we have a society which accepts this habit and as long as people find satisfaction in smoking, we must work toward the day when tobacco-related cancers and other diseases will be reduced to a minimum. With the world wide cooperation of the scientific community, the Departments of Agriculture, and the tobacco industry, it is our hope that this goal will be achieved.”

Wynder EL, Hoffmann D, “Tobacco and tobacco smoke,” *Semin Oncology*, Mar 1976. Wynder and Hoffmann pioneered research in the U.S., which linked smoking to lung cancer. Their work was central to the 1964 U.S. Surgeon General’s report on smoking and lung cancer.

“We know the best way to help people stop using tobacco is to raise its price, to make nicotine replacement therapy available, to control smuggling and avoid [tobacco] advertising. Companies [tobacco companies] have initiated elaborate schemes to fight Governments’ and WHO’s efforts to limit tobacco use.”

Gro Harlem Brundtland, Opening Remarks, 11th Global Conference on Tobacco or Health, Aug 6, 2000.

“The Council is particularly concerned when we hear pharmaceutical companies put in the same category as tobacco companies and polluters....”

National Health Council press release, 8/18/2000. The NHC is a private nonprofit organization of “national health-related organizations,” many of which are pharmaceutical corporations, along with such organizations as the AMA, the ACS, the ALA, the American Public Health Association and private health insurers.

In any war, it is necessary to conjure up a villain. The Nicotine War is no exception, and the U.S. and British cigarette manufacturers have been deliberately cast in that role. So successful has been the campaign to demonize the tobacco industry that any individual or organization accepting any tobacco funding or even defending the tobacco industry is demonized by association. The careers of highly respected scientists have been destroyed if even a fraction of their independent research was funded by the tobacco industry. Even the National 4-H Club, a squeaky-clean youth organization, was verbally stoned for accepting a no-strings-attached tobacco industry grant to fund the organization’s campaign against underage tobacco use.

But the tobacco industry was not considered to be “the enemy” back in 1976 when preeminent lung cancer researcher Ernst Wynder spoke approvingly of worldwide cooperation among the scientific community, the departments of agriculture and the tobacco industry. And for a time there was cooperation. From 1968 until 1980 National Cancer Institute scientists and others worked alongside tobacco industry scientists in a federal program to develop safer cigarettes. The federal government terminated the program abruptly in 1980.

Though the U.S. Surgeon General’s reports up to 1989 warned of the health risks of smoking, they did not vilify the tobacco industry. The only reference to the tobacco industry in the preface of the 1989 S.G.’s report, “Reducing the Health Consequences of Smoking: 25 Years of Progress,” was to cigarette marketing targeting “blacks and Hispanics.” But by 1994, the Surgeon General’s reports had stepped up their attacks on the tobacco industry and its marketing practices:

“Current research suggests that pervasive tobacco promotion has two major effects: it creates the perception that more people smoke than actually do, and it provides a conduit between actual self-image and ideal self-image—in other words, smoking is made to look cool. Whether causal or not, these effects foster the uptake of smoking, initiating for

many a dismal and relentless chain of events” (M. Joycelyn Elders, Surgeon General, Preface, “Preventing Tobacco Use Among Young People: A Report of the Surgeon General, 1994).

And by 2000, the Surgeon General’s report was out for tobacco industry blood.

“The most important force for smoking is the totality of industry activity, including advertising, promotion, organizational activity, support for ancillary issues, and political action, which maintains marketability and profitability of the product.” (Jeffrey Koplan, Director, Centers for Disease Control and Prevention, Foreword, “Reducing Tobacco Use: A Report of the Surgeon General, 2000).

The phrase “tobacco industry” appears countless times (always negatively) in the 2000 report, along with references to “marketing to children” and “addiction” and, of course, effective means of “treating” addiction. The report also calls for government regulation of tobacco products, enforcement of “clean indoor air standards,” and “protecting” children from the allure of tobacco products. And, unlike lung cancer expert Ernst Wynder, it warns against low-tar cigarettes.

“Cigarettes with low tar and nicotine contents are not substantially less hazardous than higher-yield brands. Consumers may be misled by the implied promise of reduced toxicity underlying the marketing of such brands” (a CDC “Tobacco Products Fact Sheet” for the 2000 S.G. report).

A time-limited search of PubMed using “tobacco industry” as a key phrase shows a similar pattern of increasing focus on the tobacco industry itself. For the sixteen years from 1965 through 1990 only 72 citations to published journal articles appear, but from 1991 through 2000--only nine years--888 citations for “tobacco industry” appear.

These trends would seem to indicate that the actual demonization of the tobacco industry began in the late 1980s or early 1990s, just about the time the FDA approved the nicotine patch and the pharmaceutical funding began flowing into the anti-tobacco movement.

The Pharmaceuticals

Paving the way for the pharmaceutical multinationals to enter the nicotine war were the 1988 U.S. Surgeon General’s report designating nicotine as an addictive drug and the 1990 Surgeon General’s report focusing on smoking cessation and “treatment” for nicotine “addiction.” But it was the U.S. Food and Drug Administration’s 1991 approval of the nicotine patch for smoking cessation that appears to have sounded the official call to action. The Robert Wood Johnson Foundation began funding anti-tobacco efforts in that same year.

It may be that the entrance of the pharmaceutical companies into the tobacco wars and the escalation of the attacks on the tobacco industry are purely coincidental, but the chronology of events suggests otherwise:

1988 – The report of the Surgeon General (C. Everett Koop) focuses exclusively on the nicotine in tobacco as an addictive drug.

1990 – The report of the Surgeon General (C. Everett Koop) focuses exclusively on smoking cessation.

1990 - David Kessler becomes FDA chief.

1991 – The FDA approves Johnson & Johnson’s Nicotrol and SmithKline Beecham’s Nicoderm as prescription smoking-cessation aids. Pharmacia’s and SmithKline Beecham’s Nicorette gum had been approved in 1984.

1991 – The Robert Wood Johnson Foundation (funded by stock ownership in J&J) begins focusing on tobacco control as a priority area and initiates a grant program to fund anti-tobacco efforts.

1991 – Nancy Kaufman joins the RWJF to work on tobacco control.

1992 – The nicotine patch (Nicotrol and Nicoderm) is introduced to the market.

1993 – The FDA prohibits over-the-counter smoking cessation products because they have not been proven to be effective according to FDA standards. SmithKline Beecham's Nicorette gum and Nicoderm patch, as well as J&J's Nicotrol patch are not affected since they are available only by prescription.

1994 – FDA Commissioner Kessler testifies that cigarettes may qualify as drug delivery systems, bringing them under FDA jurisdiction.

1994 – The RWJF launches its SmokeLess States tobacco control grant program, which is administered by the American Medical Association.

1995 – RWJF V.P Nancy Kaufman officially becomes a member of the federal Interagency Committee on Smoking and Health.

1995 – FDA Commissioner Kessler declares tobacco use a “pediatric disease.”

1996 – The RWJF provides primary funding for the establishment of the Tobacco-Free Kids coalition. TFK has always been extremely active in promoting the demonization of the tobacco industry.

1996 – The FDA approves Nicorette gum, the Nicotrol and Nicoderm patches for over-the-counter sale.

During this same period, particularly after the founding of Tobacco-Free Kids in 1996, the demonization of the tobacco industry became a full-fledged campaign by the tobacco control community, a campaign which also helped make nationwide litigation against the tobacco industry viable.

The Tobacco Industry As Scapegoat

During the 1990s the pharmaceutical industry was itself having some serious PR problems. Among other things, it was under attack for its heavy-handed marketing techniques and for maintaining artificially high prices for its products. The diversion of the public's (and the tort lawyers') attention to the “sins” of the tobacco industry helped draw attention away from the “sins” of the pharmaceutical companies.

It is no surprise, therefore, that RWJF's Nancy Kaufman rated as “a high leverage investment” the foundation's grants to economists “to develop the formulas to account for the cost of smoking to state medical assistance programs, that allowed the attorney's general to sue the [tobacco] industry” (Interview by Phillippe Boucher, “Rendez-vous with...Nancy J. Kaufman,” 2/16/01).

Focusing public attention on the “cost” of smoking-related illness was obviously preferable to having public attention drawn to the even higher “cost” of pharmaceutical drug-related illness. The highly publicized estimate for medical expenses for smoking-related illness was between \$50 and \$73 billion, but the estimate for medical expenses for drug-related illness was between \$30 and \$136.8 billion.

“Drug-related morbidity and mortality was estimated to cost \$76.6 billion in the ambulatory setting in the United States. The largest component of this total cost was associated with drug-

related hospitalizations. When assumptions of the model were varied, the estimated cost ranged from a conservative estimate of \$30.1 to \$136.8 billion in a worst-case scenario” (Johnson JA, Bootman JL, “Drug-related morbidity and mortality. A cost-of-illness model,” *Arch Intern Med*, Oct 9, 1995, pp. 1949-56.

And when WHO director Gro Harlem Brundtland began to lean on Glaxo Wellcome and other pharmaceutical companies about the high prices of their drugs (especially AIDS drugs) in developing countries, a number of the pharmaceutical companies and the international pharmaceutical trade association pledged funding and cooperation for the WHO's global anti-tobacco campaign:

“In Brundtland...pharmaceutical firms saw a likely ally. Gilmartin [CEO of Merck pharmaceuticals] had cultivated her for more than a year. He took Brundtland's counsel at gatherings of the global government and business elite in Davos, Switzerland, and he helped her round up \$1 million in private funds for her signature campaign against tobacco deaths. That cast another industry, as it happened, as the pariah.” (“A Turning Point That Left Millions Behind,” Barton Gellman, *Washington Post*, Dec 28, 2000, p. A01).

Establishing a highly publicized partnership with the WHO to eradicate the global “epidemic” of tobacco was a masterstroke for the pharmaceutical companies. It cast them in the role of heroes helping save the world from Demon Tobacco. At the same time, it diverted attention from their fierce battle to protect the relatively high prices of their patented drugs in Third World countries. But in addition to all that, it enlisted the World Health Organization in helping promote sales of smoking-cessation drugs all over the world.

The success of the campaign to demonize the tobacco industry has served the interests of the pharmaceutical multinationals very well on many fronts.

V - The Feds and the Pharms: An Unhealthy Alliance

Publication date: July 13, 2001

“A second and more serious problem is economic ties between NIH [National Institutes of Health] researchers and big drug companies, which some critics charge amount to payoffs. Earlier this week, for example, a Times report showed how the agency’s top diabetes researcher was accepting payments from at least four pharmaceutical companies that stood to gain from NIH research he directed, a clear ethics violation.

”There are also more subtle conflicts. The NIH’s cliquish ‘peer reviewers’ are often elite university researchers who may favor studies that, by proving the effectiveness of brand-name pharmaceutical drugs, bring in loads of drug company grant money for their academic departments.”

(“Flap Over ‘Public Science’,” Los Angeles Times, 1/30/99)

Though most Americans are scarcely aware of its existence, The Public Health Service (PHS) is one of the biggest and most powerful bureaucracies in the U.S. government. Its policies and regulations directly impact the lives of all Americans, and its influence is felt throughout the world. It is essentially the “Health” arm of the Department of Health and Human Services.

Though there is no question that the PHS and its agencies have contributed to the health and welfare of American citizens, there is also no question that it wastes as much money and is as prone to political influence and financial corruption as any other large bureaucracy. Perhaps no single issue better illustrates these abuses than the PHS’s involvement in the tobacco war.

No fewer than 81 different offices, agencies and programs in the PHS are involved in pursuing the war against tobacco. Eighty-one different federal entities getting funding and using staff and holding meetings to prevent American consumers from purchasing and using a legal product is surely a prime example of bureaucratic waste and overkill.

Yet another tax-funded entity, The Interagency Committee on Smoking and Health, exists for the sole purpose of coordinating governmental anti-tobacco efforts and those of non-governmental organizations such as the American Cancer Society. Headed by the Surgeon General, the Interagency Committee is composed of individuals from the public and the private sector. And therein lies the rub. Representatives from organizations with a financial stake in the tobacco war sit on the committee and help direct governmental anti-tobacco policy and programs. Robert Wood Johnson Foundation VP Nancy Kaufman has been a member of the committee since 1995, and the RWJF is the biggest single shareholder in Johnson & Johnson, marketers of smoking cessation drugs.

That pharmaceutical interests have direct input at the very top on governmental tobacco control policy is shocking enough, but it is not an isolated incidence. The PHS and its agencies are rife with such examples.

The PHS Clinical Practice Guideline

In June 2000, the U.S. Public Health Service released its “Clinical Practice Guideline” on treating tobacco use and dependence. The federal guideline, a PHS resource for physicians and others in clinical practice, recommended that every physician and every clinician in the U.S. repeatedly ask the smoking status of every patient they see. If the patient is a smoker, the guideline states he or she should be offered both cessation drugs and counseling. Prescription of at least one of five “first-line” smoking cessation drug therapies was recommended: sustained-release bupropion hydrochloride (Glaxo Wellcome’s Zyban), nicotine gum (Pharmacia and SmithKline) nicotine inhaler (Pharmacia and Johnson & Johnson), nicotine patch (Pharmacia, SmithKline, Johnson & Johnson), and nicotine nasal spray.

Heading the PHS panel that wrote and released the guideline is Michael Fiore, who has been heavily funded by Glaxo Wellcome, SmithKline Beecham, Johnson & Johnson subsidiary McNeil, and the Robert Wood Johnson Foundation. Ten of the remaining 17 panel members have also served as consultants for, given lectures or conducted research sponsored by one or more of the very pharmaceutical companies making and/or marketing the very smoking-cessation drugs the guidelines recommend. Three of the five consultants for the guidelines have the same conflicts of interest.

The National Institutes of Health

“This whole program has the flavor of a drug industry/NIH cabal.”

Sidney Wolfe, director of the Health Research Group of Public Citizen, in response to an announcement of new government cholesterol standards which would massively increase the number of Americans on cholesterol-lowering drugs. Five of the 14 members of the quasi-governmental panel recommending the new standards have financial ties to the pharmaceutical companies that manufacture the drugs (quoted in “New Government Cholesterol Standards Would Triple Number of Prescriptions,” T. Burton and C. Adams, Wall St. Journal, 5/16/01).

“Much of the early basic research that may lead to drug development is funded by the National Institutes of Health.” (Angell M, “The Pharmaceutical Industry—To Whom Is It Accountable?” *New England Journal of Medicine*, Editorial, June 22, 2000)

On October 18, 1999, the National Cancer Institute, the National Institute on Drug Abuse (two of the institutes in the NIH) and the Robert Wood Johnson Foundation announced the jointly-funded and jointly-created Transdisciplinary Tobacco Use Research Centers. According to the joint press release, the centers would “foster unique collaborations among scientists across many disciplines” and “focus on areas where there are gaps in knowledge, such as adolescent smoking.” Researchers would study “the prevention of tobacco use, initiation of tobacco use and addiction.” Total funding for the program: \$28.5 million, \$14.5 million of which is funded by the taxpayers. Michael Fiore, head of the PHS panel releasing the new clinical guidelines for treating tobacco dependence, is one of the primary recipients of funding from this program.

The Tobacco Use Research was not the first collaborative effort between the NIH and the Robert Wood Johnson Foundation. The National Institute on Drug Abuse and the RWJF cosponsored a 1998 national conference on “a transdisciplinary approach” to research tobacco use and addiction. At the conference, then Vice President Al Gore announced that the National Cancer Institute would allocate \$38 million for additional research into prevention and cessation programs to reduce tobacco use. Among the projects the NCI would fund are those “to determine if adult cessation programs, including the nicotine patch and nicotine gum work for children” and “to find new, better treatments for adults addicted to nicotine.” In other words, the National Cancer Institute would use taxpayer dollars for clinical trials and product development for the pharmaceutical industry.

In 2000, the NCI funded a teen quit-smoking study using Zyban at the University of Arizona’s Program for Nicotine and Tobacco Research. Enrollees in the Zyban study were underage smokers from 14 to 17 years old. Each participant was given \$200.

Free movie passes were given to area youngsters to encourage them to sign up for the program (“UA seeks teens for study on smoking,” Carol Alaimo, *The Arizona Daily Star*, 8/27/2000).

The Centers for Disease Control and the Surgeon General’s Office

“Like other addictions, tobacco use can be effectively treated.... In recognition of the important role that nicotine plays in maintaining tobacco use, nicotine replacement therapy is now available.... Treatment of tobacco addiction should be more widely available and should be considered at least as favorably by third-party payors [public and private health insurers] as treatment of alcoholism and illicit drug addiction.” C. Everett Koop. Preface. A Report of the Surgeon General—1988, “The Health Consequences of Smoking: Nicotine Addiction]

“When you have an intense craving, it’s nice to be able to pop a piece of gum in your mouth, have a couple chews, and relieve the craving.” Dr. Ron Davis on Nicorette gum. Davis is the

Medical Director of the Henry Ford Medical System, North American Editor of the British Medical Journal, and former head of CDC’s Office on Smoking and Health, general editor of and one of the writers for the 1988 S.G. report, on Nicorette gum. (“Nicorette gum has helped people quit smoking,” Loretta Tofani, *The Philadelphia Inquirer*, 3/28/2000)

“Public health authorities, including the World Health Organization, have called for an increased focus on the treatment of tobacco dependence to reduce tobacco-caused death and disease. Pharmacologic interventions double success rates; however, these interventions must be used for their effects to be observed. Data from this report suggest that increasing the number of treatment options and the availability of pharmacologic products increases use of these treatments.” CDC MMWR report, July 28, 2000, “Use of FDA-Approved Pharmacologic Treatments for Tobacco Dependence—United States, 1984—1998.” The report was written jointly by the CDC’s Epidemiology Br, Office on Smoking and Health, SL Burton of SmithKline Beecham, JG Gitchell and S. Shiffman of Pinney Associates, a firm hired as a consultant and Zyban ad campaign manager for Glaxo Wellcome.

The CDC’s 1996 “Tobacco Use Prevention Program: At-A-Glance” listed among its “Key Partners” The Robert Wood Johnson Foundation and the RWJF-funded National Center for Tobacco-Free Kids. However, its involvement with the pharmaceutical and addiction industries goes at least as far back as the 1988 Surgeon General’s report, “The Health Consequences of Smoking: Nicotine Addiction,” which changed the very definition of addiction in order to include tobacco use and which emphasized that smoking was an addiction to be treated with pharmacological products and counseling.

Though most people are not aware of it, the Surgeon General’s reports on smoking and health are not actually written by the Surgeon General but by a number of authors, some of whom are employees of the CDC and some of whom are selected “experts” from the private sector. The 1988 report was prepared under the general editorship of Ron Davis, who was then Director of the CDC’s Office on Smoking and Health, but many others were involved in scientific editing and writing of the report. One of the scientific editors was Jack Henningfield, who was then at the National Institute on Drug Abuse, but who later became one of the associates at Pinney Associates and a consultant to Glaxo Wellcome. At least some of the outside “experts” stood to gain financially from the report. Many of these were in the “addiction” business. One of the writers was Jed Rose, who had invented the nicotine patch in the early 1980s and had sold marketing and production rights for the patch to the pharmaceutical industry. Another was C. Tracy Orleans, who would become an employee of the Robert Wood Johnson Foundation, and others, such as Michael Fiore, Saul Shiffman and Richard Clayton, would parlay their participation into consultantships and research grants from the pharmaceutical industry, the RWJF, and the federal government.

All in all, the 1988 Surgeon General’s report was a boon to the pharmaceutical and addiction industries, and it brought much pharmaceutical and governmental largesse to at least some of those involved in the preparation of the report.

Two years later the Surgeon General’s report of 1990, “The Health Benefits of Smoking Cessation,” focused exclusively on cessation and paved the way for the marketing of the nicotine patch, which was already under review for approval as a smoking-cessation drug at the FDA, though it wasn’t officially approved until 1991. The addiction business, pharmacologic and behavioral, got another taxpayer-funded shot in the arm from the CDC’s Office on Smoking and Health.

The 2000 Surgeon General’s report, “Reducing Tobacco Use,” re-emphasized the importance of “treatment” for tobacco “addiction.” Among its primary recommendations: “Changing physician behavior, medical system procedures, and insurance coverage to encourage widespread use of state-of-the-art treatment of nicotine addiction.”

Thus the CDC’s Surgeon General reports, intentionally or unintentionally, had the effect of promoting the sales of the pharmaceuticals’ products while demonizing the tobacco industry’s nicotine products.

A lesser-known connection between the pharmaceutical companies and the CDC are the direct contributions pharmaceutical companies made to the National Foundation for the CDC. The Foundation was established in the U.S. code in 1992 for the purpose of carrying out “activities for the prevention and control of diseases, disorders, injuries, and disabilities, and for promotion of public health” (Title 42, Sec.280d-11). The Foundation, which is a private nonprofit corporation, is supported by private donations. The money may be used for programs of fellowships for state and local public health officials to work and study at the CDC, for international fellowships for public health officials from other countries to study at the CDC, and for employees of the CDC to serve in public health capacities in other countries. The fund may also be used for forums for government officials and private entities to exchange information, for meetings, conferences, courses, and training workshops, and for “studies, projects, and research,” including research on the effectiveness of prevention activities. One of the current projects of the Foundation is the National Youth Tobacco Survey, conducted by the American Legacy Foundation.

A list of corporate donors includes Glaxo Wellcome, Johnson & Johnson subsidiary Ortho-McNeil, SmithKline Beecham Consumer Healthcare and SmithKline Beecham Pharmaceuticals and other pharmaceutical giants. In fact, nearly half the corporate donors listed are pharmaceutical companies.

Thus it can be seen that the pharmaceutical industry has tremendous influence on and financial connections to many of the major bureaus of the Public Health Service, influence and connections it has used to great effect in gaining the upper hand in the nicotine war.

VI - The Feds and the Pharms, Pt. 2: The FDA

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“[A] recent study by USA Today revealed that more than half of the advisors to the Food and Drug Administration (FDA) have financial relationships with pharmaceutical companies that have an interest in FDA decisions.”

Catherine DeAngelis, “Conflict of Interest and the Public Trust,” *Journal of the American Medical Association*, 284(17), Nov 1, 2000.

“The FDA regulates products accounting for approximately 25 cents of every consumer dollar—worth more than \$1 trillion annually.”

Henry I. Miller, “The Wrong Choice for the FDA,” *The Wall St. Journal*, June 26, 1998.

No other governmental bureau under the U.S. Public Health Service has such a long and documented history of abuse and corruption as the Food and Drug Administration. And none has as intimate a relationship with the pharmaceutical industry. The FDA has absolute power to determine which drugs and medical devices can be marketed in the United States, how these products may be marketed, how they are labeled, how they may be used, and whether they are available over the counter or by prescription only. It is judge, jury, acquitter or executioner, and enforcer for every product manufactured for sale in the United States by the pharmaceutical, medical device, food and cosmetic industries.

Approval of its drug by the FDA can mean hundreds of millions of dollars in profits for a pharmaceutical company; FDA rejection of a promising drug can financially ruin a small company and deliver a multimillion-dollar hit to a big one. Given this kind of power and the huge amounts of money involved, it is not surprising that the agency has often been rocked by corruption scandals and that individuals in the agency have been found to be on the take.

“Several FDA reviewers were accepting bribes to hasten the approval of certain companies’ applications and derail those submitted by competing companies. Eventually 42 persons and 10 companies were found guilty of criminal acts.”

Robert Higgs, “An FDA Fable,” *Reason Magazine*, October 1994. This describes a generic drug scandal that climaxed in 1989. Beginning in 1990, when David Kessler was appointed head of the FDA, and for three years after that, the FDA exacted revenge on Barr Laboratories for blowing the whistle on the agency’s corruption. With or without his knowledge, Kessler’s FDA reportedly tried to put the company out of business by repeatedly inspecting its facilities and delaying approvals of its products.

“Warner-Lambert [purchased by Pfizer in 2000] played down the potentially fatal risks associated with troglitazone during the [FDA] approval process and received help from federal drug regulators in pushing the drug towards marketing approval, an article published in the Los Angeles Times has claimed.”

“The newspaper based its report on company and government documents, some secretly obtained, as well as email communications, which shows that officials from Warner-Lambert had collaborated closely with certain senior officials in the US Food and Drug Administration (FDA) during the approval process and later, when the company was being pressured to take the drug off the market.”

Reported in *The British Medical Journal*, 322; 696, March 24, 2001. This scandal took place between 1994 and 1996, during David Kessler’s reign as head of the FDA.

The agency has been investigated for corruption by the U.S. Congress and Congress has tried to “reform” the FDA. In 1997 a congressional FDA reformation effort went nowhere because it was reportedly sabotaged by Sen. Edward Kennedy (D., Mass.).

David Kessler’s FDA

“A laudatory Washington Post article concluded, ‘What he cannot accomplish with ordinary regulation, Kessler hopes to accomplish with fear.’”

James Bovard, “First Step To an FDA Cure: Dump Kessler,” *The Wall St. Journal*, 12/8/94.

“Companies interested in maintaining positive relationships with the FDA usually agree to the FDA’s remedy.”

David Kessler. (Quoted in Paul Rubin, “FDA Advertising Restrictions: Ignorance Is Death,” Chp. 3 of *Hazardous to Our Health? FDA Regulation of Health Care Products*, ed. By Robert Higgs, The Independent Institute, Oakland, CA: 1995, p. 31).

In 1990 David Kessler was appointed head of the FDA. The hope was that Kessler, a “dedicated activist” who was also an attorney and physician, would clean up the FDA, but what actually happened was that corruption at the FDA continued while Kessler focused on such things as food labeling, further politicized the agency, and instituted a reign of terror.

“In reality, the new commissioner quickly turned the agency into a fearsome police force. In his first two months, he ‘added a hundred new criminal investigators to the enforcement staff, many of them formerly with the Secret Service and the Drug Enforcement Agency.’ Then followed a series of armed raids on alternative health clinics, vitamin factories, and dealers in dietary supplements as well as greatly increased numbers of warning letters, product seizures, forced factory shutdowns, and criminal prosecutions in the drug and device industries.”

Robert Higgs, “An FDA Fable,” *Reason Magazine*, October 1994.

Armed with virtually unlimited power, Kessler promoted the image of the FDA “protecting” the public with the implacable sword of justice. However, Kessler’s sword tended to swing at some companies and some industries more than others.

In 1991, FDA storm troopers raided a Florida orange juice producer and poured 24,000 half-gallons of Citrus Hill ‘fresh choice’ juice down the drain because the agency objected to the label. There was nothing wrong with the juice, but the FDA said the phrase ‘fresh choice’ on the label was misleading since the product was not “fresh” but was made from concentrate.

In 1992, the FDA headed a guns-drawn raid on a Tahoma, Washington medical clinic because the physician in charge of the clinic had promoted nutrition and vitamins as an alternative to some traditional medical treatments.

In 1993, the FDA fined start-up company Lexicor \$1,580,000 (twice the company’s total 1993 revenues) for promoting its electroencephalographs which measure brain waves, even though the company had received FDA approval for the device, which it was selling under a different brand name.

On the other hand, Summit Technologies, a Massachusetts manufacturer of laser eye surgery devices, was supported by the FDA in selling a \$40,000 device for \$400,000. The FDA was aware that Summit may have been violating federal law by pre-selling an unapproved device along with an already-approved device, but the company’s political connections apparently influenced the FDA decision not to prosecute. The company had collected nearly \$500,000 in campaign contributions for Sen. Edward Kennedy, and according to a whistle-blower the chairman of Summit discussed a potential payment of more than \$1 million to Kennedy’s reelection campaign.

“An FDA memo dated Jan 1, 1995...shows how the FDA went about helping Summit and Senator Kennedy. ‘Summit has apparently complained a lot in the past to Ted Kennedy regarding the lack of timeliness in FDA’s responses to issues regarding [Summit’s application for approval]’ the

memo states. It then goes on to state that the FDA will not seek criminal charges against Summit, and to assert that Summit will eventually get approval.”

Robert Goldberg, “The Ethical Mess at the FDA,” *The Wall St. Journal*, 1/16/97.

Then there is the case of Ethicon and the contaminated sutures. Ethicon, a subsidiary of Johnson & Johnson, manufactures 80 percent of all medical sutures used in operations. The company accidentally distributed at least 3.6 million packages of contaminated sutures to medical supply distributors, hospitals and physicians between December 1993 and September 1994. According to class-action attorney Wendy York, the contaminated sutures were unknowingly used by surgeons and physicians all over the country, and their use resulted in raging infections, disfigurement and even death in patients who had been stitched with the medical sutures [Geoff Metcalf, worldnetdaily Sunday Q & A, Interview with Wendy York].

Did the FDA conduct an armed raid or levy a multimillion-dollar fine on Ethicon? No. According to attorney York, the FDA did issue a stern warning letter to Ethicon in 1994, but the company assured the FDA it would take care of the problem, and no further action has been pursued by the government agency.

One would gather that Ethicon and Summit “maintained positive relationships” with Kessler’s FDA, while other food companies, drug companies, and medical clinics did not.

During Kessler’s reign at the FDA, the agency initiated at least two new policies which would result in increased profits for at least the major pharmaceutical companies.

In May 1995, the FDA ruled that a new federal law extended drug patents for up to an additional three years. This news was welcomed enthusiastically by the big drug companies. Glaxo Wellcome’s Nancy Pekarek said, “This is very good news, not just for Glaxo but for upholding the patent rights of innovative companies” (Miami Herald, 5/26/95). But consumer advocates said this windfall for the pharmaceutical companies could cost U.S. consumers as much as \$6 billion.

Then in 1997 the FDA relaxed the restrictions on TV ads for prescription drugs. This gave the big pharmaceutical companies a big new marketing tool because they could promote their prescription drugs directly to the consumer. Obviously the smaller companies are without the means to pay for glossy professional television spots, but the big drug companies were quick to take advantage of television marketing for prescription drugs. Sales of these drugs soared as people began pressuring their physicians for prescriptions for the products they had heard so glowingly described in primetime TV ads.

And, of course, David Kessler also gave a big boost to the sales of the big pharmaceuticals’ “nicotine replacement” products for smoking cessation when he went after the tobacco companies.

Kessler’s FDA and Tobacco

“If members of our society were empowered to make their own decisions...then the whole rationale for the [FDA] would cease to exist.”

David Kessler. Quoted in James Bovard, “First Step To an FDA Cure: Dump Kessler,” *The Wall St. Journal*, 12/8/94.

“[A] strict application of these provisions could mean, ultimately, removal from the market of tobacco products containing nicotine at levels that cause or satisfy addiction.”

David Kessler in a letter to an anti-smoking group in 1994. Quoted in Jerry Taylor, “Clinton’s Tobacco War: How High the Constitutional Price?” *The Cato Institute*, 8/30/96.

“Cigarettes in America should be produced and sold only by a single, congressionally chartered, tightly regulated company, with no profits, former Food and Drug Administration commissioner David Kessler says.”

Joe Ward, “Should single firm make cigarettes?” *The Louisville Courier-Journal*, 3/25/01.

In 1991, Kessler’s FDA approved the Nicotrol and Nicoderm patches as prescription drugs for smoking cessation (Nicorette gum had been approved for such use in 1984). In 1992, the patch was introduced to the American public. In 1993, the FDA prohibited the sale of existing over-the-counter smoking-cessation products because the agency said they had not been demonstrated to be effective. This, of course, had the effect of eliminating all competition to Johnson & Johnson’s Nicotrol patch and SmithKline Beecham’s Nicoderm patch and Nicorette gum. Then in 1996 the FDA approved the gum and the two patches for over-the-counter sale. It all worked out extremely well for Johnson & Johnson and SmithKline Beecham.

But by far the biggest boost for the pharmaceuticals in the nicotine war was David Kessler’s attempt to regulate tobacco products as “nicotine delivery devices” under FDA jurisdiction.

Kessler first publicly expressed his interest in regulating tobacco when he went before Congress in 1994 and asked for “guidance” and “direction” before his agency took any action to regulate tobacco. Prior to Kessler, the FDA had never expressed an interest in extending its regulatory empire to tobacco. Tobacco products were not considered to be food, cosmetics, drugs or medical devices, which meant they did not fall under the scope of the FDA’s regulatory apparatus.

However, the anti-regulatory mood of the Republican-led Congress meant there was no legislative enthusiasm for giving the FDA authority to regulate tobacco products.

Kessler then by-passed Congress altogether. In 1995 he declared tobacco to be a “pediatric disease” and submitted to the very receptive Clinton White House a list of proposed FDA tobacco regulations ostensibly intended to protect the children from tobacco.

Meanwhile, the Robert Wood Johnson Foundation was funding policy studies to support FDA regulation of tobacco products. In 1994 the RWJF awarded a \$142,600 contract to Mathematica Policy Research for a “National Tobacco Survey” which would assess public attitudes “toward various government policy measures designed to limit youth access to tobacco products and make those products less attractive.” David Kessler later said the findings from the survey “played a critical role in winning the necessary support for the FDA’s tobacco control policy.”

Joseph DiFranza was given a \$99,999 RWJF grant for “Investigating the Scientific and Legal Basis for Regulations Requiring the Generic Packaging of Tobacco Products,” and Alan Morrison and David Vladeck of the Public Citizen Foundation were awarded a \$50,608 RWJF grant for a legal analysis of the proposed FDA regulations on tobacco.

By August 1996, the Clinton administration was set to approve new FDA regulation of tobacco products. Tobacco products would be considered “drug delivery devices,” and thus would be subject to FDA regulation with regard to advertising, marketing, and packaging. Cigarette vending machines would be outlawed, tobacco advertising would be banned from magazines with high youth readership, advertising on billboards would be limited to black and white text and prohibited within 1,000 feet of schools. Furthermore, the tobacco companies would be forced to fund a \$150 million annual anti-smoking education campaign. And if all these measures did not cut underage smoking in half within seven years, the FDA would be empowered to employ even harsher measures, including the banning of cigarettes as a “nicotine delivery system.”

The newly formed, RWJF-funded Campaign for Tobacco-Free Kids beat the drum for the proposed FDA rules. “This is the first national policy in history that will stop tobacco companies from marketing to kids,” said TFK’s Brian Ruberry (quoted in Brian McGrory, “New FDA rules would declare nicotine a drug,” *The Boston Globe*, 8/22/96).

Not only would the proposed FDA regulation of tobacco products expand the agency’s already wide scope of regulatory power, but it would increase its budget by 30 percent or more since the agency would get considerable extra funding to cover the cost of implementing and enforcing these regulations.

The tobacco companies immediately filed suit against the FDA to stop the new regulations. After a protracted legal battle, the case reached the U.S. Supreme Court. In March 2000, nearly three years after David Kessler resigned as head of the FDA, the Supreme Court ruled that the FDA lacked congressional authority to regulate tobacco.

But the battle over FDA regulation of tobacco products isn't over. The Robert Wood Johnson Foundation and organizations it funds are still working to convince Congress to empower the FDA to regulate tobacco products as nicotine delivery devices and shift the market advantage to the pharmaceuticals' own nicotine delivery devices. And David Kessler is touring the world to promote his new book, "A Question of Intent: A Great American Battle With a Deadly Industry," about his "heroic" battle to destroy demon tobacco.

VII - The Pharms and Doctors: Corrupting Medicine

Publication date: July 27, 2001

“It begins on the first day of medical school and lasts through to retirement, and it is the only reliable ‘cradle to grave’ benefit that doctors can truly count on any more.... It starts slowly and insidiously, like an addiction, and can end up influencing the very nature of medical decision-making and practice. It first appears harmless enough: a textbook here, a penlight there, and progresses to stethoscopes and black bags, until eventually come nights ‘on the town’ at academic conventions and all-expenses paid ‘educational symposia’ in lovely locales.”

The *Lancet* editorial is talking about pharmaceutical industry perks to physicians and influence on medical education in the U.S. (*The Lancet*, 356:781, Sept. 2, 2000).

“The corporate world owns many of our political representatives in Washington DC. The medical situation is not very different: industry owns physicians and dictates the course of education, research, and ultimately the practice of medicine in degrees previously unimaginable.”

Augusto Sarmiento, MD, Letter to the Editor, *JAMA*, 286(3), July 18, 2001.

The phrase, “First, do no harm” has been eliminated from the “modified” Hippocratic oath currently administered to graduating medical students in the U.S. The initial sentence in the Physicians’ Oath now reads: “I do solemnly swear by whatever I hold most sacred, that I will be loyal to the profession of Medicine and generous to its members.”

The relationship between physicians and the pharmaceutical industry is unavoidably intimate because physicians depend on pharmaceutical products to treat patients. Nevertheless, there is substantial evidence that pharmaceutical company influence on physicians, medical education, and patient treatment is far more pervasive and insidious than even some physicians themselves realize, and it involves far greater ethical problems than physicians’ acceptance of gifts of penlights, free lunches, and all-expense-paid trips to symposia. For example, documents released by the U.S. House of Representatives Commerce Committee indicate that some doctors make money billing Medicare and Medicaid for more than they actually pay for drugs, a practice made possible by the manufacturers of the drugs.

“Drug companies artificially inflate wholesale prices, investigators say, because Medicare and state Medicaid programs base their reimbursement on those numbers. Their goal is to have the highest wholesale price—and the lowest actual selling price.

“That way, they can market their drugs to doctors based on how much money the doctors can make by billing government programs for the higher amount.

“‘Profit maximization—it’s in the bag,’ reads a 1997 marketing memo from Glaxo Wellcome touting one of its drug’s wholesale price advantage over a competitor’s similar product.

“The Glaxo marketing document shows that a busy oncology practice using its 32 milligram bag of anti-nausea treatment could net \$13 million a year--\$2 million more than if the practice used its competitor’s product. All because the wholesale price, which no one except the government actually pays, is higher.”

(Julie Appleby, “Drug makers accused of price scheme,” *USA Today*, Sept. 27, 2000, p. 1B)

Shocking as it might be, this wholesale price inflation by pharmaceutical companies to increase profits for themselves and physicians at the expense of the taxpayers is apparently quite legal.

It’s also quite legal for big pharmaceutical companies to track individual physician’s prescription patterns and then attempt to change those patterns, even if it means encouraging the physician to prescribe a more expensive drug when a less expensive drug is just as effective.

***“Over the past decade, with the advent of sophisticated new computer technology, pharmaceutical manufacturers have been quietly compiling resumes on the prescribing patterns of the nation’s health care professionals, many of whom have no idea that their decisions are open to commercial scrutiny.*”**

“These prescriber profiles’ are the centerpiece of an increasingly vigorous—and apparently successful—effort by drug makers to sway doctors’ prescribing habits. To create them, pharmaceutical marketers are buying information from pharmacies, the federal government and the American Medical Association, which generates \$20 million in annual income by selling biographies of every American doctor.”

Sheryl Stolberg and Jeff Gerth, “High-Tech Stealth Being Used to Sway Doctor Prescriptions,” *The New York Times*, Nov. 16, 2000. In addition to increased calls from drug sales reps, physicians may be offered such perks as “consultation fees” in an effort to influence their drug prescribing practices.

And there are many other ways pharmaceutical companies influence physicians’ choices of prescription drugs—billions of dollars worth of free samples, advertising in medical publications, and direct-to-consumer advertising:

- ***“The pharmaceutical industry gave \$7.2 billion worth of samples to US doctors in 1999”*** (Gavin Yamey, “Pen ‘amnesty’ for doctors who shun drug companies,” *News, BMJ*, 322:69, Jan 13, 2001).
- ***“Of the \$13.9 billion that the drug companies spent promoting their products last year, 87 percent, or about \$12 billion, was aimed at doctors and the small group of nurse practitioners and physicians’ assistants who can prescribe some medications, about one million prescribers all told.”*** Stolberg and Gerth, “High-Tech Stealth Being Used to Sway Doctor Prescriptions,” *The New York Times*, Nov 16, 2000. Many medical journals gain most of their revenue from pharmaceutical ads.
- ***“Doctors wrote 34.2% more prescriptions in 1999 than in 1998 for the 25 drugs promoted direct to consumers that contributed most to overall drug spending. Doctors wrote only 5.1% more prescriptions for all other prescription drugs.”*** Fred Charatan, “US prescription drugs sales boosted by advertising,” *News, BMJ*, Sept. 30, 2000.
- ***“We know that 66 per cent of patients that ask the doctor for a particular product get it.”*** Thomas Ebeling, head of pharmaceuticals at Novartis. Quoted in David Pilling, “Direct promotion of brands gives power to the patients,” *Financial Times*, April 28, 2001.

These marketing practices in themselves do not necessarily compromise a physician’s prescription patterns. What is more problematic is that even highly ethical physicians depend on experts in their fields, professional journals, symposia, and reference books for their information on drugs, and these sources are largely funded by the pharmaceutical industry. For example, prominent physicians may be paid by pharmaceutical companies to promote the companies’ drugs to other physicians.

“One pharmaceutical company employs several eminent British cardiologists to lecture to other doctors around the country to promote the company’s drugs. The cardiologists, known to company employees as *The Road Show*, are each paid 3,000 to 5,000 [U.K. pounds]...plus traveling expenses for a 1 hour evening talk in the UK.... Some members of *The Road Show* have spoken fortnightly for the company. As a result they receive more money each year from the company than their annual salary from their hospital or university.... Some have admitted to me that they have kept silent about adverse effects of drugs to avoid loss of lucrative research contracts with a manufacturing pharmaceutical company. Some opinion leaders involved in pharmaceutical research now command speaker fees that are so high that their engagements are negotiated by an agent.” Wilmshurst P, “Academia and industry,” *The Lancet* 2000; 356:338-344, July 22, 2000.

Many of the top professional medical journals such as *The New England Journal of Medicine*, *JAMA*, and the *British Journal of Medicine* receive the bulk of their funding from pharmaceutical advertising. In addition,

many of the journals' editorial writers, peer reviewers and even many of the researchers whose studies appear in the journals have financial connections to the pharmaceutical industry. And many of the published drug studies themselves are funded by the very pharmaceutical companies manufacturing the drugs.

The New England Journal of Medicine published a study concluding that 30% of study subjects using bupropion (Glaxo Wellcome's Zyban) as a smoking-cessation aid stayed off cigarettes for at least a year. Not only was the study funded by Glaxo Wellcome, but "eight of the 12 doctors involved in the study declared a link to the pharmaceuticals giant" ("Anti-depressants beat the craving," BBC News, 3/4/99). Studies not funded by the manufacturer have found the drug's success rate is half that claimed in the Glaxo Wellcome funded study. Further, the NEJM article did not highlight the considerable health risks posed by the drug.

Even worse is the common practice of pharmaceutical companies buying editorials and paying physicians and researchers to affix their names to journal articles they did not write.

"The practice of buying editorials reflects the growing influence of the pharmaceutical industry on medical care. Thompson defines a conflict of interest as a 'set of conditions in which professional judgment concerning a primary interest (such as a patient's welfare or the validity of research) tends to be unduly influenced by a secondary interest (such as financial gain).' The boundaries between these interests are becoming more and more difficult to perceive, especially when information for physicians is carefully orchestrated by a public-relations firm. Indeed, the goal of public-relations firms that ghostwrite editorials and do other work for drug companies is to blur the distinction between primary and secondary interests."

"In the past, publications were written by a study's principal investigator. More recently, a practice that one might call the nonwriting author-nonauthor writer syndrome has developed.... The syndrome has two features: a professional medical writer ('ghostwriter') employed by a drug company, CRO [contract research organization], or medical communications company, who is paid to write an article but is not named as an author; and a clinical investigator ('guest author') who appears as an author but does not analyze the data or write the manuscript."

"In one study, 19 percent of the articles surveyed had named authors who did not contribute sufficiently to the articles to meet the criteria for authorship...."

The foregoing quotations are all from Brennan T, "Buying Editorials," *The New England Journal of Medicine*, 331:10, Sept. 8, 1994.

In addition to professional journals, physicians also rely on symposia and professional meetings to update themselves on information about drugs, but many of these are also funded by pharmaceutical companies.

"Most of the CME [Continuing Medical Education], the plenary sessions, and almost 75-80% of the general as well as specialty symposia are sponsored by one or the other pharmaceutical company." Kagalwala T, M.D, "The Conferences are a charade," May 26, 2001, BMJ Electronic response Jackson T, "Are you being duped?" BMJ 2001; 322:1312, May 26, 2001. The Jackson article is a review of a 24-page guide published as a supplement in the May, 2001 edition of Pharmaceutical Marketing. Jackson writes:

"So what exactly does this guide say? It advises marketers, in identifying opinion leaders, not to 'risk wasting money' on doctors 'who you eventually hear have no credibility with their peers.' Instead, marketers should aim for those who are 'on the editorial boards of key publications for ultimate target audiences,' on scientific committees, members of key professional societies, representatives of national or international guideline committees, and key players on formulary committees. 'The key aim,' says the guide, 'is to ensure that you are working with a mix of people who can ultimately be called upon to communicate on your behalf in different situations.'"

Other sources of drug information for physicians are reference works, such as the Physicians' Desk Reference [PDR] and national and international guidelines. But the PDR "was originally developed as a promotional device" and "there is no mechanism by which all clinically relevant dose-response data or important post release discoveries are regularly and rapidly incorporated into it" (Cohen J, "Dose Discrepancies Between the Physicians' Desk Reference and the Medical Literature, and Their Possible Role in the High Incidence of Dose-Related Adverse Drug Events," Archives of Internal Medicine, 161(7): 957-964, April 9, 2001). And the national and international guideline panels are loaded with researchers having strong financial ties to the pharmaceutical industry, as is the case with the U.S. Clinical Practice Guideline On Treating Tobacco Use and Dependence.

The lack of objective drug information available to physicians may account for at least some of the steep rise in fatal medication errors:

"An examination of all US death certificates over the 10-year period [between 1983 and 1993], the most recent data available to the researcher, found that fatal medication errors had increased 2.6-fold. But among outpatients, the jump in such deaths was 8.5-fold." Richard Knox, "Researchers Report Surge in Deaths Due to Medication Errors," The Boston Globe, Feb. 27, 1998, p. A1. In addition to medication errors, it is estimated that more than 100,000 Americans die each year from adverse effects of prescription drugs and that 1,000,000 more are injured so severely they must be hospitalized.

It also may account for many physicians' misinformation on the health effects of smoking and environmental tobacco smoke.

The AMA, the BMA and the Nicotine Wars

The American Medical Association (AMA) is a key player in the nicotine wars. The Association receives many millions of dollars every year from the pharmaceutical industry, and some of those millions are specifically for anti-tobacco work. The Robert Wood Johnson Foundation alone gives the AMA millions for "administering" (i.e. lending its name to) the RWJF's SmokeLess States program.

The Journal of the American Medical Association (JAMA) also receives much of its budget from pharmaceutical advertising, as does the British Medical Association's BMJ. Both journals have dedicated entire issues to "tobacco control" in addition to publishing numerous editorials supporting tobacco control and the pharmaceuticals' "smoking-cessation" products. Both journals are also quick to print pharmaceutically funded studies on smoking-cessation drugs, done by researchers with stated financial ties to the pharmaceutical industry. It isn't as though the journals' editorial staffs aren't aware of the bias in many industry-funded drug studies. Indeed, they have even published articles on the subject of researchers' conflicts of interest.

"By 1999, almost 7.6% of faculty investigators [researchers] reported personal financial ties with sponsors of their research. Throughout the study period, 34% of disclosed relationships involved paid speaking engagements (range, <\$1000-\$20,000 per year), 33% involved consulting agreements between researcher and sponsor (range, <\$1,000-\$120,000 per year), and 32% involved the investigator holding a position on a scientific advisory board or board of directors. Fourteen percent involved equity ownership, and 12% involved multiple relationships." Boyd E, Bero L, "Assessing Faculty Financial Relationships With Industry: A Case Study," JAMA, 284(17), Nov. 1, 2000.

What they generally do not publicize are the medical associations' own conflicts of interest and their own financial ties to the pharmaceutical industry, vested interests that in some instances appear to take precedence over objective publishing standards and patient well-being. Nowhere is this more apparent than in the nicotine wars.

Editors at the BMJ and JAMA and officers of the British Medical Association and the American Medical Association, among others, seem not to consider fully the possible harm of some of the anti-tobacco information they disseminate and the some of policies they advocate. One example of this is their advocacy for lowering the nicotine content of cigarettes.

Former Surgeon General C. Everett Koop said the nicotine content of cigarettes should not be lowered because smokers would just smoke more, thereby getting twice as much cancer-causing substances. “I don’t think the public health community would ever let FDA reduce nicotine remarkably in cigarettes,” said Koop. “Report: Tobacco, FDA Rift Settled,” AP, printed in The Washington Post, Aug. 24, 1997.

But the very next year both the AMA and the BMA urged their respective governments to force tobacco companies to lower the nicotine content in cigarettes, a position they justified by promoting the pharmaceutical companies’ nicotine products.

Reed Tuckson, senior vice president for professional standards of the AMA said smokers could use pharmaceutical products to supplement nicotine. “These problems can be avoided by providing alternative forms of nicotine delivery with less or little risk to health as a part of expanded access to treatment (using) products such as nicotine gum, patches, oral inhalers and nasal sprays.” “US, British doctors call for low-nicotine cigarette,” Reuters, Oct. 28, 1998.

If that sounds like a ringing endorsement of the drug companies’ products, consider this from a BMJ editorial:

“To meet the needs of the estimated 13 million current smokers in Britain, many of whom will never overcome their nicotine addiction, we also need legislation that explicitly encourages the development of alternative products that can deliver uncontaminated nicotine at a dose and rate comparable with cigarettes and in a way that is commercially and socially acceptable. If instead of nearly 13 million addicted smokers we have 13 million addicted to clean nicotine devices, so be it.” Britton J, McNeill A, Editorial, “Why Britain needs a nicotine regulation authority,” BMJ 2001; 322: 1077-1078, May 5, 2001. Both Britton and McNeill have been funded by the pharmaceutical companies which make and market smoking cessation products. In addition, McNeill participates in the pharmaceutically funded WHO partnership project on tobacco control .

Practicing Physicians

The majority of practicing physicians do not belong to the AMA, but there is no question that many if not most have accepted at least some of the misinformation they have been fed by the medical and public health establishment. Nevertheless, there are indications that at least some are uncomfortable with the constant barrage of anti-tobacco proselytizing.

A study published in JAMA in 1998 found that the journal readers polled ranked tobacco issues 55th in priority out of 73 total topics, while the editors ranked it 17th. This, of course, outraged some members of the tobacco control community, who were fearful that JAMA would change its publishing priorities to be more in line with what their readers wanted: “We wonder who is the JAMA readership, and if their readership is even representative of all practicing physicians. Their priorities certainly don’t match the best interests of public health,” wrote Dennis Wahlgren and Melbourne Hovell in the BMJ journal Tobacco Control (Letter to the editor, Autumn, 1999).

It seems the practicing physicians were far more interested in articles that had to do with the actual practice of medicine than in reading about demon tobacco, and for that they are accused of not caring about public health.

There is also some evidence that at least some practicing physicians are uncomfortable with having to identify smokers among their patients, lecture them about smoking and offer them cessation medication, as the US Clinical Guidelines mandate. For example, pediatricians are expected to find out which of their patients' parents smoke, tell the parents about the "hazards" of exposing their children to tobacco smoke, and prescribe nicotine replacement products for them. But a study published in the AMA's Archives of Pediatrics & Adolescent Medicine found that pediatricians were far less likely than family practitioners to follow these guidelines (Perez-Stable EJ, Juarez-Reyes M, Kaplan CP, "Counseling smoking parents of young children," 2001; 155:25-31). Further, there is little evidence to support that such intrusive intervention by pediatricians has any effect on getting the parents to quit smoking (France E, "Counseling Parents to Quit Smoking: Little Evidence of Long-term Success," Archives of Pediatrics & Adolescent Medicine, 155(7), July 2001).

Again, the "experts" and the major medical associations seem to be unaware of or indifferent to the negative consequences of forcing physicians to harangue patients (or parents of juvenile patients) about smoking. Perhaps the most obvious of the negative consequences is that many smoking patients become angry with their doctors and may even avoid future medical appointments.

"Conclusions: Doctor-patient relationships can be damaged if doctors routinely advise all smokers to quit." Butler C, Pill R, Stott N, "Qualitative study of patients' perceptions of doctors' advice to quit smoking: implications for opportunistic health promotion," BMJ, 316:188878-1881, June 20, 1998. Among the "key messages" in the study: "Repeated ritualistic intervention on the part of doctors may deter patients from seeking medical help when they need it."

"Recent studies have shown that people who know they have health-endangering vices (like smoking or drinking) put off appointments because they do not want a healthy-living lecture." Randi Hutter Epstein, "Major Medical Mystery: Why People Avoid Doctors," The New York Times, Oct. 31, 2000.

Thus in turning practicing physicians into scolds and smoking-cessation drug pushers, the major medical associations and the tobacco control community are not only destroying the physician-patient relationship but are actually discouraging some patients from getting needed medical care.

An even more dangerous result of the constant focus of the professional journals and professional associations on tobacco use and exaggerations about its risks is that some physicians and surgeons have become true believers and are refusing to treat smokers at all. In some countries patients have died because physicians refused to perform life-saving operations on them unless they gave up smoking.

"Some doctors have refused to perform transplants and other life-saving operations on smokers on 'medical and moral' grounds." "Smoker Dies After Doctors Refuse to Treat Him," Sky News (Australia), Feb. 10, 2001.

And there are more subtle dangers such as misdiagnoses based on the smoking status of patients. Misdiagnosis is already an enormous problem in the medical profession.

"There are distressingly high error rates reported in a wide range of medical practices with serious, sometimes fatal consequences," a summary of the [Rand Corporation] study said. "For example, autopsy studies show high rates (35 to 40 percent) of missed diagnoses, often resulting in death." "Crisis in U.S. health system worse, group charges," Reuters, Oct. 20, 1997.

"Almost one death in five in a well-regarded medical intensive care unit was misdiagnosed, and in almost half the cases a correct diagnosis would have resulted in different treatment, a recent study has found." Mitka, M, "Autopsies Show Misdiagnoses," JAMA, 285(12), Mar 28, 2001.

If physicians are focusing on a patient's smoking status to assist in diagnoses, they are going to make errors. They may, for example, overlook symptoms of lung disease in non-smokers or assume a sick smoking

patient has a “tobacco-related” disease when he or she does not. Given the sheer number of misdiagnoses, it is probable that patients’ smoking status plays a part in at least some of these.

A few courageous physicians are daring to speak out against the anti-tobacco stance advocated by the AMA and other pharmaceutically funded tobacco control “experts.” The Association of American Physicians and Surgeons, a lesser-known and far less wealthy alternative to the AMA, is one group of such physicians.

“As physicians, we find reprehensible the use of excessive government intrusion and control to force changes in behavior affecting health and well-being. Many other voluntary activities are associated with adverse health effects, some more probable and more immediate than the hazards of tobacco use.” “Doctors Criticize Clinton Tobacco Fines for Underage Smokers,” U.S. Newswire, Feb. 9, 2000. The AAPS states that it is “a national association of physicians in all specialties dedicated since 1943 to the sanctity of the patient-physician relationship, and the protection of their hundreds of thousands of patients against third-party intrusion into that relationship.”

This group at least—along with some courageous individual physicians--is not among the medical partners of the pharmaceutical industry in its ruthless quest for profits in the nicotine war.

VIII - The Pharms and the Non-Profits: Buying Respectability and So Much More

Publication date: August 3, 2001

“The national impact of the partnership between the American Cancer Society and SmithKline Beecham Consumer Healthcare has been demonstrated by the success of the American Cancer Society’s 1996 Great American Smokeout, as noted in the September 19, 1997 issue of Morbidity and Mortality Weekly Report (MMWR), published by the Centers for Disease Control and Prevention.”

PRNewswire, Nov. 18, 1997. The 1996 ACS Great American Smokeout was certainly an unqualified success for the pharmaceutical companies. According to the CDC, sales of “nicotine medications” increased by 30% during the specific week of the event.

“That ACSH [American Council on Science and Health] gets funding from the pharmaceutical industry, as does the AMA, the American Cancer Society, and many other groups in tobacco control, is not disputed.”

Thomas Houston, American Medical Association. From a Feb. 24, 2000 email message in response to a query about pharmaceutical funding.

The public perceives such organizations as the American Cancer Society, The American Lung Association, and The American Heart Association as purely charitable organizations, unsullied by politics and commerce. Unfortunately the public’s perception is far from realistic. These organizations are very much involved with politics and with chasing governmental and corporate dollars.

The political clout of these big non-profits is incalculable, and they employ professional political lobbyists to forward their agendas at every level of government. According to Edmund Burke, director of the Center for Corporate Community Relations at Boston College, “With the exception of taxes, every major domestic policy program of the past 20 years has been set, shaped and in some cases designed by advocacy groups” (quoted in Charles S. Clark, “Silence the Advocates,” St. Petersburg Times, 1/18/98).

The American Cancer Society (ACS), the American Lung Association (ALA) and the American Heart Association (AHA) are all classified by the U.S. Internal Revenue Service as 501(c)(3) “charitable” organizations. This means that donations to the organizations are tax-deductible, but it also means that the organizations must refrain from partisan politics and that their lobbying activities are restricted. Nevertheless, they lobby mightily--except they call it “issue advocacy” or “educating legislators.” Thus it is merely “issue advocacy” when one or more of these organizations takes out full-page newspaper ads or issues press releases to pressure legislators to vote for an anti-tobacco law or for funding for a state anti-tobacco coalition composed of the ACS, the ALA and the AHA.

“The Senate will surely turn to its constituency, point to these drug provisions and say, ‘Look what we did to protect kids.’ But the public should not be fooled. The Senators’ votes on Tuesday were a vote for Big Tobacco and against America’s kids.” Statement By M. Cass Wheeler, CEO, American Heart Association, and John Seffrin, Ph.D., CEO, American Cancer Society, on the Status of the McCain Bill, press release, 6/10/98.

Or, conversely, the “issue advocacy” ad or press release might reward legislators for voting the “correct” way.

“In the last weeks and days of the 1997 legislative year, the tobacco industry’s most visible efforts were to attempt to undermine the smoke-free, workplace law. ‘It was the number one priority of the tobacco industry to preserve public smoking, and they broke all the rules, and ignored all the health facts in the process,’ stated Dr. Henderson [President of the ACS, California Division].

‘We are pleased that the Legislature saw through the tobacco industry’s propaganda, and by doing so took a strong stand on behalf of the people of California.’

“The American Cancer Society placed a full-page advertisement in The Sacramento Bee and the Western Edition of The New York Times earlier this month, to draw public attention to the antics of the tobacco lobby in Sacramento.” “Bars Go Smoke-Free as of January 1, 1998,” PRNewswire, 9/13/97

The public perception of these organizations as “pure” and “charitable” lends even their most propagandistic ads an air of unassailable credibility. Moreover, since the ads are not selling a product, they are not regulated by the FTC and are not held to any standard of truth in advertising. Accountable to no one but their own board of directors for their public speech, these organizations are free to influence legislators, to spin the truth, to knowingly misrepresent facts and even to lie with impunity. They are, in other words, the perfect medium for disseminating anti-smoking propaganda. And this is just one of the qualities which made them such attractive partners for the pharmaceutical industry in the nicotine wars.

Partnerships With Government

Long before the pharmaceutical industry became publicly involved in the anti-tobacco movement, the ACS, the ALA, and the AHA were working in tandem with federal agencies involved in tobacco control, particularly the National Institutes of Health and the Centers for Disease Control.

John Seffrin of the ACS was a member of the Interagency Committee on Smoking and Health from 1988 through 1992, which meant he helped plan and coordinate the federal tobacco control program. Further, state and local divisions of the ACS, the ALA and the AHA served as point men in implementing federal anti-tobacco programs at the state level. These non-governmental organizations, NGOs as they are referred to, received federal funding from the National Cancer Institute’ ASSIST program and the Centers for Disease Control’s IMPACT program to establish and maintain anti-tobacco coalitions in every state.

In this way, these NGOs not only helped plan the government’s anti-tobacco effort, but were also paid to set up a vast network of politically active anti-tobacco coalitions throughout the United States. These state and local coalitions were charged with increasing coalition membership, cementing good relationships with local media, “educating” legislators about such issues as increasing tobacco taxes and implementing smoking bans, and training the NGOs’ army of volunteers to carry out the anti-tobacco agenda by writing letters to the editor, gathering petitions, and calling or writing national, state, and local legislators to support anti-tobacco measures.

It was a brilliant and extremely effective plan for implementing the tobacco-control agenda throughout the United States. Set up using tax dollars, the national organizational framework was ready and waiting when the Robert Wood Johnson Foundation began its SmokeLess States Program in 1994.

RWJF’s SmokeLess States Program

“During the first seven years of SmokeLess States...The RWJF provided approximately \$40 million for educational and policy efforts undertaken by statewide coalitions in 36 states and the District of Columbia. As of 2001, The Foundation committed an additional \$52 million to the program with the potential of funding statewide coalition activities in up to all 50 states.”

“SmokeLess States National Tobacco Policy Initiative,” American Medical Association website at www.ama-assn.org

SmokeLess States is funded by the RWJF and administered by the American Medical Association, which receives millions of RWJF money for its participation. Twenty-five of the 60 SmokeLess States grants totaling roughly \$19 million have gone to regional and state divisions of the American Cancer Society. The

American Lung and American Heart Associations have received six grants, and coalitions of the ACS, the ALA, and the AHA have received additional RWJF grants.

In return for the money, the state coalitions are supposed to focus on three policy areas:

- Promoting smoking bans
- Increasing state tobacco taxes
- Encouraging Medicaid, state employee health insurers and private health insurers to cover the cost of “tobacco dependence treatment.”

Each of these priority areas will, of course, promote the sale of smoking cessation drugs, including Johnson & Johnson’s own products, though that is never directly stated.

RWJF representatives work closely with state and local coalitions to make sure they adhere to the foundation’s agenda.

Meanwhile, the Centers for Disease Control, which has taken over the federal ASSIST program, continues to pour taxpayer dollars into these same state coalitions. In addition, many of the coalitions are getting millions of dollars from their state governments as a result of the states’ settlement agreement with the tobacco industry. And, as if that weren’t enough, The American Legacy Foundation also uses millions of dollars from the settlement agreement for grants to selected state anti-tobacco coalitions. Steve Schroeder, CEO of the RWJF, is on the board of directors of the American Legacy Foundation.

The National Center for Tobacco-Free Kids

“The IRS takes at least 80 to 120 days to issue such a letter [conferring favorable 501(c)(3) tax-exempt status], but in the Center’s case it issued the letter 27 days after its application was received last spring. The Center promptly injected itself into the 1996 election campaign.”

“Politics and the IRS—III,” Wall St. Journal, 2/18/97

“The IRS should review whether TFK’s lobbying expenses, which appear to be substantial, were improperly funded by the 501(c)(3) Center. In many respects, TFK’s political and lobbying activity raise questions about its tax-exempt status.” Patrick Reilly, “Blowing Smoke: Tobacco-Free Kids, Allies Overshoot Campaign,” Capital Research Center, August 1998.

“Sen. Ron Wyden (D-OR) will join the Campaign [TFK] today in calling for congressional hearings with top tobacco company executives and an increased investigative effort by the Justice Department into the ‘possible lies’ by the executives. The coalition will unveil an advertising campaign aimed at the congressional leadership that will push for a public hearing.” “Tobacco Poll: Public Wants Congress to Hold Hearings,” Health Line, American Political Network, 4/7/97.

“William V. Corr, a longtime Senate aide, chief of staff for Health and Human Services Secretary Donna E. Shalala and most recently chief counsel and policy director for Senate Democratic leader Thomas A. Daschle (S.D.) is moving to the Campaign for Tobacco-Free Kids. Corr is to be executive vice president.” “People: Dark Days Loom in the Senate: Corr Moves, Dominoes Follow,” The Washington Post, 2/18/00.

Formed in 1996 by the American Cancer Society, the American Lung Association, and the American Heart Association, the National Center for Tobacco-Free Kids (TFK) received \$20 million in initial funding from the Robert Wood Johnson Foundation. “The Campaign for Tobacco-Free Kids,” now a trademark used by the Center, was originally founded in 1995 as a lobbying group to support FDA regulation of the tobacco industry.

Among TFK’s board members are John Seffrin of the ACS, Lonnie Bristow, former president of the AMA, and Randolph Smoak, vice chair of the AMA. Seffrin, Bristow and Smoak have all served on the Interagency Committee on Smoking and Health.

TFK’s first president was William Novelli, co-founder of the giant PR firm Porter-Novelli. Novelli’s background in public relations and “social marketing” eminently qualified him to create the Campaign as an anti-tobacco marketing platform and make effective use of targeted media ads and of unpaid media exposure. Novelli resigned from TFK in December 1999 in order to become an associate executive director of the AARP. Stepping up to take his place was attorney Matt Myers, formerly TFK’s executive vice president and general counsel.

The TFK serves as the national attack dog for the anti-tobacco movement. Its chief activities appear to be demonizing the tobacco industry, pushing FDA regulation of the tobacco industry, pushing smoking bans and higher tobacco taxes, eliminating tobacco advertising, and intimidating legislators into enacting anti-tobacco legislation.

“Between September 1996 and the November 1996 elections, TFK organized an advertising campaign that targeted key legislators in their home states and attacked RJR mascot Joe Camel in three national newspapers: the Washington Post, New York Times and Wall Street Journal. Ads aimed at Congress ran in Washington, D.C. newspapers and on the radio and television.

“When it comes to tobacco, will Senators X and Y stand with America’s kids?” read several ads. They named the Senators representing the areas covered by the newspapers and urged them to accept the Food and Drug Administration’s proposed ‘rule’ giving the agency jurisdiction over tobacco-related advertising.”

Patrick Reilly, “Blowing Smoke,” Capital Research Center, August 1998.

The Robert Wood Johnson Foundation continues to fund the TFK, and the TFK continues to employ its political attack-dog strategy, still pushing for FDA regulation of tobacco products, still demonizing the tobacco industry, still supporting smoking bans and abolition of tobacco advertising, and still attempting to intimidate legislators, governors and even the President of the United States and his cabinet.

Halos of Brass: Trading Logos for \$\$\$

“Businesses paid North American charitable organizations an estimated \$535 million last year for the use of nonprofits’ names for marketing....” “Attorneys general announce report on misleading product advertising,” AP report, printed in The Milwaukee Journal Sentinel, 4/7/99.

“SmithKline Beecham PLC, the big British-based drug manufacturer, will pay the cancer society [ACS] at least \$1 million per year in sales royalties for three years. In exchange, the society’s logo will appear on NicoDerm CQ boxes and advertising, along with a reference to the two as partners in promoting smoking cessation.” Steve Sakson, AP, “Cancer Society sells its name,” The Miami Herald, 8/17/96, p.1C.

In 1997 the American Lung Association was promised \$2.5 million to lend its name for two years for use in marketing Johnson & Johnson’s Nicotrol. Reed Abelson, “Sales Pitches Tied to Charities Attract Scrutiny,” The New York Times, 5/3/99.

According to a 1996 article in The New York Times (Milt Freudenheim, “Marriage of Necessity: Nonprofit Groups and Drug Makers, August 20), the American Cancer Society’s sale of its name and logo for marketing purposes to SmithKline Beecham was part of a growing trend of affiliations between drug companies and nonprofit organizations. It’s a brilliant marketing strategy on the part of Big Drugs, because consumers assume that use of a highly respected health charity’s name on a product implies that the charity has freely endorsed that particular product.

Initially the SmithKline Beecham ads ran with no disclaimer saying that the ACS had been paid in return for use of its logo, but 12 state attorneys general felt strongly that such ads were misleading to consumers and sued the drug company. SmithKline settled the suits for a total of \$2.5 million and agreed to run the words,

“SB makes an annual grant to the ACS for cancer research and education for the use of their seal.” It was a small price to pay for such a profitable marketing deal, and the phrase about SB making a grant for cancer research even enhances the feel-good quotient of the company’s Nicoderm ads and buys priceless PR.

The use of non-profits’ names to sell drugs isn’t new and neither are the resulting lawsuits by state attorneys general. Back in 1994, The Arthritis Foundation accepted \$1 million from Johnson & Johnson’s McNeil Consumer Products for use of the foundation’s name in marketing an over-the-counter pain reliever. In that case McNeil settled with 19 attorneys general for \$2 million.

It’s not as if the non-profits are unaware that the use of their name on drug products implies endorsement.

“Some of the American Cancer Society’s own research, for instance, suggests that consumers, who place an extraordinary amount of trust in charities, assume the charity is standing behind a product when its name is used. A 1994 study, sponsored by the Michigan division of the society, concluded after conducting focus groups and consumer interviews that the use of its logo ‘is considered an endorsement by the ACS by nearly all group members’”. Reed Abelson, “Sales Pitches Tied to Charities Attract Scrutiny,” The New York Times, 5/3/99.

But these groups want the money, and they justify it by saying they are not actually endorsing the products, but are forming “educational” partnerships with the company.

As one press release spins it:

“Evidence clearly shows that, when handled responsibly, educational partnerships like that of the American Cancer Society and SmithKline Beecham increase communication of helpful, and sometimes lifesaving, information to the broader public.” PRNewsire, 11/18/97.

The same press release goes on to tout the traveling ACS/SmithKline “NicoVan,” a 34-foot mobile smoking-cessation counseling center, “customized with colorful graphics to become the ‘world’s largest stop smoking brochure.’” The smoking cessation counseling is free, as is no doubt the information on smoking-cessation drugs.

As further evidence of how lucrative such a “partnership” could be for the ACS, when the Master Settlement Agreement was being discussed between the tobacco companies and the state attorneys general in 1997, SmithKline Beecham issued a press release supporting the ACS as administrator of any cessation funding generated by the settlement.

“However, any stop smoking treatment funded by the settlement must be administered by an organization with a proven commitment to, and experience in fighting tobacco addiction. Organizations such as the American Cancer Society and other public health agencies need to play a role in delivering the treatment to ensure that the complete range of smokers’ needs are met.”
PRNewswire, 6/20/97.

Just over a year ago a three-year breast cancer “collaboration” between the ACS and Johnson & Johnson subsidiary Ortho Biotech, a maker of cancer drugs, was announced. No dollar amounts were given in the press release, but there is little question that money changed hands in the deal.

There are connections between the ACS and the pharmaceutical industry on every level. Pharmaceutical executives even sit on the organization’s board. Robert A. Ingram, CEO of GlaxoWellcome and member of the board of the Pharmaceutical Research and Manufacturers Association, is a member of the advisory board of the ACS, according to a 1997 company press release; David Bethune, past board member of the Pharmaceutical Research and Manufacturers Association and current director of St. Charles Pharmaceutical Co., was named a “founding trustee” of the ACS in January 2000.

“Partnerships” and commercial collaboration between organizations such as the American Cancer Society and the pharmaceutical industry will continue so long as the public continues to believe in the “purity” of the non-profits. And it is clear that the illusion of purity is just as much a saleable commodity as the smoking cessation drugs of the pharmaceutical multinationals.

IX - The Gum, the Patch, the Pill: The Safety and Efficacy of “Smoking Cessation” Drugs

Publication date: August 10, 2001

“The low quit rates associated with unaided and nonpharmacological quit attempts demands that pharmacological treatment be offered to all smokers planning to quit unless there is a medical contraindication.”

Okuyermi KS, Ahluwalia JS, Harris KJ, “Pharmacotherapy of Smoking Cessation,” *Archives of Family Medicine*, 9(3), March 2000. This “Clinical Review” was funded by the National Cancer Institute and the Robert Wood Johnson Foundation. Dr. Ahluwalia has been funded by and received honoraria from Glaxo Wellcome, SmithKline Beecham, and Johnson & Johnson subsidiary McNeil Consumer Products, all companies that market smoking cessation drugs.

“Of quitters polled, 59 percent quit ‘cold turkey,’ while 11 percent used nicotine replacement therapy.”

“Attitudes and Behaviors Related to Smoking Cessation: A Survey of Current and Former Smokers,” Gallup poll released Oct. 20, 1998. The poll also found that only 36 percent of current smokers are very interested in quitting.

“...interest in giving smokers up to \$600 apiece for nicotine patches and other quitting aids, for instance, might subsidize manufacturers of such products, but may do little to help most addicts. Studies show that only 10 to 15 percent of smokers give up the habit by using nicotine gum or patches.”

Catherine Clabby, “Pact doesn’t assure smokers a happy ending,” *Raleigh News & Observer*, June 26, 1997.

The 1988 U.S. Surgeon General’s report deeming tobacco use an addiction initiated a boom in the smoking cessation business, especially for the drug industry. By the mid-1990s, when the anti-tobacco organizations became partners with the pharmaceutical conglomerates in pushing smoking cessation (and smoking cessation drugs), the boom intensified.

At the end of 1995, sales of nicotine-based cessation drugs were roughly \$200 million in the U.S. and by the end of 2000 U.S. sales had more than tripled to roughly \$700 million. Considering that these figures do not include sales for Zyban, the non-nicotine cessation drug, or increasing global sales outside the U.S., it is easy to see that smoking-cessation drugs are a multi-billion-dollar business, one with even bigger potential profits in the future as the World Health Organization pushes smoking cessation globally.

The Development of Smoking Cessation Drugs

In 1971 Pharmacia developed the first nicotine replacement product for smoking cessation, nicotine-laced chewing gum. The gum was launched for use in Switzerland in 1978, and in 1984 it was approved by the U.S. Food and Drug Administration (FDA) as a smoking cessation prescription drug. SmithKline Beecham subsequently marketed the gum as Nicorette.

The patch was developed by Duke University researcher Jed Rose in the early 1980s. Manufactured by Pharmacia, the patch has been marketed in the U.S. as Nicotrol by a Johnson & Johnson subsidiary and as Nicoderm by SmithKline Beecham. The FDA approved Nicotrol and Nicoderm as prescription smoking cessation drugs in 1991, and in 1996 the FDA did away with the prescription requirement for the patches and the gum, approving them for over-the-counter sale directly to consumers.

The nicotine inhaler and nicotine spray have also been approved as smoking cessation drugs by the FDA, but to date the agency has not approved them for over-the-counter sale. Ironically, the nicotine inhaler evolved from a “smoke-free” cigarette. Sold under the brand name Favor in the 1980s, the cigarette was forced off the market by the FDA in 1987 because it was deemed a “drug delivery device.” Just ten years later the FDA approved Johnson & Johnson’s Nicotrol inhaler as a nicotine delivery device which could be used for smoking cessation.

Orally ingestible nicotine drugs have been developed but have not yet been clinically tested. One of the two Duke University inventors of this cessation drug is Jed Rose, who also invented the nicotine patch.

Glaxo Wellcome's Zyban, the only non-nicotine smoking cessation drug currently approved by the FDA, was originally developed as the anti-depressant Wellbutrin. The FDA approved Wellbutrin, the trade name for the drug bupropion, in 1985, but it was subsequently removed from the market because of concerns about drug-induced seizures. Wellbutrin was reintroduced as an anti-depressant in 1989. When researchers noted that some of those taking the drug quit or reduced their smoking, Glaxo Wellcome began clinically testing it as an aid for smoking cessation. The FDA approved Zyban as a prescription smoking cessation aid in May 1997 and approved the combined use of Zyban and the nicotine patch in 1999. Bupropion is currently marketed by GlaxoSmith Kline as an anti-depressant under the trade name Wellbutrin and as a smoking cessation drug under the name Zyban.

FDA Approval

In order for any drug or drug delivery device to be marketed in the U.S., it must first be approved by the FDA. To gain FDA approval, the pharmaceutical company intending to market a specific drug must conduct clinical tests to demonstrate that the drug is both safe for use and that it works for the purpose for which it is intended. Once clinical testing is complete, the results are presented to an FDA panel of experts for evaluation. If the panel believes the clinical test results demonstrate both safety and efficacy, the drug is recommended for approval, and the pharmaceutical company is then free to market its drug under conditions determined by the FDA (prescription or over-the-counter sales, recommended uses and doses, mandated warnings, duration of use, etc.).

On its face, the system appears to be a good one for protecting consumers from unsafe drugs and fraudulent claims about the curative powers of drugs. However, in practice the system is far from perfect. Sometimes political pressure is brought to bear on the FDA to approve—or not approve—a given drug. Sometimes there are financial ties between members of FDA panels and pharmaceutical companies seeking drug approval, and occasionally cases of outright graft have been uncovered at the FDA. But even when the approval process is uncorrupted by political interference or competing financial interests on the part of FDA employees or scientific panel members, there is still one major problem: the clinical trials are financed by and heavily influenced by the drug companies themselves. The FDA itself does none of the testing; FDA scientific panels merely examine the clinical test results the drug companies present to them, and the companies are not likely to present results which are not favorable to the companies' products.

In the case of smoking cessation drugs, the results of the company-funded clinical tests had to demonstrate that the drugs were generally safe and that they were effective for smoking cessation. The FDA standard for approval for "efficacy" was that at six weeks the drugs had to show significantly better rates than placebos (nothing) for 28 days of continuous smoking abstinence in test subjects. The fact that at the end of a year, many of those test subjects were smoking again did not enter into the FDA approval process, and the pharmaceutical companies were able to list the quit rates at six weeks on their drug labels.

To date the FDA has approved only five drugs for smoking cessation: Nicorette gum, the Nicoderm and Nicotrol patches, the Nicotrol inhaler and nasal spray, and Zyban. Of these, the gum, the patches and Zyban are the most widely used, but just how safe and efficacious are they?

The Patch and the Gum: Safe but Ineffective

Called "nicotine replacement therapy" (NRT), the patch, the gum, the inhaler, and the nasal spray all have about the same level of efficacy, which is to say that none of them is efficacious, at least in the long term.

- **“In their trial of 4 nicotine replacement therapy (NRT) products, Hajek and colleagues concluded that there were no notable differences in general efficacy among the tested nicotine patch, gum, nasal spray and inhaler.”** Letter, “Continued Dependence on Nicotine Replacement Therapy Should Be Reported and Discussed in Smoking Cessation Trials,” *Archives of Internal Medicine*, July 10, 2000.

- **“The initial report of this trial [The Transdermal Nicotine in Cardiac Patients Study] described the safety of the therapy in this high-risk outpatient population; however, 24 weeks after randomization, only 14 percent of the subjects in the nicotine-treatment group and 11 percent of those in the placebo [no nicotine] group were abstinent from smoking....”**

“At 48 weeks after randomization, 10 percent of subjects in the nicotine group and 12 percent of those in the placebo group were abstinent.” Joseph AM, Antonnucio D, “Lack of Efficacy of Transdermal Nicotine in Smoking Cessation,” Letter, *New England Journal of Medicine*, 341(15), Oct. 7, 1999. In other words, at 48 weeks, those using nothing had a higher quit rate than those using the patch. Joseph and Antonnucio point out that another recent study also showed no efficacy for the patch, and they suggest that clinical trials which did show efficacy might have selected optimal subjects or that trials with negative outcomes might not have been published.

- **“At the annual meeting of the Society for Research on Nicotine and Tobacco conference held in San Diego, CA, Scott Leischow, PhD., Associate Professor of Public Health for the University of Arizona, presented research findings indicating that over-the-counter (OTC) nicotine patches resulted in low quit rates of 4-5% at one year, which is in the range of naturally occurring smoking cessation. Published in the January/February 1999 issue of the American Journal of Health Behavior, the study also found that brief physician intervention did not improve on these rates.”** “New Smoking Study Questions the Effectiveness of the Nicotine Patch,” PR Newswire, Mar. 24, 1999.
- **“The self-reported continuous quit rate among patients originally assigned 21 mg (20.2%) was significantly higher than rates for patients assigned 14 mg (10.4%), 7 mg (11.8%), or placebo patches (7.4%).... Relapse rates among the various treatment conditions were similar after 1 year postcessation.”** Daughton DM, Fortmann SP, Glover ED, Hatsukami DK, et al, “The smoking cessation efficacy of varying doses of nicotine patch delivery systems 4 to 5 years post-quit day,” *Preventive Medicine*, 28(2): 113-8, Feb 1999.
- **“However, there was no statistically significant difference between the two groups of smokers [one group on the nicotine patch and one group on a placebo patch] after one year of follow-up.”** Perng RP, Hsieh WC, Chen YM, et al, “Randomized, double-blind, placebo-controlled study of transdermal nicotine patch for smoking cessation,” *J Formos Med Assoc* 97(8): 547-51, Aug. 1998.
- **“There was no difference between nicotine and placebo groups.... Nicotine patches had no influence on smoking cessation during pregnancy....”** Wisbord K, Henriksen TB, Jespersen LB, Secher NJ, “Nicotine patches for pregnant smokers: a randomized controlled study,” *Obstet Gynecol* 96(6): 967-71, Dec 2000.
- **“We conclude that transdermal nicotine patches are of limited efficacy in achieving long-term smoking cessation and that the relative costs and benefits of this treatment are not adequately specified.”** Mankani SK, Garabrant DH, Homa DM, “Effectiveness of nicotine patches in a workplace smoking cessation program. An eleven-month follow-up study,” *J Occup Environ Med*, 38(2): 184-9, Feb. 1996.
- **“However, users of nicotine gum and patches were found to be less likely to have given up smoking than non-users.”** Buck D, Morgan A, “Smoking and quitting with the aid of Nicotine Replacement Therapies in the English adult population,” *European Journal of Public Health* 2001, Vol 11, Issue 2, pp. 211-217.

By 1997, when it became obvious that the FDA approved nicotine-based cessation drugs were not very efficacious in the long term, an FDA panel urged that the labels for these drugs be changed to reflect the low long-term efficacy. The marketers and manufacturers of the drugs (Pharmacia, SmithKline Beecham, and Johnson & Johnson subsidiary McNeil) argued vehemently against any such labeling changes:

“The standard for approval of smoking cessation products, 28 day continuous abstinence at six weeks, and the labeling that has resulted from this standard, allows ample room for companies to market their products in a responsible way.”

George Quesnelle, VP of medical marketing and sales for SmithKline. Quoted in “FDA Panel Urges Changes in Nicotine Patch and Gum Labels,” Reuters, June 10, 1997.

So how could the FDA approve—and continue to approve—these “nicotine replacement” products as efficacious for smoking cessation when in fact at the end of a year or less they work no better than a piece of adhesive tape? Part of the answer is the FDA standard for “efficacy” in smoking cessation drugs. The company-funded clinical trials only had to demonstrate that these drugs were significantly better than placebo at six weeks. The rest of the answer is that the clinical trials were funded by the pharmaceutical companies, and, as Joseph and Antonnucio suggest above, optimal subjects may have been selected for the trials or the trials with negative outcomes may have been suppressed.

An example of how the results of early clinical trials vary from those done after FDA approval lies in two studies by Michael Fiore and D. E. Jorenby of the Center for Tobacco Research and Intervention at the University of Wisconsin Medical School. Fiore and Jorenby have both received funding from various pharmaceutical companies and their adjuncts (e.g. The Robert Wood Johnson Foundation). In 1994, they found that the nicotine patch was very efficacious: “The nicotine patch is an effective smoking cessation aid and has the potential to improve public health significantly.”

“Across 17 studies meeting inclusion criteria, overall abstinence rates for the active patch were 27% (vs 13% for placebo) at the end of treatment [6 weeks] and 22% (vs 9% for placebo) at 6 months.... The 16-hour and 24-hour patches appeared equally efficacious, and extending treatment beyond 8 weeks did not appear to increase efficacy. The pooled abstinence data showed that intensive behavioral counseling had a reliable but modest positive impact on quit rates.” Fiore MC, Smith SS, Jorenby DE, Baker TB, “The effectiveness of the nicotine patch for smoking cessation. A meta-analysis,” JAMA, 271(24): 1940-7, June 22, 1994.

In March 1998, Glaxo Wellcome (makers of Zyban) awarded \$1 million to the University of Wisconsin Center for Tobacco Research and Intervention to support a professorship in tobacco dependence. The award went to Michael Fiore. In 1999, the results of a clinical trial for Zyban (funded by Glaxo Wellcome) appeared in the *New England Journal of Medicine*:

“RESULTS: The abstinence rates at 12 months were 15.6 percent in the placebo group, as compared with 16.4 percent in the nicotine-patch group, 30.3 percent in the bupropion [Zyban] group, and 35.5 percent in the group given bupropion and the nicotine patch.... CONCLUSIONS: Treatment with sustained-release bupropion alone or in combination with a nicotine patch resulted in significantly higher long-term rates of smoking cessation than use of either the nicotine patch alone or placebo. Abstinence rates were higher with combination therapy than with bupropion alone, but the difference was not statistically significant.” Jorenby DE, Leischow SJ, Nides MA, Rennard SI, Johnston JA, Hughes AR, Smith SS, Muramoto ML, Daughton DM, Doan K, Fiore MC, Baker TB, “A controlled trial of sustained-release bupropion, a nicotine patch, or both for smoking cessation, *NEJM*, 340(9): 685-91, Mar 4, 1999. The study also noted that 34.8 percent of the study participants discontinued one or both medications, the 23.3% who stopped because of adverse “events” were in either the bupropion-alone group or in the bupropion-plus-patch group.

So in this study, which was one of only two clinical trials submitted to the FDA for approval of Zyban as a smoking-cessation drug, the patch and the placebo had about the same results, a far cry from Fiore’s and Jorenby’s glowing reports of the efficacy of the patch in 1994. Apparently the “efficacy” of the patch depends on which pharmaceutical company is doing the funding.

Zyban (bupropion): Less Safe and Not Very Effective

“My daughter was fit and healthy before she started taking this drug, but now the doctors say she has to be on medication for the rest of her life. I am blaming Zyban for this,”

Susan Sinclair, quoted in “Ban anti-smoking pill that wrecked my life,” *Northern Echo* (UK), July 23, 2001.

Though the patch and other nicotine-based cessation drugs have few, if any, side effects (a skin rash is the most common negative side effect of the patch), Glaxo Wellcome's Zyban has many. In addition, it can interact with a number of other drugs. For these reasons, the FDA has approved its use only as a prescription drug.

Included in the long list of drugs that can interact with bupropion are alcohol, cocaine, corticosteroids, kava kava, medications or herbal products for weight loss, medicines for difficulty sleeping, nicotine, phenobarbitol, some medicines for heart rhythm or blood pressure, some medicines for pain, and St. John's wort.

Among the most common serious side effects are seizures (a dose-dependent risk, according to Glaxo Wellcome), confusion, vomiting, and hives. Less common side effects are blurred vision, difficulty breathing, fast or irregular heartbeat, increased blood pressure, and hallucinations. It can also cause loss of appetite, loss of sexual drive, agitation, anxiety, constipation, wakefulness, dizziness, dry mouth, headache, nausea, tremors, chest pain, and abdominal pain. It may cause changes in menstruation in women and is not recommended for those with liver problems, since metabolites of bupropion may accumulate in the liver.

Despite all these possibly serious side effects, it was approved by the FDA as a smoking cessation aid. Further, the U.S. Public Health Service Clinical Practice Guidelines released in June 2000, recommend Zyban as “an option for first-line use as an alternative to nicotine-replacement therapy.” It should be noted that Michael Fiore, who was one of the researchers on the pivotal Glaxo Wellcome-funded Jorenby study which led to FDA approval for Zyban, was also the lead author of the U.S. PHS Clinical Practice Guidelines. Fiore has also received significant additional funding from Glaxo Wellcome and is a paid consultant to the company.

British guidelines released in December 2000 adopted a more cautious approach to Zyban, highlighting the limited evidence about the drug's effectiveness in the absence of behavioral support. An editorial in the July 8, 2000 *BMJ* was far more enthusiastic and called for the UK National Health Service to include bupropion on the list of reimbursable prescriptions. The authors of the editorial, John Britton and Martin Jarvis, have both received honoraria and other funding from Glaxo Wellcome, the drug's manufacturer, and the editorial itself drew some highly critical responses:

“Britton and Jarvis could have pointed out that half of patients who successfully stop smoking with the aid of bupropion will start again within 12 months of coming off the drug. They could also have referred in more detail to the side effect profile and the number of patients for whom the drug will be unsuitable. Bupropion may have a 1 in 1000 risk of inducing seizures (product information from Glaxo Wellcome, the manufacturer of the drug). This may be an acceptable risk for drugs to treat disease but is less so for lifestyle drugs.” Harrison C, “Bupropion may not be as good as editorial implies,” Letter, *BMJ*, Feb 17, 2001.

“Britton and Jarvis's editorial on bupropion does not mention that the drug is an amphetamine derivative.... Bupropion has been released in the United Kingdom on the strength of only two American clinical trials financed by the manufacturer [the highly-positive Jorenby and Fiore study and the Hurt/Sachs/Glover study].... Bupropion is being foisted on an unsuspecting British public with little evidence that it works much better than placebo.” Kinnell HG, “Drug is almost identical in structure to diethylpropion, a controlled drug,” *BMJ*, Feb 17, 2001.

In the first year after Zyban was released in the UK as a prescription drug for smoking cessation, 40 people died after taking it and thousands of others reported serious negative reactions. As a result, the country's Committee on Safety of Medicines ordered changes to the prescribing regimen and stronger warnings about its use ("Anti-smoking drug must carry stricter warnings," James Meikle, *The Guardian*, June 1, 2001).

The reported deaths and masses of complaints about Zyban didn't prevent the BMJ from publishing another editorial in May 2001 supporting the use of nicotine replacement products and bupropion for those who smoke 10 – 15 cigarettes a day or more. Time Coleman and Robert West, the writers of the editorial, both received funding from Glaxo Wellcome and the pharmaceutical companies manufacturing nicotine replacement products.

In Canada, too, there have been reported deaths by Zyban users, and some experts feel the side effects are too serious for the drug to be used for smoking cessation:

"It is very unusual to get 300-plus adverse drug-reaction reports in the first year of marketing a drug. The question is whether the benefit of the drug justifies the risk...and the answer is no." Rick Hudson, a medical consultant to British Columbia's Pharmacare program, quoted in Krista Foss, "The hidden cost of kicking the habit," *Toronto Globe and Mail*, Aug. 31, 1999.

Australia also has had reports of deaths and negative reactions in Zyban users:

"A federal Government committee monitoring the anti-smoking drug Zyban has had almost 800 reports of adverse reactions in the seven months since the drug became available [in Australia].... There have been nine deaths which may be associated with the use of the drug." "Hundreds of adverse effects to anti-smoking drug Zyban reported," Australian Broadcasting Corporation, June 17, 2001.

"Authorities at Sydney's Westmead Hospital say at least one person a week is admitted suffering from side effects after using the drug." Australian Broadcasting Corp., June 18, 2001.

Interestingly, there are few if any media reports on the adverse reactions to Zyban in the U.S., and despite the known risks of the drug, clinical trials on children and pregnant women are continuing in the United States. The National Cancer Institute and pharmaceutical interests are funding Zyban smoking cessation clinical trials on children as young as 13 at the University of Arizona and at Children's Hospital in Pittsburgh. Bupropion is also being clinically tested on adolescents with attention deficit hyperactivity disorders.

Glaxo Wellcome also maintains a pregnancy registry for pregnant users of bupropion. The purpose of the registry is "to gain more information about the potential teratogenicity [the potential for causing fetal malformations and birth defects] of these drugs during pregnancy" (White AD, Andrews EB, "The Pregnancy Registry program at Glaxo Wellcome Company," *J Allergy Clin Immunol*, Feb 1999; 103 (2 Pt 2): S362-3).

Despite all its serious side effects, is Zyban really effective for smoking cessation? The two Glaxo Wellcome funded clinical trials (Jorenby/Fiore and Hurt/Sachs/Glover/Offord, which were submitted to the FDA to demonstrate the drug's efficacy) found supportive evidence for efficacy.

- **Jorenby:** Zyban resulted in a 30.3 percent quit rate at 12 months, compared to 16.4 percent in the nicotine patch group and 15.6 percent in the placebo group. This meant that Zyban was almost twice as effective as either the patch or nothing at the end of a year. However, 11.9 percent of those in the Zyban group stopped treatment because of "adverse events," and another 11.4 percent in the Zyban plus patch group discontinued because of "adverse events." [Jorenby DE, Leischow SJ, Nides MA, Rennard SI, Johnston JA, Hughes AR, Smith SS, Muramoto ML, Daughton DM,

Doan K, Fiore MC, Baker TB, “A Controlled trial of sustained-release bupropion, a nicotine patch, or both for smoking cessation,” *New England Journal of Medicine*, Mar 4, 1999].

- **Hurt/Sachs/Glover/Offord:** Zyban resulted in quit rates at 12 months of 19.6 percent for those taking 100 mg, 22.9 percent of those taking 150 mg, and 23.1 percent of those taking 300 mg of Zyban. This compared to 12.4 percent of those taking only placebo. “The rates for the 150 mg group and the 300 mg group—but not the 100 mg group—were significantly better than those for the placebo group.” (Hurt RD, Sachs DP, Glover ED, Offord KP, et al, “A comparison of sustained-release bupropion and placebo for smoking cessation,” *New England Journal of Medicine*, Oct 23, 1997).

These two studies found far higher cessation rates for Zyban takers at the end of a year than subsequent studies have. Nevertheless, in the Jorenby study Zyban was *not* effective as a smoking cessation drug in 70 percent of those taking it, even after a fairly large number of participants had dropped out because of “adverse events.” And in the Hurt/Sachs study Zyban was not effective as a smoking cessation drug—even at maximum dosage—for 77 percent of those taking it. Those on the minimum dosage of Zyban did not do significantly better than those on nothing, so at low doses the drug was completely ineffective as a smoking-cessation medication.

A more recent study funded by Glaxo Wellcome (now GlaxoSmith Kline) found that Zyban was no more effective at helping people give up smoking than the gum or the patch:

“Ms Renee Bittoun, director of the Smoking Research Unit at Sydney University [Australia], said she could not reveal the precise results of the study, which was sponsored by the drug’s manufacturer, GlaxoSmith Kline, because her contract would not allow it.... But the study did not show that Zyban was any more effective at helping people give up smoking than the gums or patches, she said.” Judith Whelan, “Anti-smoking drug all puff, says tester,” *Sydney Morning Herald*, June 1, 2001.

So the question is: Given that Zyban does *not* help the vast majority of people using it to quit smoking, even according to company-funded trials, is it worth the risks it imposes? The answer is that it is not, at least not for those who have been harmed by the drug:

“I would rather die after 35 years of smoking than overnight from taking a Zyban tablet.”
Alan Gardiner, a UK smoker who had a massive seizure after using Zyban to quit smoking. Quoted in “Zyban...Over 37 Deaths,” *The Daily Record*, June 1, 2001.

X - The Marketing of Smoking Cessation Drugs

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“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.”

IMS Health Drug Monitor, Oct. 2, 1998.

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

“Use of FDA-Approved Pharmacologic Treatments for Tobacco Dependence—United States, 1984-1998,” Centers for Disease Control, MMWR, July 28, 2000.

“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%.”

“Impact of Promotion of the Great American Smokeout and Availability of Over-the-Counter Nicotine Medications, 1996,” Centers for Disease Control, MMWR, Sept. 19, 1997.

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....” “Use of FDA-Approved Pharmacologic Treatments for Tobacco Dependence—United States, 1984-1998,” U.S. Centers for Disease Control, MMWR, July 28, 2000.

“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 Robert Wood Johnson Foundation and the ACS funded an Advocacy Institute legal analysis of the constitutionality of government efforts to restrict tobacco advertising and to outline “suggestions for crafting federal legislation” that would essentially skirt constitutional protections of commercial free speech (Sutton

C, Thain G, “Advertising Regulation in Tobacco Prevention and Control,” Policy Analysis No.13, The Advocacy Institute).

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:

"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 Marriion 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.

Increasing Bans, Increasing Sales

"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 makers may be facing an unusual rival as long-term suppliers of nicotine fixes: the pharmaceutical industry," The Wall St. Journal, Feb 27, 1998.

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.”

XI - Big Pharmaceuticals, Big Money

Publication date: August 24, 2001

“The top 10 drug companies are reported to have profits averaging about 30 percent of revenues—a stunning margin. Over the past few years, the pharmaceutical industry as a whole has been by far the most profitable industry in the United States.”

Angell M, “The Pharmaceutical Industry—To Whom Is It Accountable?” *New England Journal of Medicine*, June 22, 2000.

“In every year since 1982, the drug industry has been the most profitable in the United States, according to Fortune magazine’s rankings. During this time, the drug industry’s returns on revenue (profit as a percent of sales) have averaged about three times the average for all other industries represented in the Fortune 500.”

Public Citizen Report, “Rx R&D Myths: The Case Against the Drug Industry’s R&D ‘Scare Card,” July 23, 2001.

“Put together, the market capitalization of the four largest [pharmaceutical] companies is more than the economy of India.”

David Earnshaw, formerly director of European government affairs for SmithKline Beecham, now leader of Oxfam’s campaign on access to medicines. Quoted in Roger Dobson, “Drug Company lobbyist joins Oxfam’s cheap drugs campaign,” *BMJ*, 322, April 28, 2001, p. 1011.

The international illegal drug cartel no doubt makes a lot of money, but the risks are very high and include death by multiple gunshot wounds. The big pharmaceutical companies, on the other hand, make even more money, and the worst risks they face are such things as lawsuits. Furthermore, instead of trying to put them out of business, the U.S. government uses tax dollars to help them develop highly profitable new products.

Just how much money is involved in legal drug sales? According to IMS Health’s Drug Monitor Report, pharmaceutical sales in major world markets were \$179 billion for the fiscal year ending March 1998. Of that, U.S. sales accounted for \$68.7 billion. By March 2000, IMS America reported that in the U.S. alone prescription drug sales had climbed to an astonishing \$145 billion, and those monitoring U.S. prescription drug sales expect this trend to continue at least for the next nine years. Since 1993, nationwide spending for prescription drugs has increased at an average annual rate of 12%, while all other types of health spending increased at an average annual rate of only 5%. The cost of drugs is now outpacing the cost of physician care in the U.S. and Canada.

“Historically, hospitals have constituted the greatest of Canada’s total health expenditures, followed by the combined cost of all physicians’ services, with drug expenditures in third place. In 1997 drug spending vaulted into second place, at 14.5% of the total \$79 billion spent on public and private health costs. (Spending on physicians’ services represented 14.2% of expenditures; hospitals 32.5%). By 2000, drugs were 15.5% of total expenditure.” Candis McLean, “The Real Drug Pushers,” *Report Newsmagazine*.

The enormous growth in drug sales isn’t due to a growth in revolutionary new drugs. According to a new report by Public Citizen, only about 22 percent of new drugs brought to market in the last 20 years were truly innovative drugs representing important therapeutic improvements over existing drugs (Public Citizen report, “Rx R&D Myths: The Case Against The Drug Industry’s R&D ‘Scare Card,” July 23, 2001). According to many experts, the single biggest factor in the increase in drug sales can be summed up in one word: Marketing.

Breakthroughs Down, Marketing Up

“Last year, the Food and Drug Administration approved just 27 wholly new drugs, down from 53 in 1996.” Gardiner Harris, “Pitch to Switch,” *Wall St. Journal*, May 21, 2001, p.1A.

“Overall, the industry’s marketing and administration expenses are generally more than twice those of research and development. At Pfizer, for instance, marketing and administration make up 39% of expenses, compared with 17% for R&D.... A Pfizer spokesman says the company ‘is very optimistic about the future’ and relies not only on launching new medicines but increasing the sales of old ones. While that can be done by testing new uses to old drugs and combining them with other drugs, the best means is boosting marketing budgets.” Gardiner Harris, “Drug Firms, Stymied in the Lab, Become Marketing Machines,” *Wall St. Journal*, July 6, 2000, p. A1.

“If one company epitomizes the modern drugs industry it is Pfizer. Just a decade ago, it was regarded as an industry also-ran. But the US company has powered its way up the global ranking list to its unassailable position thanks mainly to its marketing prowess.... While some of Pfizer’s research has been excellent, its success stems largely from its ability to turn drugs—often ones licensed in from its competitors—into multi-billion dollar products.” David Pilling, “Pharmaceuticals 2001/Sales & Marketing: Relentless rise in role of reps and big launches,” *Financial Times*, April 26, 2001.

While they have not run completely dry, the pharmaceutical industry’s labs simply aren’t producing many important new medicines. As one industry spokesman put it, all the low-hanging fruit has already been picked. Because the big companies’ own labs aren’t coming through, they are increasingly relying on licensing new drugs from universities, government or smaller companies that hold the patents for them.

Sometimes these licensing agreements are very complex. For example, Advanced Therapeutic Products (ATP) patented the technology forming the basis of both the Nicorette and Nicotrol nicotine inhalers. Pharmacia acquired the production rights for the inhaler from ATP for a percentage of product payments. Pharmacia, in turn, manufactured the Nicorette inhaler for SmithKline Beecham and the Nicotrol inhaler for Johnson & Johnson subsidiary McNeil, and these two companies market the inhalers under their own trademarks.

Many, if not most, of the biggest-selling drugs are actually developed through government grants to universities or individual researchers.

“According to NIH [National Institutes of Health], taxpayer-funded scientists conducted 55 percent of the research projects that led to the discovery and development of the top five selling drugs in 1995.” “Rx R&D Myths: The Case Against the Drug Industry’s R&D ‘Scare Card,”” Public Citizen report, July 23, 2001.

Though it has not yet been clinically tested for FDA approval, the new orally ingestible nicotine for smoking cessation drugs was developed by two Duke University researchers with funding by the U.S. Department of Veterans Affairs. The researchers have already sold production rights to a small pharmaceutical company. This company in turn will no doubt sell ingestible nicotine formulations to one or more of the big pharmaceutical companies, which will fund the clinical trials, get FDA approval, and then market the new cessation drugs under their own trademarks.

Thus, the taxpayers, not the big pharmaceutical companies, actually pay for much of the basic research for new drugs entering the market.

“In 1999, the National Institutes of Health (NIH) provided \$17.8 billion for research, and the major proportion was expended for basic research; the top 10 pharmaceutical

companies spent \$22.7 billion, primarily on clinical research. DeAngelis CD, “Conflict of Interest and the Public Trust,” JAMA 284(17), Nov 1, 2000.

“45 of the 50 top-selling drugs from 1992-1997 received government funding for some phase of development, according to an investigation by The Boston Globe. In all, taxpayers spent at least \$175 million helping to develop these 50 drugs.” “Rx R&D Myths,” Public Citizen report, July 23, 2001.

In addition to licensing new drugs to market, the big drug companies are also focusing on developing “me too” drugs (products almost identical to drugs already on the market), finding new medical applications for existing drugs, and marketing “new” formulations of older drugs. But all of these require little investment in basic research. In fact, they are more akin to new marketing tools than anything else, despite the clinical testing that must be conducted for FDA approval.

“Consider the welter of very similar drugs to lower cholesterol levels. Developing genuinely innovative drugs is difficult and chancy. It is easier to make ‘me-too’ drugs or minor variants of established products. To be profitable, the variation need only be sufficient to secure a new patent, and the rest is marketing.” Angell M, “The Pharmaceutical Industry—To Whom Is It Accountable?” *New England Journal of Medicine*, June 22, 2000.

Johnson & Johnson’s Nicotrol patch is essentially the same as SmithKline’s Nicoderm patch and neither was developed by the companies marketing them. Glaxo Wellcome’s Zyban for smoking cessation is exactly the same thing as Glaxo Wellcome’s older drug Wellbutrin for depression. GlaxoSmithKline’s see-through patch is the same old wine in a new bottle as is the company’s “new” orange-flavored Nicorette gum.

Direct-to-Consumer Marketing

Since 1997, when the FDA relaxed television and radio advertising restrictions for prescription drugs, the big pharmaceutical companies have increasingly turned to direct-to-consumer (DTC) marketing to increase their profits.

“Last year pharmaceutical companies spent \$1.8 bn on ‘direct to consumer’ advertising, mostly on television. Advertising expenditure in 1999 rose by 38.5% from the 1.3 bn spent in 1998, and was 33 times the amount spent on media advertisements in 1991.” Fred Charatan, “Prescription drug sales boosted by advertising,” BMJ, 321, Sept. 30, 2000, p. 783.

And it appears to be working. As the big drug companies have poured more and more money into DTC television ads, drug spending has risen enormously, and the bulk of the rise was accounted for by increased sales of the most heavily advertised prescription drugs.

“Doctors wrote 34.2% more prescriptions in 1999 than in 1998 for the 25 drugs promoted direct to consumers that contributed most to overall drug spending. Doctors wrote only 5.1% more prescriptions for all other prescription drugs.” Charatan, BMJ, Sept. 30, 2000, p. 783.

However, some physicians and industry watchdog organizations are becoming increasingly alarmed by the influence of the drug companies’ direct-to-consumer advertising tactics. They point out that not only do all drugs—especially prescription drugs—have negative side effects, but that such continual bombardment by drug ads “normalizes” taking drugs.

“It’s insidious; companies want you to think there’s something wrong with you. It’s saying in effect, ‘If you’ve got a problem, the way to deal with it is through pills.’ It’s also ‘medicalizing’ a problem which may not be a problem you need to deal with, like male pattern baldness or shyness. Once you have a drug, it becomes a medical problem.” Dr. Joel Lexchin, a Toronto physician and member of Medical Reform Group. Quoted in Candis McLean, “The real drug pushers,” Report Newsmagazine, Mar 19, 2001.

Americans appear ready to pop a pill to alleviate almost anything they feel is a problem, from feeling blue to thinning hair or stopping smoking or having more sex or losing weight or quieting unruly children. Though none of these problems is a genuine disease in and of itself, the drug ads suggest that they need “treatment” using one of their “medications.”

In addition to increasing numbers of these highly profitable “lifestyle” drugs, the pharmaceutical industry has capitalized on the current medical focus on *prevention* by turning out more and more medications designed to prevent disease, such as drugs to lower cholesterol and blood pressure levels and a host of new vaccines. While some of these drugs undoubtedly do help prevent disease for some people, they are sometimes prescribed when there is not a clear and compelling need for them (or when industry-friendly quasi-government panels lower the bar for what is deemed high blood pressure or high cholesterol).

Even such toxic and costly pharmaceuticals as chemotherapy drugs are sometimes used without sufficient justification, despite their serious side-effects.

“Many patients with cancer receive chemotherapy at the end of life, even if their kind of cancer is known to be unresponsive to the drugs, according to a study reported at the recent annual meeting of the American Society of Clinical Oncologists held in San Francisco.” Gottlieb S, “Chemotherapy may be overused at the end of life,” *BMJ*, 322, May 26, 2001, p. 1267. Dr. Ezekiel Emanuel, lead author of the study, also noted that chemotherapy is very expensive, \$38,308 for treatment of a patient in the final year of life as compared to \$27,567 for a patient not in the final year of life.

While treating cancers known to be unresponsive to chemotherapy with these drugs may do nothing to help suffering patients, it certainly benefits the pharmaceutical companies providing the drugs.

The fact is that *all* drugs, not just chemotherapy drugs, have potentially serious side effects, and no drug should be prescribed unless it is truly necessary to the health and well-being of a patient. Not even if the patient insists on having it because he or she has seen an upbeat television ad and is convinced that the advertised wonder drug will cure all of life’s pains and anxieties.

Side-effects and Medication Errors

“[P]rescription drugs...account for more deaths each year than all murders, auto accidents and airplane crashes combined. It is estimated that 100,000 people die every year from the adverse effects of prescription drugs, and 1 million are injured so severely they require hospitalization.” Thomas Moore, “Prescription drug risks are too high,” *The Miami Herald*, April 12, 1998, p. 6L.

“It has been estimated that fatalities directly attributable to adverse drug reactions are the fourth to sixth leading cause of death in US hospitals, exceeding deaths caused by pneumonia and diabetes. The economic burden resulting from drug-related morbidity and mortality is equally significant and has been conservatively estimated at \$US30 billion dollars annually, and could exceed \$US130 billion in a worst-case scenario.” White TJ, Araakelian A, Rho JP, “Counting the costs of drug-related adverse events,” *Pharmacoeconomics*, 15(5): 445-58, May 1999.

“David Lawrence, CEO of Kaiser Permanente, the nation’s oldest HMO, calls medication errors ‘the number one public health risk in the United States, ahead of tobacco, alcohol, [illegal] drugs, or guns.’” Ted Sandoval, “Cutting Medication Errors Requires Proactive Steps,” Web MD, Medcast, June 20, 2000.

All drugs have negative side effects, even aspirin. However, prescription drugs have far more potentially dangerous side effects than do over-the-counter medications. Most people who take these drugs according to their physicians’ directions do not experience serious side effects, but some do. Some people have severe allergic reactions, some suffer heart attacks or seizures, and some experience organ damage because of the prescription drugs they take. One of the most common serious drug problems is liver damage because most medicines taken by mouth are ultimately processed through the liver.

In addition to the negative side effects induced by individual drugs, some drugs interact negatively with certain foods or with other drugs.

Another factor involved in the large number of people killed or made ill by prescription drugs are medication errors, and the primary reason for medication errors can be traced to the sheer number of prescription drugs on the market.

“There are currently more than 17,000 trade and generic names for drugs in the United States, according to the Institute for Safe Medication Practices in Huntingdon Valley, Pa. The organization also estimates that the number of drugs on the U.S. market has grown 500% in the last decade.” Braus P, “Want to avoid drug errors? New software can help,” American College of Physicians-American Society of Internal Medicine Observer, April 2001.

The vast majority of these drugs are not important, breakthrough medications, but “me-too” drugs, generic versions of name-brand drugs, new variations of older drugs, and old drugs with new names for new medical applications. But with so many medications and so many names for the same medications, it is not surprising that there are medication errors, including negative drug interactions.

“With so many people on so many pills, small wonder that part of the increase in healthcare costs is illness caused by drug interactions. A Queen’s University study of seniors’ medication released in January, for example, found that in 96% of cases studied, doctors’ knowledge of their patients’ medication use was inaccurate. On average, the patients had a daily dose of seven medications.” Candis McLean, “The real drug pushers,” Report Newsmagazine, March 19, 2001.

Given so many potential hazards—from prescription errors to life-threatening side effects—it is clear that pharmaceutical products can kill as well as cure. Nevertheless, most people naïvely continue to believe that FDA approval means a drug has been thoroughly tested and is safe for them to use.

Clinical Tests

“Baycol is the 12th prescription drug to have been taken off the U.S. market because of dangerous side effects since 1997. Some critics said many of those bans happened because the FDA, under political pressure, had sped up drug approvals during the 1990s. Baycol was not a ‘fast-track’ drug: The agency spent 11 months reviewing it before approving it in 1997.” “Bayer Pharmaceutical’s Cholesterol-Lowering Drug Baycol Linked to Deaths, Pulled Off Market,” AP, Aug. 8, 2001. One of the statin drugs, Baycol destroyed muscle tissue and was linked to 31 deaths in the U.S. and 9 abroad.

“Rezulin [a diabetes drug] was taken out of pharmacies and off the market. But by then it was linked to 63 deaths from liver failure.” “FDA: Guardian Or Rubber Stamp?” CBS Evening News, July 12, 2001.

Critics of the FDA point out the agency’s close ties to the big drug companies as one of the problems in the drug approval process. A USA Today report found that more than half the advisors to the FDA have “financial relationships” with drug companies that have an interest in FDA decisions (De Angelis C, “Conflict of Interest and the Public Trust,” JAMA, Nov 1, 2000). But even if panel members involved in approving a drug are scrupulously honest, they still depend on data from that company’s clinical trials to approve the drug as safe and efficacious, and the data can be misleading.

Pharmaceutical companies are well aware of how to manipulate clinical trials and the resulting data to show their products in the most favorable light.

“Efforts by drug companies to suppress, spin, and obfuscate findings that do not suit their commercial purposes were first revealed to their full, lethal extent during the thalidomide tragedy. Although government drug regulation schemes around the world are now in place, the insidious tactics of big pharma have changed little.” “The Tightening Grip of Big Pharmaceutical Companies,” Editorial, *The Lancet*, April 14, 2001.

For example, a clinical trial might over-select young, healthy subjects when the drug being tested is intended for use primarily on older patients.

“Rochon et al. found that only 2.1 percent of subjects in trials of nonsteroidal anti-inflammatory drugs were 65 years of age or older, even though these drugs are more commonly used and have a higher incidence of side effects in the elderly.” Bodenheimer T, “Uneasy Alliance—Clinical Investigators and the Pharmaceutical Industry,” *New England Journal of Medicine*, 342(20), May 18, 2000.

After FDA approval, it was discovered that Glaxo Wellcome’s flu medication Zanamivir could be dangerous for patients with underlying respiratory diseases such as asthma or other chronic pulmonary illness. After some deaths were reported, the FDA issued a warning and required labeling changes for the drug.

Or in comparison trials, the drug being tested might show that it is more efficacious than the drug it is being compared with simply because higher dosages of the new drug were administered. And, since the data from the trials are generally housed and often analyzed by the drug companies themselves, unfavorable results can be suppressed or long-term data showing negative effects might not be presented.

The highly advertised (and expensive) anti-inflammatory drug Celebrex was hailed by an article in the *Journal of the American Medical Association* as vastly superior to existing (and far less expensive) anti-inflammatory drugs such as aspirin and Ibuprofen (Motrin and Advil) because it eliminated the problem of gastric bleeding associated with these drugs. However, researchers at the Therapeutics Initiative in Canada discovered that the study’s authors had cut the trial data off at six months. The longer-term results showed that Celebrex was also associated with gastric bleeding, but that it just took longer for these side effects to manifest themselves. The FDA had concluded that there were no major differences between Celebrex and the existing medications, but the published study in *JAMA* left out the longer-term data.

“Perhaps even more importantly, the [Therapeutics Initiative] report suggests significant safety concerns. ‘Any benefit in serious gastrointestinal side effects appear to be cancelled by increased cardiovascular events, including heart attacks, clotting, hypertension and heart failure,’ Dr. Wright [director of TI] declares. Celebrex may be ‘trading off a decreased chance of stomach ache and ulcer for potentially serious cardiovascular problems.’” Candis McLean, “The real drug pushers,” *Report Newsmagazine*, March 19, 2001.

Celebrex is now being clinically tested for lung cancer prevention and has already been approved by the FDA for use in preventing colon cancer in patients who are at particularly high risk for the disease (“Celebrex Under Study for Lung Cancer Prevention,” *ScienceDaily Magazine*, Aug. 8, 2001).

As bad as some of the manipulations of clinical trials and study data and published clinical reports are, none approach the sheer immorality of some of the drug companies’ clinical trials conducted in developing countries. Test subjects in developed countries today are legally protected against abuse, but protective laws in some poorer countries are more lax and are not as rigidly enforced.

“An investigation into corporate drug experiments in Africa, Asia, Eastern Europe and Latin America reveals a booming, poorly regulated system in which experiments involving risky drugs

proceed with little independent oversight, and impoverished, poorly educated patients are sometimes tested without understanding that they are guinea pigs. These foreign trials speed new drugs to the marketplace—where they are often sold mainly to patients in wealthy countries.” Joe Stephens, “Testing drugs: Overseas trials lack oversight: Companies target patients in poor nations,” The Miami Herald, Jan 7, 2001, p. 1L.

“We’re colonizing a region for clinical trials’ declared Juan Pablo Guzman, who has worked on clinical trials in Latin America for Searle and Pharmacia, at June’s annual meeting of the Drug Information Association in San Diego. ‘We have to believe there is gold at the end of the journey.’” “Latin America is fertile ground for experiments,” The Miami Herald, Jan 7, 2001, p. 3L.

In one such instance, researchers for Pfizer clinically tested what the company believed to be a promising new antibiotic on Nigerian children who had fallen victim to the country’s meningitis epidemic. Among the 200 test subjects, 11 died and others suffered meningitis-related symptoms such as seizures, blindness, deafness, and lameness. The drug being tested, orally-administered Trovan, had never been approved or tested for use with children, and chemically similar drugs had caused joint damage in animal experiments. According to an article in the Miami Herald, Pfizer’s own internal report showed children did die shortly after taking oral Trovan.

“The experiment’s final report concluded that Trovan and the comparison drug were equally safe and effective.” Joe Stephens, “Testing drugs: Overseas trials lack oversight,” The Miami Herald, Jan. 7, 2001.

But of course many of the sick and dying in these countries will never be able to afford treatment with the successful drugs once they are approved as safe and efficacious by the FDA.

Maintaining the High Cost of Medicines

Increasingly the big multinational drug companies are coming under fire for doing everything in their power to maintain the high costs of their products, even when those costs mean that essential drugs will not be available to the poor (or even to some of our own elderly who have limited incomes).

“Using big money, creative court challenges and a regulatory system prone to delays, the nation’s leading manufacturers of brand-name drugs are fighting harder than ever to keep cheaper generic imitations off the market.... Generic drug makers have at times enriched themselves by keeping their products off the market, deliberately, in exchange for payments from patented drug companies.” Greg Fields, “Brand-name drug makers’ tactics slow generics,” The Miami Herald, Aug. 17, 2000, p. A1.

By far, the greatest public outcry over the high cost of drugs came as a result of the AIDS epidemic in Africa. AIDS drugs, such as those manufactured by GlaxoSmithKline, are extremely expensive, far too expensive for them to be used in developing countries where the disease is truly at epidemic proportions.

“These drugs aren’t expensive because of the cost to develop and manufacture them (many were actually invented at public universities using grants from taxpayers). Rather they’re expensive because some of the pharmaceutical giants that market them demand huge profits, estimated by Brazil’s health minister, Jose Sera, at up to 10 times cost, or 1,000 percent.” Tom Fiedler, “AIDS fight boils down to dollars vs. lives,” Miami Herald editorial, June 24, 2001, p. 5L.

Smaller drug companies in such countries as India and others in sub-Saharan Africa sought to manufacture affordable versions of the AIDS drugs for use in their own and other poor countries, but the big multinationals sued the smaller companies, alleging they were pirating patented drugs.

GlaxoSmithKline ultimately bowed somewhat to public pressure and lowered the cost of its antimalarial and newer HIV and AIDS drugs to developing countries. However, as critics pointed out, even with the lowered prices of the AIDS drugs, they will still be too expensive for the huge majority of Africans.

At the same time, the burden of medication expense for many of our own elderly citizens, who often take multiple medications, means that they are either doing without essential drugs or are lowering their use of the medications by deliberately skipping doses (which in some cases could be more dangerous than not taking the drugs at all). Medicare does not cover prescription drugs except those administered in hospital. According to Public Citizen, the big drug companies are charging these seniors twice as much on average as the companies charge their most favored customers such as HMOs and the Departments of Veterans Affairs and Defense. Public Citizen claims that the mark-up for Medicare outpatients for Merck's high cholesterol drug Zocor is 144%. The organization says that the mark-up for Pharmacia's diabetes medication Micronase is a whopping 363%, and that Abbot Laboratories' hormone treatment Synthroid is even worse at an incredible 1,446%.

The current political solution to this problem of medication cost to seniors is to have the taxpayers assume the burden for it, but since the taxpayers have already paid for the basic research to develop many of these drugs and have even paid for some of the clinical trials, that seems asking a bit much of the taxpayers. Perhaps a better solution would be to put pressure on Big Drugs to come up with a reasonable plan to lower the cost of necessary medications for seniors—or at least give them the same price breaks they give their “favored” customers.

There is no question the pharmaceutical industry provides important and necessary products to improve the health of Americans and save the lives of those who have infectious and parasitic diseases. However, the big drug companies' marketing and testing abuses and their almost unbridled influence on public policy (and government agencies) are major problems in this country and in the world. It could be that their control of the practice of medicine and of public health policy is even more dangerous to the health of society in the long run than some of their drugs are to the health of individual consumers.

Suggested Supplemental Reading Online

“The real drug pushers,” by Candis McLean, Report Newsmagazine, March 19, 2001.

<http://193.78.190.200/10a/the%20real%20drug%20pushers.htm>

“Rx R&D Myths: The Case Against The Drug Industry's R&D ‘Scare Card,’” Public Citizen report, July 23, 2001.

<http://www.citizen.org/congress/drugs/R&Dscarecard.htm>

“The Drug-Induced Lung Diseases,” Pneumotox Online.

<http://www.pneumotox.com>

XII - Saving Lives or Pushing Drugs and Agendas?

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***“The pharmacrats’ agenda, based on the new coercive-therapeutic concept of disease, differs radically from the medical scientist’s agenda, based on the old noncoercive-pathological concept of disease. To advance their agenda, the pharmacrats shift the focus—their own and the public’s—from phenomenon to tactic, from objectively demonstrable disease to dramatically advertised prevention and treatment.*”**

“The medical doctor treats cancer of the lung. The political doctor treats smoking, preventable by legislation, litigation, and taxation, and curable with nicotine administered by any route other than inhalation. Sanctimony and hypocrisy replace honesty and self-discipline.”

Dr. Thomas Szasz, “The Therapeutic State: The Tyranny of Pharmacocracy,” *The Independent Review*, 5(4), Spring 2001, p. 510.

Internationally renowned psychiatrist Dr. Thomas Szasz has written extensively on the medicalization of America and the rise of the therapeutic state. In the therapeutic state, individual choice and responsibility are subverted in the name of health. What were once matters of private health, important only to individuals, become matters of collective health, important to the state. The public health focus is not on treating physiological disease, but on preventing behaviors which could lead to disease. Ultimately the state defines these behaviors themselves as *diseases* to be treated. This is precisely what has happened in the global war against smokers.

A quarter of a century ago, smoking was considered to be a habit hurting only those who chose to indulge in it. As habits go, smoking was not viewed particularly negatively. Everyone knew smoking was not good for those who over-indulged in it, and about a tenth of those who did so eventually contracted lung cancer. The public health establishment—rightly—warned people repeatedly about the health risks of smoking. Those who took up the habit did so knowing of the risks, but apparently feeling that the pleasure and benefits of smoking outweighed its long-term risks. Or, if they eventually concluded the pleasure and benefits were not worth the risks, they stopped smoking. In fact, something like 50 million U.S. smokers have quit, almost all of them on their own without “treatment” of any kind.

In the 1980s, after pharmacological smoking “treatments” began to emerge, the health warnings about smoking changed focus. The public health establishment began putting forth the notion that smokers were not just hurting themselves but were hurting society at large. They claimed that second-hand smoke was not only annoying to non-smokers, but could harm them as well. Further, they said that society as a whole was harmed financially because of excess health care costs of treating “smoking-related” diseases.

Then, with the publication of the 1988 Surgeon General’s report, tobacco use officially became a *disease*, an “addiction” needing “treatment.” Of course, by then the pharmaceutical industry was ready with drugs to treat this new “disease,” the physicians and addiction therapists were eager to prescribe the drugs, and the public health establishment was delighted to marshal its considerable influence and resources to attack the “epidemic” of tobacco use and push drugs, litigation and legislation to “treat” it.

“Today, when scientific medicine is a robust adult, physicians routinely effect near-miraculous cures; politicians and their lackeys, led by Surgeons General, define disease; the state shows intense interest in the concept of disease; and the term treatment is often used in lieu of the term coercion.” Szasz, “The Therapeutic State,” p. 487.

By the mid-1990s the nicotine war was fully engaged. Smoking—a legal, voluntary adult behavior-- was declared to be a global “pandemic,” the “number one cause of premature death,” and FDA head David Kessler even went so far as to deem it “a pediatric disease,” though no children die from smoking. Ambient tobacco smoke became a deadly toxin, killing thousands of innocent babies and adults, and smokers were ghettoized as social undesirables who could be redeemed only with “treatment.”

An April 1999 World Health Organization “Fact Sheet” illustrates perfectly the pharmacrats’ use of language to stigmatize and medicalize smoking. Entitled “Tobacco Dependence,” the three-page publication uses the word “treatment” no fewer than *thirty-six* times. The WHO tract also refers to smoking as “a paediatric epidemic” and implies that it kills millions of children and adolescents: “This epidemic is predicted to kill 250 million children and adolescents who are alive today, a third of whom live in developing countries.” And it reinforces the notion that smokers cannot help themselves because they are in thrall to their addiction: “...quitting is not simply a matter of choice for the majority of tobacco users. Instead, it involves a struggle to overcome an addiction.”

This propaganda was, no doubt, funded by the pharmaceutical companies marketing the “treatment,” but in an effort to legitimize such outrageous claims the WHO notes that the “fact” sheet was “based upon the best available scientific information” and “was written by a group of experts from developed and developing countries.” The “experts” names are not given, but there is little doubt that at least some of them were paid consultants to the drug companies in partnership with the WHO, possibly even the same consultants who wrote the U.S. clinical guidelines on treating tobacco “dependence.”

The astonishing transformation of a relatively innocuous—albeit individually risky—personal habit to a global disease pandemic in fewer than twenty years could not have happened without the active complicity of the governmental and private members of the public health establishment, the American Medical Association, powerful “health” organizations such as the American Cancer Society, the World Health Organization, and the pharmaceutical industry. And each of these profited handsomely from their partnership in the pharmacratic nicotine war.

Unfortunately, in this war, as in all wars, there have been casualties. Among them are honest science, truth, individual freedom, and the millions of real children and adults in developing countries who are suffering from actual, not manufactured, diseases. While the WHO and wealthy countries such as the U.S. devote billions of dollars to wipe out adults’ choice to use a legal product, in just one year at least 5 million babies born in developing countries die in their first month of life, 17 million people worldwide die from infectious or parasitic diseases, and millions of South Africans contract HIV. Apparently the pharmacrats have been more interested in lining their pockets, solidifying their political power and controlling behavior of citizens in affluent countries than they have been in treating actual preventable disease in developing countries.

Even more dangerous than the misplaced priorities of the WHO and their American anti-tobacco partners are the political ramifications of their focus on “health” as appropriate *behavior*. Not since Nazi Germany has the world seen such emphasis on the medicalization of private behavior as a means to achieve public health.

“The truth is that the Nazi health ideology closely resembles the American health ideology. Each rests on the same premises—that the individual is incompetent to protect himself from himself and needs the protection of the paternalistic state, thus turning private health into public health.”
Szasz, p. 505.

In fact, the anti-tobacco movement could well have borrowed many of its tactics directly from the Third Reich. Like the National Socialists, the U.S. and the WHO have developed and funded agencies for the sole purpose of eliminating tobacco use, agencies which have created vast propaganda campaigns against smoking. Hitler’s Germany severely restricted tobacco advertising and enacted public smoking bans, two of the major goals of the WHO and U.S. anti-tobacco movements. During the Third Reich, children were subjected to anti-tobacco education in school, youth clubs were enlisted to pass out anti-tobacco literature, and smoking was banned in public places for anyone under 18. All these are key parts of the youth anti-tobacco campaigns in the United States today.

It is understandable that the pharmaceutical corporations would fund efforts to demonize tobacco use, prohibit tobacco advertising, enact smoking bans, and push smoking “treatment.” All these measures increase sales of their smoking cessation products, especially when the public health establishment, including government agencies, pushes these products relentlessly, coercing even children to use them. The only

agenda for any corporation is to make money, and the means of making that money is of little concern so long as they increase profits. The nicotine war benefits the drug companies in many ways: increasing profits, opening new lines of drugs to market, and promoting further development of the therapeutic state, which will ensure increased future profits.

What is less obvious is why legislators, public health officials, doctors and scientific researchers would allow themselves to become drug pushers and facilitators for anti-tobacco programs like those developed by the Nazis of the Third Reich. Many of the current anti-tobacco tactics go far beyond those in the Third Reich. Even the Nazis did not prohibit smoking outdoors or set up “snitch” lines for “good” citizens to report errant smokers, as some locations in California and Canada have done. Even the Nazis did not conduct studies to “prove” that smokers are ill educated, poor, and mentally disturbed, though numerous “studies” like these are publicly funded and conducted in the United States today. Even the Nazis did not call smokers “child abusers,” though this epithet is being used more and more frequently by anti-tobacco workers in the United States.

It should not be forgotten that many doctors, scientists and public health workers condoned genocide as “hygiene” and atrocities as scientific experiments in the Third Reich, and they did so because at least some of them believed they were improving the health of the society and saving lives. Many of the modern anti-tobacco workers also believe they are improving health and saving lives and that extreme measures are necessary to prevent people from harming themselves by using tobacco. These are the True Believers for whom safety and health are revered above all else.

“It was not fascism, which was not genocidal, but medical Puritanism that motivated the Nazis to wage therapeutic wars against cancer and Jews. This is a crucial point. Once we begin to worship health as an all-pervasive good—a moral value that trumps all others, especially liberty—it becomes sanctified as a kind of secular holiness,” Szasz, p. 505.

However, the power wielders in the anti-tobacco movement are more cynical and self-interested. They know that tobacco use isn't the greatest of society's ills and that preventing people from smoking won't make any appreciable difference in mortality rates. After all, if people don't die from “smoking-related” diseases, they will die from something else, but the anti-tobacco movement is a moneymaker and a career maker for them. The drug companies pay well for anti-tobacco work and for anti-tobacco and nicotine research, as does the federal government.

Only the most highly trained biomedical scientists can get grants for trying to find a cure for cancer, but even mechanical engineers and attorneys can easily get health-related, million-dollar government grants for studies in tobacco prevention and control.

Non-governmental organizations such as the American Cancer Society and the American Medical Association increase their income substantially with grants and contracts from drug companies and from the Centers for Disease Control and other agencies in the Public Health Service. They also increase their influence on public policy by sitting on governmental tobacco control committees and panels.

State and federal agencies also benefit financially from tobacco control. Because these public agencies and their anti-tobacco “partners” have made tobacco a hot-button political issue, legislators are persuaded to increase funding for their anti-tobacco programs. Legislators who support anti-tobacco are rewarded, while those who do not are said to have “sold out” to Big Tobacco because of campaign donations and/or they are excoriated in newspaper ads as being “for Big Tobacco and against children.”

Everybody makes out well riding the anti-tobacco horse.

In the long-term view, organizations, government agencies and researchers involved in the anti-tobacco movement are not at all averse to medicalizing America because they will thrive financially and accrue

enormous power in a therapeutic state. Though such a state is undoubtedly tyrannical, they have no reason to fear it, because they will be among its powerful elite.

It is the rest of us who have much to fear, because the Nicotine War is about far more than mere nicotine, and it has nothing to do with saving lives.

“Formerly, people rushed to embrace totalitarian states. Now they rush to embrace the therapeutic state. By the time they discover that the therapeutic state is about tyranny, not therapy, it will be too late,” Szasz, p. 516.