

The Feds and the Pharms: An Unhealthy Alliance

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“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.