

Yet it would not be politically acceptable simply to let the industry name its price. Thus, at a minimum, some direct price negotiation by the government is likely to occur regardless of which candidate is elected.

At first blush, Kerry's positions appear to be more "consumer friendly" than Bush's. Kerry supports policies that create stronger downward pressure on prescription-drug prices than Bush's policies do. This more aggressive stance toward controlling today's drug prices must be considered in light of the effect of lower prices on the flow of new drugs that will be available to the next generation of consumers. Bush supports policies that protect the existing drug-price structures in the name of ensuring adequate economic incentives to innovate.

The United States is entering uncharted waters in both of these key areas — the importation of prescription drugs and the role of the government in controlling their cost. A voter's choice between the candidates might well be guided by philosophy and a sense of whether profits in the pharmaceutical industry are high enough so that reductions in drug prices would not substantially impede the development of future drugs.

Importation would have some predictable consequences: U.S. prices would decrease, the world would move toward a single price for a given drug, and Canada and Europe would probably make larger contributions toward the cost of research and development. The magnitude of the financial gain in the United States, however, is uncertain; my guess is that there would be modest price reductions for consumers in the United States and substantial price increases for Europeans and Canadians.

From the Department of Health Care Policy, Harvard Medical School, Boston.

1. Levit K, Smith C, Cowan C, Sensenig A, Catlin A. Health spending rebound continues in 2002. *Health Aff (Millwood)* 2004;23(1):147-59.
2. Baker C. Would prescription drug reimportation reduce U.S. drug spending? Economic and budget issue brief. Washington, D.C.: Congressional Budget Office, April 29, 2004.
3. Badger D. Ask the White House. February 4, 2004. (Accessed September 10, 2004, at <http://www.whitehouse.gov/ask/20040204.html>.)
4. President Bush discusses quality, affordable health care: remarks by the President on access to health care. January 28, 2004. (Accessed September 10, 2004, at <http://www.whitehouse.gov/news/releases/2004/01/20040128-2.html>.)
5. Republican National Committee. Republican party platform. (Accessed September 10, 2004, at <http://www.gop.com/about/partyplatform>.)

## The Tobacco Buyout and the FDA

Steven A. Schroeder, M.D.

An unlikely alliance between tobacco growers and tobacco-control advocates will be tested this fall, as a congressional conference committee attempts to reconcile separate versions of tobacco legislation that the House and the Senate have attached to the Foreign Sales Corporation Act. On June 17, 2004, the House voted to abolish a long-standing quota system (whereby a defined number of farmers are permitted to grow tobacco in quantities set by the government each year) and to pay \$9.6 billion from the federal treasury to tobacco farmers to ease the transition. In addition, the House bill would eliminate all existing restrictions on tobacco growing, thereby moving tobacco farming to a free-market system. On July 15, the Senate passed a related bill, but it differs from the House version in a number of significant ways (see Table). The Senate version designates more money — \$13 billion — for relief for

tobacco farmers, with the money to come from tobacco manufacturers, through government assessments. It places some restrictions on future tobacco farming and, in an important step, authorizes the Food and Drug Administration (FDA) to regulate the tobacco industry — the contents of tobacco products, as well as companies' marketing strategies and release of information — in the future.

Tobacco farming in the United States is governed through a complicated system of quotas that were established during the Depression. The federal government imposes rules concerning who may grow tobacco and how much they may grow, setting yearly quotas on the basis of tobacco-product manufacturers' estimates of expected purchases. Government also sets a minimal price for the growers that is well above the price of tobacco grown elsewhere in the world. Many tobacco farmers,



**Tobacco Farmers, Wilson N.C.**

Photograph by Logan Mock-Buntin, Getty Images.

especially small ones, have fallen on hard times, as imported tobacco has supplanted domestic products for use by U.S. cigarette manufacturers, thereby forcing U.S. farmers to reduce their crop production.

In contrast with its tight regulation of tobacco-leaf production, Congress has never given the FDA the authority to regulate tobacco, though medicines used to help smokers to quit — such as nicotine-replacement products — are tightly regulated. In 1994, the FDA asserted its authority to regulate tobacco products, but the Supreme Court ruled in 2000 that such authority must be delegated by an act of Congress.

If either version of the bill is enacted, most of the bailout money will go to the large farm holders, who own the majority of the quota rights to grow tobacco, though many of them do not actually grow the crop. It has been estimated that under the House version, more than 400 farmers will receive \$1 million or more apiece, and that 10 percent of those who are eligible for “relief” will get two thirds of the \$9.6 billion. The House bill would also consolidate the market, probably prompting small and financially struggling farmers to exit; the overall

number of tobacco farmers is expected to decrease by 50 percent. Because there would be no restrictions on future tobacco growing, it is difficult to predict the effect on domestic tobacco-leaf production, but it is clear that neither version would have a direct effect on smoking rates in the United States.

The Senate version, however, limits the possibilities for tobacco farming to expand into areas where tobacco was not previously grown and restricts the total amount of domestic tobacco farming. It also blocks the use in tobacco products of foreign-grown tobacco that fails to comply with U.S. standards regarding pesticides and residues. Since neither version restricts tobacco importation directly, the tobacco-farmer bailout would have no effect on the number of cigarettes produced and sold in the United States, though the Senate version would presumably generate a small increase in the cost of tobacco products, as manufacturers sought to recover the \$13 billion paid to farmers.

The Senate bill would give the FDA the potential for regulatory control over the content of tobacco products, including the permissible levels of nicotine and other components, stronger warning labels about the hazards of tobacco use, oversight of new

**Table. Key Features of the House and Senate Versions of the Tobacco Legislation.**

Feature	House Bill	Senate Bill
Funding for relief to tobacco farmers		
Estimated amount	\$9.6 billion	\$13 billion
Source	Federal treasury	Tobacco-product manufacturers
Restrictions on tobacco growing	None; creates free-market conditions for growing	Limits on expansion into new areas; restrictions on total farming; prohibition of use in tobacco products of foreign-grown tobacco not compliant with U.S. pesticide and residue standards
FDA regulation of tobacco products	None authorized	Authority to regulate content, including levels of nicotine and other components, and to require stronger warning labels; oversight of products; supervision of marketing tactics; banning of unauthorized use of terms such as “low-tar” and “light”; publication of information about product ingredients and smoke constituents
Supporters	Many big tobacco farmers and conservative politicians	Most mainstream tobacco-control advocates and health care organizations; some smaller tobacco farmers; Philip Morris

and existing tobacco products, and supervision of marketing tactics. The bill would eliminate the use of terms such as “low-tar” and “light” unless they were specifically approved and would make available to the public and the scientific community information about the actual ingredients contained in tobacco products and the constituents found in tobacco smoke. The extent to which such control would be exercised would depend on how aggressively the FDA acted, whether the administration in power encouraged or discouraged such actions, and whether the regulations withstood legal challenges.

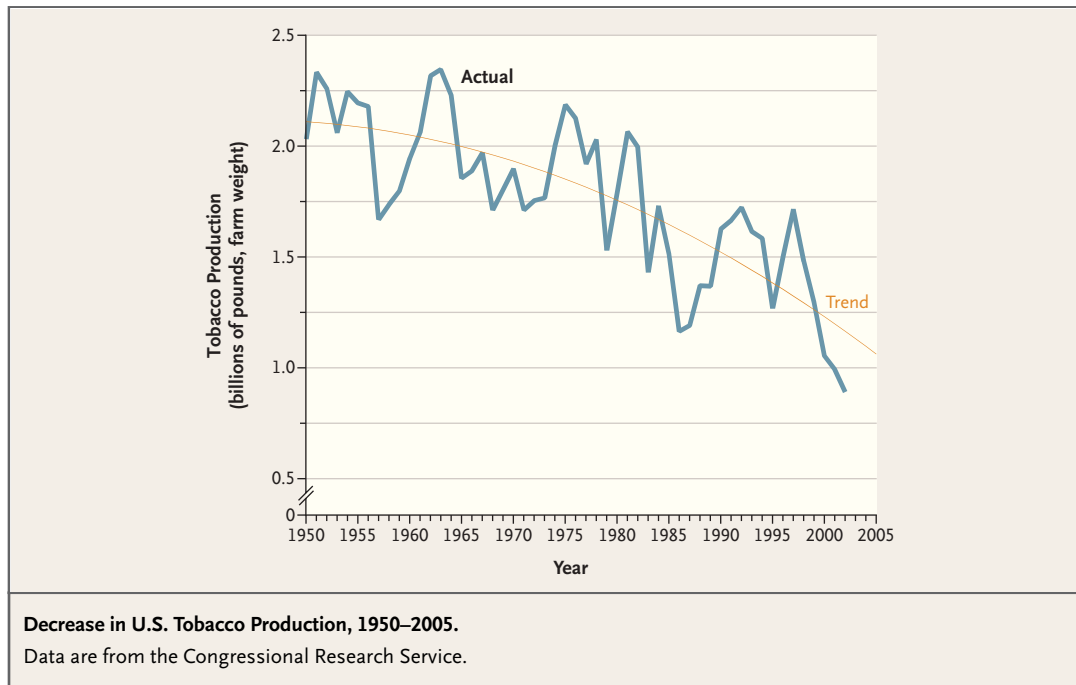
The maneuverings surrounding the upcoming conference committee demonstrate that politics really does make strange bedfellows. Not surprisingly, many big tobacco farmers and conservative politicians favor the House version, whereas many tobacco-control advocates, including a long list of major health care organizations, favor the Senate version, as do some tobacco farmers. But some grassroots tobacco-control advocates are opposed to both versions, and the tobacco industry is divided, with market leader Philip Morris (which has about 50 percent of the domestic market share and so would benefit from the adverse effects on smaller competitors) supporting the Senate bill and other manufacturers opposing it.

Those in the tobacco-control community who support the Senate bill hope that the buyout will neutralize the historical political opposition to tobacco-control measures from tobacco-growing states, such as North Carolina, Kentucky, and Vir-

ginia. They also expect that FDA regulations will become a powerful weapon for tobacco control and that the \$13 billion payment by the industry will raise the price of cigarettes (though much less than the \$209 billion from the 1998 Master Settlement Agreement) and thereby decrease tobacco consumption.

On the other side, tobacco-control advocates who oppose the Senate bill argue that because FDA regulation would inhibit the introduction of new products and impose regulatory costs that would hit small rivals harder, the net effect would be to shore up Philip Morris’s dominant market position — an outcome of which they are wary. They also view the payments to big tobacco farmers as wasted money, doubt that the new FDA authority will amount to much, and worry that future litigation will be inhibited by the regulatory shield of potential FDA oversight.

There are many possible outcomes from the conference committee and the subsequent up or down votes in the House and Senate. If a bill resembling the House version emerges, tobacco-control advocates should unite in opposition, despite the movement’s habit of internal conflict. If the House version passed, those in favor of FDA regulation would see their hopes of piggybacking regulation onto the buyout doomed, possibly forever, and others would simply find no particular merit in the bill. If a bill like the Senate version emerges, it will drive a wedge between certain manufacturers of tobacco products and other manufacturers, between main-



stream and less traditional tobacco-control advocates, and between some conservative politicians and other conservative politicians. Of course, there are also multiple ways to split the differences between the two versions, or the bill could hit a dead end, stalling in committee, being rejected by either or both chambers of Congress, or being vetoed by President George W. Bush, who has not indicated his preference to date.

Whatever happens, it is clear that domestic tobacco production in the United States is on the wane, as is the traditional opposition of tobacco farmers to tobacco control. This is also the closest Congress has come to granting the FDA the author-

ity to regulate tobacco products, which are still the number-one preventable cause of death and disability in the United States and the rest of the world. And while this debate in Congress rages, the Department of Justice's \$289 billion lawsuit against the largest tobacco companies for reasons of "fraudulent and deceptive marketing practices" was scheduled to open in court on September 21, 2004. Despite what we may be hearing about the new U.S. obesity epidemic, the tobacco wars remain the best public health show in town.

From the Smoking Cessation Leadership Center, University of California, San Francisco.

## Medical Marijuana, Physician-Assisted Suicide, and the Controlled Substances Act

Robert Steinbrook, M.D.

The Controlled Substances Act is a 1970 law designed to prevent drug abuse and trafficking and to control the authorized distribution of narcotics, barbiturates, and other scheduled drugs. Nearly 35 years after its passage, the act is at the center of heated legal controversies about the medical use of

marijuana and physician-assisted suicide. Cases related to both of these issues test the power of Attorney General John Ashcroft, the conservative former senator from Missouri, who is a long-standing opponent of both activities.

States license physicians and regulate the prac-