



On Thursday, May 20<sup>th</sup>, Senators Mike DeWine (R-OH), Ted Kennedy (D-MA) and Representatives Tom Davis (R-VA) and Henry Waxman (D-CA) introduced identical bills in the Senate and House to grant the U.S. Food and Drug Administration (FDA) authority to regulate tobacco products. Public health groups, including the American Cancer Society, American Heart Association, American Lung Association and the Campaign for Tobacco-Free Kids, have been working with these members of Congress to fashion bipartisan legislation that grants the FDA strong and effective authority to regulate tobacco.

Tobacco remains this nation's most unregulated consumer product. The tobacco industry has long taken advantage of the lack of regulation to market to young people, hide the truth about their products, deceive consumers about the relative safety of their products and resist making any meaningful change to their products. Effective regulation of the tobacco industry has been a priority of the major public health organizations for over 15 years. In 1996, with the active support of virtually everyone in the public health community, the FDA sought to assert jurisdiction over tobacco products, but the Supreme Court later held that only Congress could grant FDA such authority.

The legislation introduced into Congress by Senators DeWine and Kennedy (S. 2461) and Congressmen Waxman and Davis (H.R. 4433) are the strongest, most bipartisan comprehensive bills ever introduced to give FDA authority over tobacco. They meet our criteria for determining what is strong and effective. In our opinion and in the opinion of Senators DeWine and Kennedy and Representatives Davis and Waxman, these bills give FDA the tools and resources to protect the public health through effective regulation of tobacco products.

**Q. What are some of the reasons the American Cancer Society, American Heart Association, American Lung Association and Campaign for Tobacco-Free Kids are supporting these bills?**

These bills would give FDA the tools and resources it needs to protect public health.

- The bills would reinstate the FDA's marketing and youth access restrictions, as well as the rest of the 1996 FDA rule.
- The bills would give FDA broad authority over tobacco marketing based on considerations of public health - something that no agency currently has. At worst, FDA won't use it. At best, FDA will go after a broader category of marketing that encourages tobacco use or misleads consumers about the relative health effects of different products.
- The bills would do away with the current misleading FTC tar and nicotine reporting system. While we know that the current system misleads consumers, without new

- legislation the current broken system will continue to mislead. The bill gives FDA broad authority to come up with a new system for testing whatever components and smoke constituents FDA deems appropriate. Equally important, it stipulates that FDA should require the disclosure of this information on packs and ads if it can find a way to do so that won't mislead consumers about the health significance of the information - a vitally important step forward.
- The bills would prevent the use of terms such as "light", "low tar", "mild" unless given specific authority by FDA. The bill would require tobacco companies to tell FDA what is in each brand - not just the ingredients but smoke constituents as well, and would give FDA the authority to tell the tobacco companies how to test for these substances. It would also require the tobacco companies to tell FDA when it changes the amount of any of these ingredients or smoke constituents. This information in the hands of government scientists could be very helpful in efforts to reduce the harm and addictiveness of tobacco products.
  - The bills give FDA the authority to require the removal of ingredients and smoke constituents based on what will protect the public health. Will FDA use this authority? No one can be sure, but under the right FDA Commissioner, this authority represents a powerful new tool.
  - The bill gives the government new and real authority over claims related to whether new tobacco products actually present less of a risk than other products on the market. No standards currently exist. The current unregulated environment only gives tobacco companies the incentive to create the impression that so-called product innovations make a difference - as happened with low tar products - without any real meaningful change and leaves consumers in the dark. Although no standards are immune from the potential for misuse, the standards in the new bill are tough. If implemented in good faith, they should make it very, very hard for tobacco companies to claim that any of their products are safer than other products. They should also encourage the development of science in this area - an important by-product.
  - By imposing tough standards for reduced risk claims for tobacco products, it seems likely that the bill would give a boost to non-tobacco NRT's in the marketplace. The bill also encourages FDA to fast track NRT products to help with cessation. An effective FDA handle on tobacco products may be the best boost we can give to clean NRT.

**Q. Why don't we wait for a time when the leadership of the House and Senate and the White House are more supportive and possibly seek even stronger FDA legislation?**

We have concluded that this is a good bill from a public health perspective or else we would not be supporting it. If we can pass this bill in its present form, it would be a public health victory. No one can be certain that a better bill could be developed or passed no matter who is President. We have also concluded that it is important to take advantage of the current opportunity to move a bill. The absence of FDA jurisdiction is the status quo. We currently do not have a situation where the market place protects the public health or where we know for certain that tobacco companies will be held liable for the failure to adequately warn consumers. In the current environment, we have worthless health warnings, no control over what tobacco companies say

about the relative health effects of their products, no authority for the states to curtail tobacco marketing beyond the MSA, no control over the products and no ability to find out what the industry is doing with the products. The new health warnings the legislation would mandate won't provide the tobacco industry more protection against lawsuits, they already have all the protection they will receive as the result of the existing health warnings.

Were this legislation to pass, enactment into law simply marks the beginning of the process to ensure effective regulation of tobacco products; all of us must face the challenge to aggressively push the tobacco control and public health community to work with FDA to constantly hold the agency's feet to the fire, and to use all of the tools that the legislation provides to it.

We will have the ability to actively participate in the regulatory process through public comments and actively advocate before the agency.

**Q. What impact could this legislation have on DOJ and other lawsuits?**

The bill will have no direct impact on the lawsuit brought by the Department of Justice. That lawsuit is scheduled for trial in September 2004 and it will proceed separately from the legislation. The one potential impact it may have relates to the remedy. The Department of Justice has indicated that if it proves its legal claims, it will ask the court to impose a range of remedies, including, for example, restrictions on youth advertising. To the extent that those restrictions are imposed by legislation enacted by Congress, then they would not be part of the Justice Department's request for relief, if it prevails in the case. The bill will not change the rules applicable to product liability litigation brought by citizens against the tobacco industry.

**Q. What compromises were made?**

Like any piece of legislation, this bill contains compromises, but even with these compromises, we believe that this is the strongest bipartisan bill ever introduced. We also believe that the compromises contained in the bill do not undermine FDA's ability to act.

What are the major compromises? Under these bills, while FDA can require many changes to tobacco products, Congress reserves the right to ban any broad class of products (all cigarettes, all smokeless tobacco) and to require the reduction of nicotine yields of a tobacco product to zero. This does not prohibit FDA from requiring major changes in tobacco products or requiring dramatic decreases in nicotine. We also preferred to expand states' rights to give them unfettered authority to regulate tobacco marketing. The bill expands states' current authority but not as broadly as we wished. We also sought broad provisions to govern exports. Instead, we were only able to achieve provisions requiring monitoring and reporting on exports. These are meaningful concessions, but do not impact the overall strength of the legislation.

**Q. How can the legislation be good if Philip Morris supports it?**

Philip Morris's support for legislation is always good reason for suspicion. This decision by Philip Morris reflects a change in their prior position on the kind of bill it is willing to support. Philip Morris may well believe that it will benefit at the expense of the other companies, which in the past have stated their opposition to FDA legislation. We believe Philip Morris has likely made a decision that regulation – even strict regulation – will give it a competitive advantage

over the other tobacco companies and that it believes it will increase its share versus the other companies.

We believe the DeWine/Kennedy/Davis/Waxman bill is very strong legislation, indeed stronger in some critical areas than the FDA bills we have supported in the past. It is important that this legislation is being introduced by two longtime champions of public health, Representative Henry Waxman and Senator Edward Kennedy, as well as by Senator Mike DeWine who has been a stalwart supporter on this issue for years. We reached our opinion about the legislation on the merits of the legislation and independent of Philip Morris' position. We would have reached the same conclusion -- that this is strong FDA legislation that protects the public health and should be strongly supported -- even if Philip Morris had not supported it.

**Q. Does this mean FDA legislation will be passed this year?**

Introduction of these bills by no means guarantees that they will be voted on or passed in this Congress. But the introduction of these bills significantly strengthens the position of the public health community as Congress considers what to do about both FDA tobacco regulation and a proposed quota buyout for tobacco farmers. The tobacco buyout has received significant media attention in tobacco states in recent weeks and pressure is growing on Members of Congress from tobacco-growing states to get something done before the election. Introduction of these identical and bipartisan FDA bills strengthens the position of the public health community in working to make sure that if a buyout bill begins to move, it is attached to strong FDA tobacco authority that benefits public health.

**Summary of Key Provisions**

Below is a short summary of how the DeWine-Kennedy and Davis-Waxman bills deal with the issues that have been considered critical in any FDA bill.

**Youth Access and Marketing.** These bills would grant FDA the same broad authority regarding the sale and distribution of tobacco products, including access, advertising and promotion that FDA asserted in 1996. This would allow FDA to restrict advertising and promotion, including advertising that impacts children or misleads consumers, beyond the restrictions of the 1996 FDA Regulations, to the extent permitted under the First Amendment. The FDA could also take further action to ensure that tobacco products are not illegally sold to children.

**Youth Access and Marketing Restrictions of the 1996 Rule to Help Reduce Youth Tobacco Use Reinstated.** These bills require that one month after enactment, FDA republish the 1996 regulations, which restrict marketing that targets children and youth access to tobacco products, and require that these regulations shall become effective one year after enactment. These regulations include bans on outdoor advertising within one thousand feet of schools and limiting all remaining outdoor and point-of-sale tobacco advertising to black-and-white text only. The regulations, which will be identical to the regulations promulgated by the FDA in 1996, would become effective one year after enactment

After the regulations have gone into effect, the bills give the Secretary of the Department of Health and Human Services (HHS) the authority to amend these regulations through a standard

rulemaking process, which will provide for public discussion about the necessity of any changes to the regulations.

**Health Information Disclosure.** These bills require the tobacco companies to submit within six months of the date of the bill's enactment a listing of all tobacco ingredients and additives to tobacco, paper and filters by brand and by quantity in each brand, a description of the content, delivery and form of nicotine in each product, as well as all documents developed after enactment that relate to health, toxicological, behavioral, or physiological effects of current or future tobacco products.

The Secretary of HHS may also require the tobacco companies to submit information on all research related to health, behavioral or physiologic effects of these products and their marketing, as well as information about whether technology exists to reduce the harm caused by their products.

**“Public Health” Standard.** The existing FDA standard for approving drugs and devices is whether there is a “reasonable assurance that a product is safe and effective.” A different standard is necessary with tobacco products because there is no such thing as a safe cigarette. As the public health community has requested, under these bills the FDA would seek to determine whether an action regarding a tobacco product will “protect the public health.” This standard would require consideration of whether a product change would reduce the overall harm caused by tobacco use, including the harm caused to individual tobacco users and the impact on the population as a whole.

**Health Warnings.** These bills would revise the health warning on both cigarettes and smokeless tobacco products and grant FDA the authority to further revise and add health warnings and to alter their format, including, but not limited to, changing their size, location and color. The bill would result in an immediate change in health warning to require them to cover at least 30% of the front and back of cigarette packs and strengthen the warning's content.

**Authority to Establish Performance Standards.** These bills provide FDA with the authority to require changes to tobacco products to protect the public health, such as the reduction or elimination of ingredients, additives, constituents, including smoke constituents or reduction in nicotine yields through the issuance of performance standards. A performance standard would be the primary way in which FDA would require tobacco products to be made less harmful.

While the bill allows FDA to require changes to the product, the bill reserves to Congress the narrow and specifically tailored authority to ban “all cigarettes”, or “all smokeless tobacco products”, or “all little cigars”, or “all cigars other than little cigars”. While FDA can require the reduction of nicotine on its own, even to very low levels, the bill also reserves to Congress the right to require the reduction of nicotine yields of a tobacco product to zero. The language related to the ban is straightforward language that ensures that only Congress can ban cigarettes but it does not prevent the FDA from requiring meaningful changes to tobacco products.

**Modified Risk Products.** FDA authority over new products that the tobacco industry wants to portray as less harmful is increasingly important as new products are marketed with such slogans

as, “All of the taste...Less of the toxins” and “Reduced Carcinogens. Premium Taste.” Under these bills, FDA would be able to prohibit these claims unless it had first determined that the manufacturer had proven that these claims have been scientifically proven.

The bill prohibits any person from labeling, advertising or taking any other action directed to consumers that states or implies that the product is less hazardous or risky than other tobacco products or reduces one’s exposure to substances in tobacco products without first having sought and obtained FDA approval according to the standards set forth in the bill. The bill would also prohibit the use of descriptors, such as “light”, “mild” and “low” to characterize the level of a substance in a product. Any product for which such a claim is sought to be made would have to meet the standards for a “modified risk product” under the bill.

Under the bills, the Secretary shall approve an application for a modified tobacco product only if the applicant demonstrates that the product, as actually used by consumers, will significantly reduce harm, and the risk of tobacco-related disease to individual tobacco users and benefit the health of the population as a whole – taking into account both users of tobacco products and persons who do not currently use tobacco products.

The bill also sets out criteria for certain products where the manufacturer does not seek to make a claim for reduced risk, but seeks to assert that the product contains a reduced level of a substance, or presents a reduced exposure to a substance. The Secretary may only approve an application for a product for which the manufacturer wants to make this type of claim when a number of criteria have been met. They include a requirement that the manufacturer has demonstrated and the Secretary has found, that scientific evidence is not available, and using the best available scientific evidence, it cannot be demonstrated without conducting long term epidemiological studies to meet the strict standards to make a modified risk claim, but that the Secretary concludes that the evidence that is available demonstrates that a substantial reduction in morbidity or mortality among individual tobacco users is anticipated. Under this provision, a product can be approved for no more than five years at a time and the manufacturer must conduct and submit to the Secretary of HHS post-market surveillance and studies annually. This type of application may also be approved only if the Secretary also determines that the manufacturer has demonstrated that the product would be appropriate to promote the public health, is expected to benefit the public as a whole, and will not mislead customers into believing that the product is less harmful than other products.

**State and Local Authority.** The bills expand state authority over tobacco marketing. Today states have no right to regulate tobacco marketing. Under the bills, states and localities could impose bans or restrictions on the time, place and manner, but not content of the advertising or promotion of any cigarettes. Under these bills, state and local governments would be free to adopt measures related to the sale, distribution, possession, exposure to, access to, use of tobacco products, or fire safety standards for tobacco products.

FDA would maintain exclusive authority in such areas as tobacco product standards, pre-market approval, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk products. States could not establish requirements in these areas.

**Adequate Funding.** These bills include adequate funding for FDA to effectively carry out the requirements outlined. The funding is provided through a user fee on tobacco manufacturers.

**FDA Authority over Tobacco Farms or Tobacco Growers.** These bills do not give FDA authority over the growing of tobacco.