A Comment on the Impact of Proposed Cigarette Price Increases

by
Charyn D. Sutton
The Onyx Group

This comment seeks to respectfully dissent from the position of Frank J. Chaloupka, Ph.D. in his paper entitled "The Impact of Proposed Cigarette Price Increases" that earmarking of funds for the tax, while helpful, is not essential for an increased federal tax on tobacco to be effective. On the contrary, the major successes in using increased tobacco excise taxes to impact smoking rates that have been documented in the United States have been in states that earmarked funds for tobacco prevention and control. That combination of increased tax plus earmarking should serve as the model for the federal tobacco tax legislation.

California and Massachusetts are two excellent examples of higher taxes and earmarking of funds to combat tobacco.[1] California was the first success story. Its 1988 Prop 99 victory ushered in a 25 cent per pack tobacco tax increase that allocated a nickel per pack to tobacco prevention and control. The strategic use of dollars raised by the tax in funding community-based tobacco prevention and control projects, cultural networks, hard-hitting counter-advertising campaigns, and cessation programs allowed California to decrease smoking rates.[2] California continues to register impressive gains in tobacco control even though it is no longer a high tobacco tax state. While its cigarette tax rate was the third-highest in the nation when the Prop. 99 increase was implemented in 1989, as of January 1, 1998 the state ranked #21 out of 50 states plus the District of Columbia.[3]

Massachusetts offers another strong example. Passage of its tobacco tax increase of 25 cents in 1992 tax gave the state the highest excise tax on cigarettes in the nation.[4] Despite increases by other states, Massachusetts remains a leader with a cigarette tax rate as of January 1, 1998 that is fifth highest in the nation at 76 cents per pack.[5]

With the tobacco excise tax and the successful "Let's Make Smoking History" campaign that was funded by the tax, Massachusetts has turned the corner on smoking rates. It has even managed to decrease smoking rates among African American adolescent males, a group that has had the highest percentage increase in tobacco use in the country over the last two years.[6] Other states that increased tobacco taxes but did not earmark the funds for tobacco prevention and control have not seen such dramatic results.

In his paper, Chaloupka makes reference to the value of earmarking when he states: "[W]hen combined with other tobacco control activities, including prevention and cessation programs, counter-advertising, comprehensive and aggressive enforcement of limits on youth access, and more, even larger reductions in youth and adult smoking could be achieved." However, Chaloupka also states that even without mandating that some of the revenues generated by a large cigarette tax increase to tobacco prevention and control programs, the tax as a stand-alone intervention would have a major impact on bringing down smoking rates, especially among youth — especially if it is a substantial tobacco tax. While this conclusion can be drawn from the econometric models, it is clearly easier to convince the general public of the efficacy and fairness of maximizing the impact by using funds for tobacco prevention and control rather than as a pool of extra money to be

used to fund other projects with no connection to tobacco.

There are five basic reasons why the linking of any increased tobacco tax with funds earmarked for tobacco prevention and control should be a requirement in any federal legislation. All five are compelling.

The first and strongest reason, which has already been mentioned, is that the best results to date have been from states that combine increases in the price of cigarettes through tobacco tax increases with funds earmarked for tobacco prevention and control — including dramatic results with youth. That is a record advocates can point to as a way to counter those who claim that higher tobacco taxes have no effect on rates of tobacco use.

Second, earmarking provides an additional front for battling the tobacco industry's massive arsenal of marketing techniques — one of which is price. Clearly, the effectiveness of the tobacco tax increase comes because the addition of a higher tax ordinarily translates into a corresponding increase in the price of cigarettes. If the price to the consumer does not rise in real dollars, then there can be no effect. However, a rise in tobacco taxes does not always lead to a rise in the price of cigarettes to the smoker. Because there is such a large profit margin in manufacturing and sale of cigarettes, tobacco companies have been known to lower the wholesale price of cigarettes when they have found it in their interest.

There are numerous examples of the tobacco industry's price manipulation. In 1993, Philip Morris lowered the price of its premium cigarettes by 40 cents per pack and its mid-price cigarettes by 25 cents a pack[7] — an action that was quickly matched by its competitors. That decrease effectively wiped out smaller increases in tobacco taxes that some states had passed. In some instances, industry price cuts have actually exceeded state excise tax increases. Using a portion of the revenue raised by the increased tax for counter-advertising campaigns, quit smoking hotlines and local tobacco prevention coalitions assures that there will be an impact on smoking behavior even if the actual price of cigarettes does not rise, rises less than was anticipated or even falls.

Third, the impact of higher cigarette prices caused by an increase in the federal tobacco tax affects different people differently. Nowhere is that truer than among children and teenagers. Among youth we can expect that higher prices will a) encourage some youth to quit, b) some youth to smoke fewer cigarettes, c) some youth to smoke less often, d)some youth to delay smoking until they are older and have more money, e) some youth to decide against smoking at all and f) some youth to continue to smoke without any change in behavior.

While the stated goal of increased tobacco taxes is to help to eliminate illegal underage smoking entirely, there are benefits that can be derived if large numbers of youth simply scale back their smoking or delay the onset of tobacco use. Each of these situations provides public health advocates with an opportunity to intervene. However, the public health community does not have much experience with interventions that are effective with children and teenagers who are regular or occasional smokers. Funds are needed to develop new interventions to stem increased smoking among children and youth and tobacco taxes can provide those funds.

Almost all of the field experience and research in tobacco cessation, for example, has been with adults — whose smoking habits and situations are different from those under age-18. And while some good work has been done in developing counter-advertising that reaches youth (especially in California and Massachusetts), even this is in the early stages. Earmarking money from the tobacco tax will provide the necessary resources to develop culturally-appropriate, youth-oriented cessation programs for young people who are

already addicted to tobacco as well as youth who are just beginning to get involved with tobacco, better prevention programs and counter-advertising that works better than existing materials.

Fourth, while the primary goal is to prevent the addiction of children to tobacco, it is the adults who smoke who will be paying most of the tax. Targeting the money in ways that send funds back as a benefit to low-income tobacco users in proportion to their expenditures is a fairer way to tax this segment of the population. Even though the increased cost of cigarettes will provide incentive for low income smokers to quit, as Dr. Chaloupka has pointed out in his paper, the addictive nature of the nicotine in tobacco will undoubtedly complicate their efforts. There are also a wide range of cessation aids — like the nicotine patch, nicotine gum, nicotine spray — but many are priced at levels and in ways that make it difficult for low-income persons to afford. Using funds for cessation programs and to underwrite the costs of smoking cessation aids will add to the incentive provided by the increased cost of cigarettes and increase quitting rates across the board.

Furthermore, many current smokers are from ethnic and racial minorities that have been bypassed in the development of cessation interventions in the past. These groups do not have a range of proven programs and materials for smoking cessation and tobacco use prevention that the public health community can draw on to assist these individuals in quitting or never starting. With funds supplied by the tax, tobacco prevention and control programs at the federal, state and local levels will also have sufficient funds, for the first time, to develop targeted, culturally appropriate programs and materials to meet this need.

In addition to returning funds in a meaningful way to low-income communities and communities of color, using tax-generated funds in this way will have a measurable benefit on children. Numerous research studies have shown that one of the highest risk factors for a child or teenager becoming a smoker is to be part of a family where the adults smoke.[8] So using tobacco tax revenue to support adult-focused cessation efforts helps children and teenagers because having parents and other adults who serve as role models for young people quit smoking is one of the best ways to help children and teenagers to quit or never start.

Fifth and finally, earmarking a portion of the revenue raised by increased tobacco tax for public health and tobacco control will make it far less likely that the government itself will become "hooked" on the use of tobacco revenues to run the everyday business of government. So-called "sin taxes" have traditionally been a fall-back when governments at all levels have needed money. These taxes — on tobacco, alcohol and gambling — tend to fall disproportionately on low-income individuals who are less likely to vote and, as a result, are popular with elected officials who continually have to find new sources of revenue. Many states, for example, have turned to casino gambling and state-run lotteries in recent years as ways to fund programs for seniors, schools, and other essential government programs.

Dependence on tobacco industry funding to provide the revenues for essential government services can easily become a form of government addiction. This is not unlike the situations of many nonprofit organizations that have found their organizations relying on tobacco industry contributions to pay bills. Dr. Harold Freeman, Chief of Surgery at Harlem Hospital and former national president of the American Cancer Society, said this about tobacco industry support of groups like the National Association for the Advancement of Colored People, the United Negro College Fund and the National Urban League, "Early on, the tobacco industry began

to offer money when no other was there. Now these groups are just as addicted to the money as smokers are to the cigarettes."[9] Governments run the same risk.

The goal should be for the revenue raised by tobacco taxes to disappear over time — raising less money as fewer people use cigarettes and tobacco products. It makes sense to use the money in a way that follows a downward spiral, with less funding being needed as time passes. What better way to do this than to use a sizable portion of the revenue raised through an increased tobacco tax to help people who are current tobacco users quit for good and to help children who are not yet regular tobacco users stay addiction-free. That way, as the numbers of tobacco users decrease, the need for the funds will decrease proportionately.

These are all powerful reasons for supporting a tax that is large and that also includes earmarking of at least a portion of the funds for tobacco prevention and control activities at the federal, state and local levels. We must remember that the impetus for the current action in Congress came as a result of the Settlement Agreement between the attorneys general of a number of the states and the tobacco industry which included funding for counter-advertising, cessation and prevention efforts from the tobacco industry.[10] Tobacco prevention advocates said that it was not necessary to depend on an agreement from the tobacco industry to fund these efforts when the government itself could fund them using the mechanism of an increase in the federal tobacco tax.

It would be unfortunate indeed if the potential programs to decrease tobacco use became expendable and the tax alone remained as way to bring down smoking rates. A tobacco tax as a stand-alone policy intervention can only do part of the job. Earmarking is necessary, especially to address the special needs of the poor and people of color. To be truly effective, an increased federal tax on cigarettes and other tobacco products must be seen primarily as a way of providing the resources and the environment for the public health community to truly move this entire nation — youth and adults — toward a tobacco-free future.

NOTES

1. "Cigarette Smoking Before and After an Excise Tax Increase and an Antismoking Campaign–Massachusetts, 1990-1996," *Morbidity and Mortality Weekly Report (MMWR)*, U.S. Centers for Disease Control and Prevention (CDC), November 8, 1996, Vol 45, No. 44.
2. "Changes In Cigarette Consumption, Prices, And Tobacco Industry Revenues Associated With California Proposition 99," by Stanton A. Glantz, *Tobacco Control*, Winter 1994.
3. Federation of Tax Administrators, State Tax Rates & Structure, State Cigarette Excise Tax Rates as of January 1, 1998.
4. "Massachusetts Passes 25 Cent Cigarette Tax Increase Modeled on Prop. 99," *SCARC Action Alert*, Advocacy Institute, November 8, 1992.
5. Federation of Tax Administrators, State Tax Rates & Structure, State Cigarette Excise Tax Rates as of January 1, 1998.
6. "Smoking Threatens Gains in Minority Health" by Bob Hohler, *Boston Globe*, April 28, 1998.
7. "New Price Move by Philip Morris Intensified the War," *Wall Street Journal*, July 21, 1993.
8. "Why Children Smoke (And Why They Won't Listen)", by Lawrence Kutner, *New York Times*, February 6, 1992.
9. "Kiss of Death: African Americans and the Tobacco Industry," by Claudia Morain, *American Medical News*, (Vol. 36, No. 43), November 15, 1993.
10. Proposed Settlement Agreement between the state attorneys general and the tobacco companies, June 20, 1997.

HEALTH SCIENCE ANALYSIS PROJECT

Policy Analysis No. 10

POTENTIAL LOOPHOLES AND DRAFTING ISSUES

By

David T. Sweanor, LL.B.
Senior Legal Counsel
Smoking and Health Action Foundation

April 14, 1998

HEALTH SCIENCE ANALYSIS PROJECT

Policy Analysis No. 10

POTENTIAL LOOPHOLES AND DRAFTING ISSUES

By

David T. Sweanor, LL.B.
Senior Legal Counsel
Smoking and Health Action Foundation

Table of Contents

The Health Science Analysis Project (HSAP) is an Advocacy Institute project, supported by grants from the Robert Wood Johnson Foundation, the American Cancer Society, and general contributions to the Advocacy Institute.

HSAP is directed by its Executive Committee. No grantor has editorial control over the scope of the project, or the content of the analyses it produces.

POTENTIAL LOOPHOLES AND DRAFTING ISSUES

David T. Sweanor, LL.B.
Senior Legal Counsel, Smoking and Health Action Foundation*

INTRODUCTION

This paper analyzes the details of four tobacco control proposals - S. 1414 (the "Universal Tobacco Settlement Act") sponsored by Senators McCain and Hollings, S. 1530 (the "Placing Restraints on Tobacco's Endangerment of Children and Teens (PROTECT) Act"), sponsored by Senator Hatch, S. 1638 (the "Healthy Kids Act"), sponsored by Senator Conrad, and S. 1648 (the "Preventing Addiction to Smoking among Teens (PAST) Act"), sponsored by Senator Jeffords – in order to identify "loopholes" and unintended consequences resulting from the language and drafting strategies used. The analysis is informed by experiences with major tobacco legislation in other countries, as well as the history of tobacco industry action in the United States.

Experience with tobacco control laws around the world shows that the tobacco industry, given an ability to exploit a loophole, will almost certainly use it. This is caused by collective interest in avoiding measures which could reduce sales. It is also driven by competitive interests, with each company seeking an advantage over the others by pushing the limits to legislative interpretation.

All of the proposed bills share the problem of being long and complicated. This leaves more opportunities for the discovery of loopholes. Legislation that gives broad regulatory power to an administrative body are much better at preventing the exploitation of loopholes, as administrative rules can be changed much more rapidly than actual legislation.

Given the bills which have been tabled, this paper attempts to analyze each of them with a view to identifying potential loopholes.

S. 1414: THE UNIVERSAL TOBACCO SETTLEMENT ACT

Sec. 100. Definitions

1) The combined definitions of the sub-categories of tobacco products do not cover all possible tobacco products. The definition for "tobacco product" only includes specifically defined products, each of which leaves potential for alternative tobacco products which are not defined under the Bill. For instance, a 'cigarette' which heats rather than burns tobacco does not appear to fit within any of the definitions. The difficulty of non covered products is that there is a risk that some current or potential products could either, based on design, avoid coming within this law or be prevented from operating within this law. Neither of these outcomes are necessarily in keeping with the intent of this law.

Other tobacco laws try to cover any conceivable product. For example, Canada's Tobacco Act uses the following definition:

---

* In preparing this analysis, I worked closely with Neil Collishaw of the World Health Organization, John Garcia of the ASSIST Coordinating Center and Steve Woodward of Protocol Management in Australia.

> "tobacco product" means a product composed in whole or in part of tobacco, including tobacco leaves and any extract of tobacco leaves. It includes cigarette papers, tubes, and filters but does not include any food, drug or device that contains nicotine to which the Food and Drugs Act applies.

2) The definition of "manufacturer" does not include associated companies. This raises the concern that a tobacco manufacturer could set up a new company, which does not actually make tobacco products, to do things which the manufacturer is prohibited from doing. By way of comparison, the Canadian Tobacco Act defines "manufacturer" as follows:

> "manufacturer", in respect of tobacco products, includes any entity that is associated with a manufacturer, including an entity that controls or is controlled by the manufacturer or that is controlled by the same entity that controls the manufacturer.

Sec. 101. Advertising

1) The prohibition on outdoor advertising by a "manufacturer" is an example of where the restricted definition of "manufacturer" could cause a problem. An associated company could, apparently, run billboard ads.

2) The prohibition on human images, cartoons, and use of the internet only applies to a "manufacturer, distributor or retailer". There does not appear to be any limitation on some third party (and potentially a related entity) running such ads. Should there be a general prohibition on anyone running such ads? The Canadian Tobacco Act uses more inclusive terminology, using "no person" rather than "no manufacturer, distributor or retailer".

3) The prohibition of human imagery (Sec. 101 (b)) has limitations, as has been witnessed in the United Kingdom. There, the absence of people in tobacco ads has simply led to even more creative imagery.

4) There is confusion over the meaning of the word "location" in Sec. 101 (d)(3)(A). The term is not defined. Does it mean each retail outlet, or each location within that outlet where tobacco products are sold? Is a department store with three separate entrances, and a tobacco kiosk at each, going to be seen as three, or as one, "location at which tobacco products are offered for sale"? Experience elsewhere indicates, that, in the absence of greater precision, a lax interpretation will arise. The alternative is a much more difficult and litigious enforcement environment.

5) Sec. 101 (d)(5) gives protection from loophole seekers, at least for point of sale material. It is drafted widely. There is a possibility that the tobacco industry will seize upon wording such as ". . .or any other indicia of product identification similar or identical to those used for tobacco products. . ." as being overly vague. On the other hand, anything more narrowly focused would leave potential loopholes.

Sec. 102. General Restrictions

1) Sec. 102(a) allows a loophole for products sold "on or before January 1, 1995". The word "before" raises the possibility that something sold decades ago could be revised. Removing "or before" would solve this potential problem. Changing it to "on, and continuously since January 1, 1995"would also mean once a product ceases being marketed it cannot come back.

2) Sec. 102 (b)(2) requires disclosure to the Commissioner but does not give any specific authority to the Commissioner to do anything, not even to establish standards for the information the industry must supply.

3) Sec. 102(c) gives another example of where the narrow terms "manufacturer, distributor or retailer" will cause problems. A tobacco manufacturer could not pay to have a tobacco product used in a movie. But it appears a tobacco manufacturer could incorporate a separate entity to do it.

4) Sec. 102(d) uses more inclusive language than 102(c), in that it covers both "direct and indirect payments". But there is a potential problem with defining what is meant by ". . .for the purpose of promoting the image or use of a tobacco product. . .". This seems to invite argument over the "purpose" of an association; was it to use a rock band to promote cigarettes, or a cigarette brand to promote rock music? An alternative is simply to prohibit the association, out of concern about the effect rather than the purpose of the association.

Sec. 103. Format and Content Requirements for Labeling and Advertising.

1) Sec. 103(a) uses the narrowly defined "manufacturer, distributor or retailer", raising concerns that associated entities could do what tobacco companies cannot do directly.

2) A legislative limitation to black and white removes the ability of an administrative body to determine a different color scheme, or to require varied colors. By contrast, SEC 104(c) gives the Commissioner broad regulatory authority on statements of intended use. The lack of regulatory authority is a recurring problem in the Bill.

Sec. 105. Ban on Nontobacco Items. . .

1) The narrow definition of "manufacturer, distributor or retailer" will again cause potential problems.

2) The inclusion of "importer" in Sec. 105(a) is an improvement. But it helps make the point that such an entity should be covered in other sections of the Bill. It raises the question of whether Brown & Williamson could do extensive advertising under other sections of this Bill if it stopped manufacturing cigarettes and merely imported them.

Sec. 111. Cigarette Warnings

1) The SEC 111(b)(1) specification of "front panel" for the placement of the health warnings could cause problems, particularly in the case of cartons. In 1989 Canada enacted health warnings which specified warnings to be placed on the "principle display panel".[1] The tobacco industry interpreted "principle display panel" to be the small 'end' panels of a carton. A similar interpretation could be made of "front panel" in this bill. The Canadian government did not solve this problem until 1994, when new regulations were implemented requiring a health message on all panels of each carton.

2) Sec. 111 (b)(2) of the bill specifies the type and color of the warning. Once again, the language is not as precise as may be needed. Rather than specifying the typeface the bill states that the message will have to "appear in conspicuous and legible type, in contrast. . .". This granting of discretion to the tobacco industry could lead to liberal interpretations, as was found in Canada after the 1989 regulations (s. 15) stipulated that warnings would be "legible and prominently displayed in contrasting colors". The result in Canada was package labeling that the then Minister of

Health was quoted as saying could teach our military about effective camouflage.[2]

The solution to problems with industry interpretations is greater certainty in the language of the laws. For instance, the 1994 Canadian regulations specified 'Helvetica Bold' type.

3) There is a potential loophole in Sec. 111(b)(3) in dealing with flip top packages. The bill states that any flip top package (offered for sale on the date of enactment of this section) where that top is less than 25% of the panel would have the health warning reduced to the size of the flip top. This gives an incentive to introduce smaller flip top openings, gives time to introduce them, and gives an advantage to such products which appears to take precedence over health warnings. It is as if preventing a message from 'breaking' and reassembling with each opening of the pack is seen as more important that the prominence of the warning itself.

4) The is language ambiguity in Sec. 111(d) with respect to rotation. While clearing meaning to require all warnings to appear equally often, the language is not clear. The language could be interpreted to mean that the labels must rotate, and must all appear at the same time, but some could appear more or less often in specific markets. This section states that the government authority "shall approve a plan submitted by a manufacturer. . .", which limits discretion. This is a potential flaw as it appears that a manufacturer could institute a system of rotation which ensures some messages are seen more or less than others in certain parts of the country, at certain times of the year or in certain neighborhoods. There would be no discretion to stop such a plan provided all the warnings appeared "at the same time" and appeared an equal number of times for each brand each year in the country as a whole (Sec. 111(d)(2)(C). This section could be improved by simply adding FTC discretion over approval of rotation plans.

5) Sec. 111(c)(1) and (2) limit the warning on ads to just 20% of the surface, giving no discretion to the Commissioner as to warning sizes. Without clear evidence that 20% is all that is needed to adequately inform, this creates an obstacle to effective communication of information to consumers and potential consumers. Other tobacco control laws around the world give far greater regulatory authority.

6) There does not appear to be discretion to force the warning into a specific location on the ad. In the past tobacco companies have placed the warnings at the bottom, where it is often visually obscured.

7) On advertisements likely to be viewed from a distance the stipulated warning, in complying with the text and size requirements, may not be in lettering large enough to be read by many viewers. This is an existing problem with billboard warnings and this law does not necessarily correct the problem. As such, ads would have "warnings" but consumers and potential consumers would not receive warnings.

8) This bill does not give regulatory authority to amend the package messages. Sec. 114(c) simply empowers the FTC to implement the warnings stipulated in his bill. This greatly limits timely communication of effective package-based information.

Sec. 115. Preemption

Sec. 115 preempts any other "statement relating to the use of cigarettes or smokeless tobacco products and health". The existence of this preemption means that the tobacco industry only has to deal with Congress to prevent improved labeling. The only apparent

possibility under this bill would be for other authorities to require 'non-health' statements (e.g. "Smoking a pack a day will cost $1,000 per year").

Canada has taken an opposite approach in dealing with labeling. Canadian legislation (Tobacco Act, s.16)states:

> This part does not affect any obligation of a manufacturer or retailer at law or under an Act of Parliament or of a provincial legislature to warn consumers of the health hazards and health effects arising from the use of tobacco products and from their emissions.

Sec. 122 Manufacture, Sale, and Distribution

The minimum package size specified in Sec. 122(a), by being in legislation rather than regulation, creates a potential problem for future regulation. There is some evidence from countries such as Germany and Finland that simply reducing pack size from 20 to 19 or 18 actually reduces smoking. Apparently many of those who smoke according to how many cigarettes are in a pack simply adjust their smoking. If there was sufficient evidence to establish a smaller or larger minimum pack size in the United States, or reason to establish a maximum package size, this bill would not authorize action.

Sec. 904. Minimum Requirements

Sec. 904(b) requires the Commissioner to determine that an additive "significantly increases the risk to human health". Words like "significantly" are difficult to define and even more difficult to prove. Wording such as "has a significant likelihood of increasing the risk to human health" would reduce the onus on the Commissioner and make the standard easier to use. It would perhaps be even better to move to the much lower standard of proof usually required to justify actions to protect the public health (e.g. the standard required by FDA in looking at the potential for adverse health impact associated with food additives.)

Sec. 905. Performance Standards for Tobacco Products

Sec. 905(b)(1) speaks of the effect of product modification on "consumers". This appears to leave out the potential effect of such products on current non-users (non-smokers - particularly children - and ex-smokers). As such a product could meet the standard by reducing harm to existing consumers while actually increasing overall harm by luring more consumers into (or back into) the tobacco market. This potential problem could possibly be corrected through replacing "in consumers" with "to the public".

Sec. 907. Requirements Relating to Nicotine and Other Constituents

Sec. 907(b)(1)(A), like Sec. 904, imposes a very high standard to be met before modifications can be mandated for tobacco products. By requiring a determination that the change "will result in a significant reduction in the health risks", there is a problem with the level of necessary evidence. Certainty of benefit may be impossible to establish. It may be better to require a 'significant likelihood' that health risks will be reduced.

Sec. 908. Reduced Risk Products

1) Sec. 908(a) appears to set a higher standard of proof for deception than is found in other consumer protection laws. The words "can reasonably be interpreted by an objective consumer" raise a question of whether the fact of deception can exist without a violation of the law provided the consumers in question

are shown to be taking an unreasonable interpretation, or are not objective. Given the impact of addiction and health fears, plus the low socio-economic status of many smokers, there is a real potential for deception without recourse under this law. Other consumer protection laws simply prohibit "false, misleading or deceptive practices".

2) Sec. 908(c) talks about the risk of products to the user. The language used means there is no obligation in the case of technology which could reduce the risk to non-users (e.g. second hand smoke, or likelihood of children starting to smoke).

3) The narrow definition of "manufacturer" in this bill could reduce the disclosure possibilities under Sec. 908(c). A tobacco company could apparently set up a separate entity to develop or acquire technology. As long as the manufacturing entity did not do this work directly there would be no disclosure requirement.

Sec. 155. Termination of Certain Entities

The language used in this section allows the terminated entities to be recreated in essentially the same form. If this is not the intention the section word need to be changed.

Sec. 202. Determination of Underage Use Base Percentages

Sec. 202(a) and Sec. 203(b) are based on those who smoked every day for a year. Measures that simply reduced a teen's smoking to zero on a single day (such as ETS laws) would therefore meet the standard necessary to remove that teen from the smoking statistics. It may be that a less rigid standard would give a result that better identified the real impact on health of changing patterns of teen consumption.

Sec. 205. Application of Surcharges

1) The definition of "profit per unit" (Sec. 205(b)(3)) will understate the value of tobacco sales to teens. Additional units of production have higher profit margins and the present value of future earnings are higher for sales to new customers.

2) Sec. 205(e) makes payments based on overall market share rather than market share among underage smokers. This gives each company an incentive to 'cheat', since it is the industry collectively which pays the cost but each individual company which accrues the benefit. It would be better to set up a mechanism where each company could seek reimbursement of these payments from their competitors to the extent their competitors are selling a higher proportion of the cigarettes reaching children. This would require a re-writing of the Abatement Procedures in Sec. 206.

Sec. 402. Liability of Industry Sources

Sec. 402(b)(3) only includes domestic sales in the determination of how much is owed. Since tobacco sent to smugglers need not count as domestic sales the industry is given a financial incentive to promote smuggling, which complements the incentive for smuggling associated with the threat of smuggling being a condition for preventing the implementation of product modification (Sec. 907(a)(2) and (3)). The tobacco industry has the ability to facilitate smuggling and then benefit from its existence.

Sec. 511. National Smoking Cessation Program

Sec. 511(b)(1)(A) only allows grants to be made to public and nonprofit entities. Once again, the lack of broad regulatory power in the bill causes potential problems. This

section would preclude grants going to private institutions even if such entities could show themselves to be more effective and cheaper at delivering the necessary services.

Sec. 512. National Reduction In Tobacco Usage Program

As with Sec. 511, the language of this section prevents private entities from receiving grants. The lack of discretion to include other entities in deciding upon grants could mean reduced effectiveness for the programs.

Sec. 611. Consent Decrees

State authority on consent decrees raises the question of whether some states could implement lower standards in the hope of attracting, or retaining, companies with a vested interest in 'jurisdiction shopping'. This has been a significant problem elsewhere, with differing national standards causing tobacco companies to locate activities in the countries with lax legislation.

Sec. 702. Civil Liability for Past Conduct

This section would give absolute protection while giving the industry an incentive to find ways to bend the rules on other parts of this bill. It would be better to give a sunset on the liability protection (three years) with Congress having the option for periodic renewals based on a determination that the tobacco companies are (among other things) adhering to the spirit of the agreement.

Sec. 921. Payments for Lost Tobacco Quota

Sec. 921(a) ties payments to the reduction in demand for domestically produced tobacco. This is different from a domestic reduction in demand for U.S. tobacco. Farmers in the U.S. could be compensated even if U.S. domestic consumption increases. As such this section is not tied to better public health in the United States.

Sec. 923. Tobacco Community Economic Development Grants

These grants do not appear to be tied to decreasing tobacco consumption. In Canada programs which gave non-tied money caused problems. They put financial resources into the hands of groups which were fighting the implementation of the very health measures for which they were supposedly being compensated. If the money is not tied to tobacco control measures actually reducing tobacco consumption it can indirectly finance opposition to health measures.

S. 1530: THE PROTECT ACT

Sec. 5. Definitions

1) The definitions of the various types of tobacco products do not cover all possible tobacco products. The definition for "tobacco product"(Sec.5.(25)) only includes specifically defined products, each of which leaves potential for alternative tobacco products which are not defined under the Bill. For instance, a 'cigarette' which heats rather than burns tobacco does not appear to fit within any of the definitions. The difficulty of non-covered products is that there is a risk that some current or potential products could, based on design, either avoid coming within this law or be prevented from operating within this law even if they wanted to be covered.

Other tobacco laws try to cover any conceivable product. For example, Canada's Tobacco Act uses the following definition:

> "tobacco product" means a product composed in whole or in part of tobacco, including tobacco leaves and

> any extract of tobacco leaves. It includes cigarette papers, tubes, and filters but does not include any food, drug or device that contains nicotine to which the Food and Drugs Act applies.

2) The definition of 'manufacturer' (Sec. 5(11) does not include associated companies unless (Sec. 5.(11)(C))they are established by an actual manufacturer of tobacco products. This raises the concern that a tobacco manufacturer could set up a new company, which does not actually make tobacco products, which could then set up a company that can do things which the manufacturer is prohibited from doing. It also leaves the possibility that the parent company of a manufacturer could establish such an entity.

By way of comparison, the Canadian Tobacco Act defines "manufacturer" as follows:

> "manufacturer", in respect of tobacco products, includes any entity that is associated with a manufacturer, including an entity that controls or is controlled by the manufacturer or that is controlled by the same entity that controls the manufacturer.

Sec. 104. Enforcement

The penalty in Sec. 104(b) is set at $100,000 per day. A company the size of Philip Morris, which would owe billions of dollars per year, would see this as effectively giving a very cheap interest rate on a delay in the required payment. If, for instance, $5 billion was owed, the total penalty for a one year delay in payment would be $36.5 million, which is an effective interest rate of less than 1%. This is much like the 'license to pollute' problems of former environmental protection laws.

Sec. 212. Advertising

1) The prohibition on outdoor advertising by a "manufacturer" (212(a)) is an example of where the restricted definition of "manufacturer" could cause a problem. An associated company could, apparently, run billboard ads.

2) The prohibition on human images, cartoons, and use of the internet (212(b) and (c)) only applies to a "manufacturer, distributor or retailer". There does not appear to be any limitation on some third party (and potentially a related entity) running such ads. Should there be a general prohibition on anyone running such ads? The Canadian Tobacco Act uses more inclusive terminology, using "no person" rather than "no manufacturer, distributor or retailer".

3) The prohibition of human imagery (Sec. 212 (b)) has limitations, as has been witnessed in the United Kingdom. There, the absence of people in tobacco ads has simply led to even more creative imagery.

4) There is confusion over the meaning of the word "location" in Sec. 212 (d)(3)(A). The term is not defined. Does it mean each retail outlet, or each location within that outlet where tobacco products are sold? Is a department store with three separate entrances, and a tobacco kiosk at each, going to be seen as three, or as one, "location at which tobacco products are offered for sale"? Experience in Canada indicates, that, in the absence of greater precision, a lax interpretation will arise. The alternative is a much more difficult and litigious enforcement environment.

5) Sec. 212 (d)(5) gives protection from loophole seekers, at least for point of sale material. But it does not cover for billboards. It is also drafted to include a wide range of

possibilities. There is a possibility that the tobacco industry will seize upon wording such as ". . .or any other indicia of product identification similar or identical to those used for tobacco products. . ." as being overly vague. On the other hand, anything more narrowly focused would leave potential loopholes.

Sec. 213. Consensual Restrictions

1) Sec. 213(a) allows a loophole for products sold "on or before January 1, 1995". The word "before" raises the possibility that something sold decades ago could be revised. Removing "or before" would solve this potential problem. Changing it to "on, and continuously since January 1, 1995" would also mean once a product ceases being marketed it cannot come back.

2) Sec. 213 (b)(2) requires disclosure to the Commissioner but does not give any specific authority to the Commissioner to do anything, not even to establish standards for the information the industry must supply.

3) Sec. 213(c) gives another example of where the narrow terms "manufacturer, distributor or retailer" will cause problems. A tobacco manufacturer could not pay to have a tobacco product used in a movie. But it appears a parent of a tobacco manufacturer could incorporate a separate entity to do it. This is not just a theoretical problem. Recently in Canada there were full page multi-color newspaper ads showing Formula 1 driver Jacques Villeneuve dressed in his Rothmans racing outfit. The ad was ostensibly for Baume & Mercier watches. But Rothmans and Baume & Mercier are both owned by the same corporation, which is not itself a tobacco manufacturer.

4) Sec. 213(d) uses more inclusive language than 213(c), in that it covers both "direct and indirect payments". But there is a potential problem with defining what is meant by ". . .for the purpose of promoting the image or use of a tobacco product. . .". This seems to invite argument over the "purpose" of an association; was it to use a rock band to promote cigarettes, or a cigarette brand to promote rock music? An alternative is simply to prohibit the association, out of concern about the effect rather than the purpose of the association.

Sec. 214. Agreement on Format and Content Requirements for Labeling and Advertising

1) Sec. 214(a) uses the narrowly defined "manufacturer, distributor or retailer", raising concerns that associated entities could do what tobacco companies cannot do directly.

2) A legislative limitation to black and white in Sec. 214(a) removes the ability of an administrative body to determine a different color scheme, or to require varied colors. The lack of regulatory authority is a recurring problem in the Bill.

Sec. 215. Agreement to ban on Nontobacco Items...

1) The narrow definition of "manufacturer, distributor or retailer" will again cause potential problems.

2) The inclusion of "importer" in Sec. 215(a) is an improvement. But it helps make the point that such an entity should be covered in other sections of the Bill. It raises the question of whether Brown & Williamson could do extensive advertising under other sections of this Bill if it stopped manufacturing cigarettes and merely imported them.

Sec. 904. Cigarette Warnings

1) The SEC 904(b)(1) specification of "front panel" for the placement of the health warnings could cause problems, particularly in the case of cartons. In 1989 Canada enacted health warnings which specified warnings to be placed on the "principle display panel".[3] The tobacco industry interpreted "principle display panel" to be the small 'end' panels of a carton. A similar interpretation could be made of "front panel" in this bill. The Canadian government did not solve this problem until 1994, when new regulations were implemented requiring a health message on all panels of each carton.

2) Sec. 904 (b)(2) of the bill specifies the type and color of the warning. Once again, the language is not as precise as may be needed. Rather than specifying the typeface the bill states that the message will have to "appear in conspicuous and legible type, in contrast. . .". This granting of discretion to the tobacco industry could lead to liberal interpretations, as was found in Canada after the 1989 regulations (s. 15) stipulated that warnings would be "legible and prominently displayed in contrasting colors". The result in Canada was package labeling that the then Minister of Health was quoted as saying could teach our military about effective camouflage.

The solution to problems with industry interpretations is greater certainty in the language of the laws. For instance, the 1994 Canadian regulations specified "Helvetica Bold' type.

3) There is a potential loophole in Sec. 904(a)(2)(C) in dealing with flip top packages. The bill states that any flip top package (offered for sale on the date of enactment of this section) where that top is less than 25% of the panel would have the health warning reduced to the size of the flip top. This gives an incentive to introduce smaller flip top openings, gives time to introduce them, and gives an advantage to such products which appears to take precedence over health warnings.

4) The is language ambiguity in Sec. 904(a)(4) with respect to rotation. While clearing meaning to require all warnings to appear equally often, the language is not clear. The language could be interpreted to mean that the labels must rotate, and must all appear at the same time, but some could appear far more often than others. This section states that the government authority "shall approve a plan submitted by a manufacturer. . .", which limits discretion. This is a potential flaw as it appears that a manufacturer could institute a system of rotation which ensures some messages are seen more or less than others in particular locales, or at certain times of the year. There would be no discretion to stop such a plan provided all the warnings appeared "at the same time". This section could be improved by simply adding that the warnings must appear in a way approved by the Secretary.

5) Sec. 904(a)(3) limit the warning on ads to just 20% of the surface, giving no discretion to the Commissioner as to warning sizes. Without clear evidence that 20% is all that is needed to adequately inform, this creates an obstacle to effective communication of information to consumers and potential consumers. Other tobacco control laws around the world give far greater regulatory authority.

6) There does not appear to be discretion to force the warning into a specific location on the ad. In the past tobacco companies have placed the warnings at the bottom, where it is often visually obscured.

7) On advertisements likely to be viewed from a distance the stipulated warning, in

complying with the text and size requirements, may not be in lettering large enough to be read by many viewers. This is an existing problem with billboard warnings and this law does not necessarily correct the problem. As such, ads would have "warnings" but consumers and potential consumers would not receive warnings.

8) This bill gives regulatory authority to amend the package messages in Sec. 904(d), but then limits this authority to the "text" of the statements. This effectively removes the potential for regulations established in Sec. 901.

9) Sec. 904(e) preempts any other "statement relating to the use of cigarettes or smokeless tobacco products and health". The existence of this preemption means that the tobacco industry only has to deal with Congress to prevent improved labeling. The only apparent possibility under this bill would be for other authorities to require 'non-health' statements (e.g. "Smoking a pack a day will cost $1,000 per year").

Canada has taken an opposite approach in dealing with labeling. Canadian legislation (Tobacco Act, s.16) states:

> This part does not affect any obligation of a manufacturer or retailer at law or under an Act of Parliament or of a provincial legislature to warn consumers of the health hazards and health effects arising from the use of tobacco products and from their emissions.

Sec. 905. Reduced Risk Tobacco Products

1) Sec. 905(b)(1) speaks of the effect of product modification on "the user". This appears to leave out the potential effect of such products on current non-users (non-smokers - particularly children - and ex-smokers). As such a product could meet the standard by reducing harm to users while actually increasing overall harm by luring more consumers into (or back into) the tobacco market. This potential problem could possibly be corrected through replacing "in consumers" with "to the public".

2) Sec. 905(b)(1)(A) creates what may well be an impossible standard for reduced risk products. Manufacturers would have to demonstrate "that the product reduces the risk to the health of the user. . .". Given that scientific evidence of actual reduction in risk could take years to prove, and could be conditional on a large sample size using the product, the standard may be too high. Perhaps a better standard, assuming Congress really does want to promote less hazardous products, is to say that the manufacturer would have to demonstrate to the Secretary that 'there is a significant likelihood of reduced risk. . .'.

S.1638: The Healthy Kids Act

Sec. 4. Definitions

1) The definition of "cigarette", by using the terminology "any role of tobacco wrapped in paper" raises the possibility that a lot of novel products such as Eclipse, may not come within the definition. This could be a desired outcome, as such products would then likely come within FDA authority over other drugs and devices.

2) The question of what would be included and excluded in this law is further complicated by the definition of "tobacco", which is restricted to "tobacco in its unmanufactured form". This raises a question as to what becomes of cigarettes which used tobacco that has been subjected to a manufacturing process. An example of such a manufactured product

goes beyond Eclipse to include the reconstituted tobacco that is so widely used in American cigarettes. All of the products which fail the definition of "tobacco" would automatically be outside of the definition of "cigarette". If a product can avoid being classified as a "cigarette" it can apparently avoid coming within many components of this bill. If FDA authority is exercised in some other way this might be seen as a benefit, but is clearly something that needs to be thought through when considering these bills.

3) The definition of "tobacco product" includes products "derived from tobacco leaf". This would appear to bring within the definition of "tobacco product" those products which would not otherwise meet the definitions of specific categories of tobacco products. The result could be that legislative language referring to "cigarettes" (e.g. the Sec. 575 warning requirements) might not include some products that are included when the proposed law talks about "tobacco products". So it may be that many products would escape residual FDA authority by coming within this bill, but be exempt from major parts of this bill by nature of not being "cigarettes". In addition nicotine replacement therapy products which are based on nicotine 'derived from tobacco leaf for human consumption. . .' might come within the current definition of "tobacco product".

4) To avoid confusion, other tobacco laws try to cover any conceivable product. For example, Canada's Tobacco Act uses the following definition:

> "tobacco product" means a product composed in whole or in part of tobacco, including tobacco leaves and any extract of tobacco leaves. It includes cigarette papers, tubes, and filters but does not include any food, drug or device that contains nicotine to which the Food and Drugs Act applies.

5) The definition of 'manufacturer' does not include associated companies. This raises the concern that a tobacco manufacturer could set up a new company, which does not actually make tobacco products, to do things which the manufacturer is prohibited from doing. A parent or subsidiary company would apparently have far greater latitude for action, which would destroy much of the intent of the bill.

By way of comparison, the Canadian Tobacco Act defines "manufacturer" as follows:

> "manufacturer", in respect of tobacco products, includes any entity that is associated with a manufacturer, including an entity that controls or is controlled by the manufacturer or that is controlled by the same entity that controls the manufacturer.

Sec. 102. Liability of Tobacco Manufacturers

1) The determination of payments based upon 1996 market capitalizations raises questions about the non-tobacco operations of publicly traded tobacco companies. Since only the capitalization of a "manufacturer" is to be included in the calculation (Sec. 102(a)(3)), and "manufacturer" is very narrowly defined, the calculation of market capitalization could be very contentious. Further, this measurement gives a huge advantage to debt-financed, rather than equity-financed, companies.

2) The annual assessment on cigarettes (Sec. 102(b)) gives an advantage to cigarettes as long as six and one half inches in length, as these would be taxed at the same rate as smaller cigarettes. There is a long history of tobacco companies taking advantage of loopholes to

reduce the taxes on their products. In Australia weight based taxes have led to lower weight products, in many European countries ad valorem taxes have led to the introduction of some low-margin products. If a six and a half inch cigarette is taxed at the same rate as one only half as long it is likely we will see longer cigarettes. One idea a tobacco company floated in Canada a few years ago was whether two cigarettes joined at the filter (but easily detached) could meet the definition of a single cigarette, thus effectively cutting the tax in half.

3) The assessments on snuff, chewing tobacco, pipe tobacco and roll your-own are based solely on weight. This gives an incentive to move to lower weight products. For instance, Canadian roll-your-own tobacco is now often manufactured using 'expanded' tobacco. As this product is lower in weight the process effectively lowers the tax. Until now taxes have played only a very small part in the overall price of products such as smokeless tobacco. As any assessment will effectively be a tax increase, the weight-based taxation system will create a huge incentive for such things as lower weight smokeless products.

4) The assessment of roll-your-own tobacco, based on the current average weight of a r-y-o cigarette, works out to between a half and a third of the assessment on cigarettes. This differential can be widened further as manufacturers implement the technology which allows for lower weight r-y-o tobacco. This will almost certainly cause a substitution effect in which smokers will switch from cigarettes to r-y o. It will also give incentives for hybrid products designed to meet the r y-o definition in order to save on costs.

5) The inflation adjustment formula in Sec. 102(c) uses only the medical consumer price percentage as its inflation measure. This will not necessarily reflect consumer price inflation or the changes in prices of tobacco products. If tobacco companies rapidly increased prices the adjustment formula would not allow the assessment to avoid being eroded as these price increases reduce consumption. It might make sense to substitute a measure of the highest of several measures of inflation, with the tobacco sub-component of the CPI and overall CPI among the measures. Keeping the 3% minimum increase rule would also protect the assessment in the event of little measured inflation or a revision of the CPI measurement technique.

6) Sec. 102(e) appears to eliminate the ability to write off the assessment as a cost of doing business. If the tobacco companies must bring this money in as revenue but cannot expense it, the overall cost of the assessment is much higher. It would also have different impacts on different companies depending on taxable income and tax rates. The resulting market distortions may not have been fully thought through.

7) Sec. 102(h) talks about a Healthy Kids "stamp". Given that not all forms of marking products require an actual stamp (e.g. a security ink impregnation) it would be preferable to use the term "marking". This would give greater latitude to keep up with changing technology and allow implementation of the most effective marking measures rather than being limited to 'stamps'.

8) Sec. 102(i)(1) gives the possibility for an exemption. This may be a "Liggett exemption". If a company does meet this criteria it is given an overwhelming advantage in the market, capped only when it reaches a 3% market share (102(i)(3)). Its prices would be massively lower that its competitors. It could pick up market share through this massive price differential and also buy brands from less favored competitors. Such a

company could, for instance, buy brands from Philip Morris for more than the brand would be worth to Philip Morris and make huge profits by then being able to sell the product without paying the assessment. As a result one can assume that the total assessment will be lower by 3% for each company that could qualify for the exemption.

Sec. 203. Treatment of Tobacco Products as Drugs and Devices

The definition of "tobacco product" (Sec. 203(a)(3)) raises the same problems as the way the term is defined in Sec. 4. If defined broadly, nicotine replacement therapies appear to be included as they are (at least in part) derived from tobacco leaf. If defined narrowly, such that essentially the whole product must come from tobacco leaf, products such as Eclipse appear not to be covered. Given the regulatory authority granted in Sec. 203(b) this may not be a clear legislative drafting problem, but it does raise political and public perception problems.

Sec. 574. Disclosure and Reporting

Sec. 574(d)(1) limits disclosure to the "package". Given the quantity of information which may be in need of disclosure ("all ingredients, constituents, substances or compounds contained in the product") the package may be an insufficient vehicle. It may be better to grant the Secretary the authority to require disclosure though a wider range of vehicles.

Sec. 575. Tobacco Product Warnings, Labeling and Packaging

1) There is authority (Sec. 575(a)(1)(C)) for the Secretary to authorize additional or altered warnings after an 18 month period after enactment of this subchapter. The criteria is that the Secretary determine that the new warnings "would be more effective in deterring the use of cigarettes". The standard of proof required by the Secretary in order to change the messages is not clear. It might not be possible to prove anything more than a 'reasonable likelihood' that a different message would be more effective in deterring cigarette use. In which case that is the standard that could be written into the law.

2) The warnings would be required to be displayed on both the front and rear panels (Sec. 575 (a)(2)). This doubles the exposure given to the health messages and makes it harder to obscure the warnings through product positioning. This greatly limits the ability of the tobacco industry to skirt the intention of the law.

3) The typeface of the warnings can be adjusted by the Secretary ((Sec. 575(a)(2)(B)). The language would allow larger as well as smaller typeface. This limits the ability of the tobacco industry to skirt the intention of the law.

4) The flip-top box exemption only exists for products offered for sale on June 1, 1997 (Sec. 575(a)(3)). This prevents the introduction of new products seeking to exploit this potential loophole. At the same time it allows pre-existing products to have a potential advantage in the marketplace. As with the other bills there is a question of why the drafters would consider a message that is altered on opening and closing a package is improved by making the message smaller.

5) The rotation of the warnings (Sec. 575(a)(4)(A)) requires random distribution of the warnings "in all areas of the United States". This should prevent the selective airing of warnings according to where they might do the least harm to tobacco sales. As further protection against abuse, this subsection requires that the tobacco

companies' plans for distribution be submitted to, and approved by, the Secretary. Unfortunately this protection is effectively negated by Sec. 575(a)(4)(C), which specifies that the Secretary "shall" approve a plan if the warnings are displayed at the same time. As a result, compliance with the letter of the law is necessary but compliance with the spirit of the law is voluntary.

6) The Secretary retains authority to change the text or layout of any of the warning statements or labeling provisions (Sec. 575(d)). The authority given to the Secretary to change the required warnings also extends to "any of the labeling provisions". This appears to give authority to change the size, positioning, etc., of the messages provided it makes "such statements or labels larger, more prominent, more conspicuous, or more effective." It also allows the Secretary to make the determination of when such changes are necessary. In effect this means that minimum, rather than maximum, standards are being implemented and can be improved. This is a well-worded section in terms of giving authority to the Secretary to protect public health, and should take precedence over the limiting language used elsewhere in this section.

7) Common law and state statutory law liability is expressly retained (Sec. 575(e)(2)). This can play a key role in forcing compliance with the spirit of informed consent since the alternative is that the tobacco companies invite litigation.

8) There is a continuation of the problem of the stated warnings using capital letters for the first letter of each word. This can make the messages harder to read.

9) The bill talks about "warnings" rather than "messages". This could prevent non-warning messages (e.g. information on quitting or on the costs of smoking).

10) State package warnings are preempted (Sec. 575(e)(1)). This raises all the problems discussed in the review of the previously introduced bills. The lack of state authority to improve on federal warnings increases the probability that tobacco companies will fight to weaken federal package warning efforts since state action is not a threat. There are, however, other important preemption questions raised by the language of Sec. 576

11) Sec. 575(a)(3)(ii) specifies that the language of advertising warnings will be in the language of the advertisement. In the case of advertisements which allow imagery this is an invitation for abuse. An image based ad need not have any words. If a tobacco company added a single word of Thai or Burmese to the ad it could then apparently write the warning in that language. This would ensure very few people could read it.

Sec. 576. Preservation of State and Local Authority

Since Sec. 575(e) only refers to "warning labels" it appears other levels of government would be allowed to require labels which are not in the nature of a "warning". If the term "warning" is not changed in Sec. 575 this preemption requirement is not as onerous. A state could still, for instance, require the placement of cessation information or economic information.

Sec. 578. Public Disclosure of Health Research

Sec. 578(d) gives protection to 'trade secrets'. If such protection is not conditional on strong regulatory control over tobacco products there could be a problem. Other consumer products can be offered such

protection because the manufacturing standards ensure that they are not health risks. For instance the Coca-Cola formula can be a secret without risk to public health since, by law, it can only include ingredients which are approved for human consumption. Tobacco products will have it 'both ways' if they can avoid legislation that requires its products to have minimal health impact while also avoiding disclosure of information that could help consumers make decisions about the health risks.

Sec. 302. Child Tobacco Use Surveys

1) Sec. 302 requires the Secretary to conduct surveys to determine levels of youth smoking by brand. It may be easier to authorize the Secretary to do a survey for the purposes of determining overall youth smoking, but let the tobacco companies fight it out over which company has what share of the youth market, and the resulting financial obligations. Otherwise it is the Secretary who has the obligation to accurately measure something that is far from guaranteed to be accurate. This puts the Secretary on the defensive. If the Secretary simply measured youth smoking, financial obligations could be allocated by total (adult) market share. This could be combined with the right of a tobacco company to convince the Secretary (or some other entity) that the allocation should be readjusted based upon the tendering of evidence that their youth market share is smaller than their adult market share. As a result the onus to prove youth market shares would fall on the parties with the biggest vested interest in showing their own success in keeping cigarettes away from children.

2) The baseline youth smoking rate established in Sec. 302 (c)(1) is for 1999. As a result the manufacturers are given an incentive to increase youth smoking over the course of this year and next.

Sec. 304. Noncompliance

1) In detailing financial penalties this section uses a confusing combination of dollar symbols, cents and decimal points. For instance "$.10 cents". If it said "$.10" it is clearly 10 cents. If it said ".10 cents" it is clearly a tenth of a cent. But the combination causes confusion as to whether the decimal point is tied to the 'dollar' or to the 'cents'.

2) Sec. 304 (a) applies the industry-wide penalty "to each unit of the tobacco product involved". Sec. 304(b) does the same for manufacturer specific penalties. Yet "unit" does not appear to be defined. Does it mean a cigarette or a package of cigarettes? If it is a package, is it a package of 20? What is a unit of smokeless? Of roll-your-own?

3) SEC 304 (c) applies a 'de minimis rule' to manufacturers with less that 0.5% of the youth market. Unless the definition of manufacturer is expanded to include associated companies this gives an incentive for tobacco companies to use a number of subsidiaries to market tobacco products. As currently worded it would appear to exempt RJR's 'Moonlight Tobacco Co.' from payments associated with sales to young people.

Sec. 601. Tobacco-Related Research

1) Sec. 601(a)(1) could be improved by adding "and/or" after "non addictive" in the last full line of text. Otherwise it can be construed as aiming for products which are simultaneously non-addictive and reduced risk rather than more clearly leaving open research avenues for products which meet at least one of these standards.

2) The list of research areas presented in Sec. 601(a)(1) is not worded in such a way as to give authority for other research areas. As currently drafted topic areas not listed could

not be funded. This would appear to eliminate some current areas of research and closes potential new areas of research which scientific advances might open up in the years ahead.

Sec. 624. International Tobacco Control

The agency set up in Sec. 624(b)(1) is not given authority other than to "reduce and prevent the use of tobacco". As such it may not be able to deal with exposure reduction and the development of less deadly products. This would be inconsistent with the wider range of action authorized in the United States.

Sec. 727. Consensual Restrictions

The narrow definition of "manufacturer" used in the bill could render the provisions of this section essentially meaningless.

Sec. 729. Agreement on Nontobacco Items

The narrow definition of "manufacturer" used in the bill could render the provisions of this section essentially meaningless.

Sec. 731. Federal Enforcement

The civil penalties in Sec. 731(a)(3) may not be sufficient to deter large tobacco companies. The maximum fine of $250,000 a day is just over $90 million per year, which could be seen as a license to misbehave.

Sec. 804. Prohibition on Sale or Distribution of Tobacco Products to Children

The wide definition of who must comply with this section, including subsidiaries and affiliates, compares favorably with the narrow definition of "manufacturer" used elsewhere in the bill.

Sec. 805. Labeling

1) The requirement of U.S.-style labeling on tobacco products made or sent overseas by U.S. companies raises many problem areas. One is that this would put U.S. companies at a potentially huge competitive disadvantage compared to the many international tobacco companies headquartered elsewhere (BAT, Richemont/Rothmans, Gallahers, Imperial Tobacco Group, Japan Tobacco, Reemtsma, etc.). This could cause great loss of sales to U.S. companies without necessarily reducing international tobacco consumption.

2) One possible result of such a section would be, should the warnings be seen as a major obstacle, that U.S. companies would simply sell certain brands to foreign companies not governed by the U.S. law. This would not be unusual for tobacco products. For instance, 'Benson & Hedges' is owned by Philip Morris in the U.S., Rothmans in Canada, Gallahers in the U.K. and B.A.T. in Asia.

3) The presence of American warnings in other countries could be counter- productive. For example, local tobacco companies in places like Vietnam currently apply U.S. warnings to packages as a marketing ploy since 'Americana' sells well.

4) The presence of American warnings in other countries could also retard development of local warnings in some countries. This could happen through local companies convincing their governments that bigger warnings on the American packages protect local manufacturers from foreign competition. This local company advantage would end if the local companies were forced to implement similar warnings.

S. 1648: THE PAST ACT

Sec. 900. Definitions

1) There is no definition of "manufacturer". Other bills use a very narrow definition which would likely cause significant problems. The lack of a definition might be an improvement, but still leaves uncertainty as to what is intended to be governed by the law.

2) The definition of "cigarette" includes products intended to be "heated" as well as "burned". This appears to be an effort to include Eclipse-type products within the definition. It may be that such products are better dealt with through a different mechanism, such as the FDA authority over other drugs and devices. Even if Eclipse-type products are meant to be included, this definition may not be expansive enough to include new alternative forms of delivery. For instance, a product which neither burns nor heats would not qualify.

3) The definition of cigarette requires a "roll of tobacco". This term is not defined. As Eclipse contains things in addition to a roll of tobacco, such products would only qualify if the definition was met by having a roll of tobacco in the product regardless of the other components. If that is the case it would appear that any product could come within this bill, rather than the more onerous conditions of FDA control over drugs, by ensuring there is a roll of tobacco and that the product is heated or burned.

Sec. 902. Submission of Health Information to the Secretary

1) Sec. 902(a) requires significant disclosures by tobacco companies, including disclosures on research. While disclosure is mandatory, it is not mandatory for the companies to do the research. A possible result is that the companies simply decide to abandon health research in favor of a concentration on marketing, which need not be disclosed. For an industry with a decades-long culture of secrecy it is even more likely that health research (which can still harm the litigation position of these companies or their affiliates in other countries) will simply be discontinued. To ensure that research is actually done the law would have to have the ability to force the companies to do the work, not just to force its disclosure.

2) Sec. 902(d) gives protection to 'trade secrets'. If such protection is not conditional on strong regulatory control over tobacco products there could be a problem. Other consumer products can be offered such protection because mandated manufacturing standards ensure that they are not health risks. For instance the Coca Cola formula can be a secret without risk to public health since, by law, it can only include ingredients which are approved for human consumption. Tobacco products will have it 'both ways' if they can avoid legislation that requires its products to have minimal health impact while also avoiding disclosure of information that could help consumers make decisions about the health risks.

Sec. 903. Tobacco Product Health Risk Reduction Standards

Sec. 903(d)(2) grandfathers the use of currently used ingredients for a period of five years. This gives an advantage to existing products compared to any new ingredient, which is immediately subject to the provisions of this section. The likely result is that product innovation, rather than being promoted, is stalled for five years.

Sec. 905 Tobacco Product Warnings, Labeling and Packaging

1) There is authority (Sec. 905(d)(2)(A)) for the Secretary to authorize changed warnings text after a one year period after the final rule is published. This authority is, however, constrained (Sec. 905(d)(2)(B)) for five years, during which time it is only available where the Secretary "can demonstrate extraordinary circumstances". This authority, by being limited to changes in the "text" of the statements also appears to leave no authority to change the layout, positioning or size of the warnings.

2) Sec. 905(d)(2)(C) requires the Secretary to assess the effectiveness of the warning labels. The Secretary is authorized to periodically evaluate the "effectiveness of the warning labels in deterring youth smoking. . ." This could create the basis for improved warnings. Unfortunately, limiting the evaluation to issues of youth smoking will make the review less important for tobacco control than would otherwise have been case if overall smoking deterrents were the basis of the analysis. A further constraint is that the assessments can not be done any more frequently that once every three years.

3) The warnings would be required to be displayed only on the front panel (Sec. 905 (a)(2)(A)). This allows messages to be less visible than in S. 1638 which requires warnings on both main panels. It also encourages the promotion and display of tobacco packages so that the messages are not visible.

4) The typeface of the warnings can be adjusted by the Secretary ((Sec. 905(a)(2)(B)). This language would allow larger as well as smaller typeface. But regulatory authority over the warnings is greatly constrained in this subsection by inclusion in the bill of nebulous wording such as "conspicuous and legible type", which as discussed in the analysis of other bills, can create major interpretation problems.

5) The language of 905(a)(2)(B) also constrains the use of the "conspicuous and legible type" by specifying that this is in "contrast by typography, layout, or color". The use of "or" appears to allow the tobacco companies to determine which of these types of contrast will be met.

6) Sec. 905(a)(2)(B) also specifies that the messages be printed in a black and white format as determined appropriate by the Secretary. This requirement would appear to replace the requirements as to the warning being conspicuous or in contrast. As such the subsection could be more tightly worded. A bigger problem, though, is that the inclusion of black and white text as a necessary standard under the bill would remove regulatory authority to implement a different but more effective system.

7) The flip-top box exemption only exists for products offered for sale on April 1, 1997 (Sec. 905(a)(2)(C)). This prevents the introduction of new products seeking to exploit this potential loophole. But it still allows any pre-existing product a potential advantage in the marketplace by allowing for smaller warnings.

8) The rotation of the warnings (Sec. 905(a)(4)(A)) requires approval by the Secretary. This could prevent abusive behavior such as non-random distribution based on minimizing health impact of messages. Unfortunately, the wording of this subsection goes on to say "[t]he Secretary shall approve a plan. . ." that meets the specified rotation requirements. As a result the Secretary appears to lack the discretion to deny approval to a rotation plan that meets

the technical requirements of the law but flouts its purpose.

9) There is a continuation of the problem of the stated warnings using capital letters for the first letter of each word. This can make the messages harder to read.

10) The bill talks about "warnings" rather than "messages". This could prevent non-warning messages (e.g. information on quitting or on the costs of smoking).

11) As with other bills, the label statement on advertising (Sec. 905(a)(3)) does not specify location of the message. As a result there will be a race to the lowest standard of communication of the health message. Elsewhere, the failure to specify location has resulted in warning messages located at the bottom of advertisements, where they are the least visible.

11) The general use statements in 905(c) appear to be without strong evidence of effectiveness and with no apparent mechanism for changing these messages as research comes available.

Sec. 906 Restriction on Marketing and Advertising

1) The effectiveness of the proposed constraints on advertising are largely tied to the operational definition of such terms as "manufacturer", which is not defined. If affiliated companies can do what the actual manufacturer cannot, these provisions will have little effect.

2) Sec. 906(a)(4)(B) allows point of purchase advertising at "each location where tobacco products are offered for sale". It is not clear whether a "location" is each retailer, or each place within a retailer where tobacco products are sold. If each check-out counter is a "location" there could be many more signs than if each retail outlet counted as only one location.

3) Sec. 906(b)(1) grandfathers tobacco trademarks on nontobacco goods. In doing so it protects such products sold in the United States "on or before January 1, 1995". This leaves open the possibility that some products could re-emerge, such as the now defunct Harley-Davidson cigarettes. It might be preferable to ensure that the association had to exist on a set date, and not ceased any time after that.

4) Sec. 906(b)(2)(B), while requiring tobacco companies to submit advertising to the Commissioner does not appear to give the Commissioner any authority to do anything to control or limit this advertising.

5) Sec. 906(b)(4) seeks to end glamorization of tobacco products. It tries to prevent any promotion "that appeals to persons under 18 years of age". Without an operational definition of such criteria it will undoubtedly be as contentious as the voluntary codes of the tobacco industry which used similar language.

6) Sec. 906(d)(1)(A) seeks to prevent tobacco manufacturers from sponsoring events, or causing events to be sponsored. This raises a question of what 'causes' a sponsorship, and the definition of "manufacturer". For example, Philip Morris USA is a manufacturing entity, but it is owned by a holding company. If the holding company sets up a separate entity to sponsor events it could be argued that the manufacturer did not cause this to happen, as it cannot dictate policy to its parent corporation. If that was the case the sponsorship does not violate this subsection.

Sec. 907. Reduced Risk Tobacco Products

1) The definition of 'reduced risk tobacco products', by requiring toxins, may create perverse incentives. If tobacco products are to be less tightly regulated than pharmaceuticals, companies could have an incentive to add a toxin to a product simply to come within the category of reduced risk tobacco products.

2) Sec. 907(a)(3)(A) gives a wider market for reduced risk tobacco products than exists for pharmaceutical nicotine products. It does so by specifically authorizing such products as replacements for tobacco products, thus opening the field of nicotine maintenance at a time when this field is closed to pharmaceuticals. This adds to the incentive to add toxins to alternative nicotine products.

3) Sec. 907(b) grandfathers reduced risk tobacco products for five years after being designated before there can be a revocation of the designation. The inability to remove the designation for five years, and the standards necessary to have a revocation of the designation after that time, could create abuse of the designation. It also gives much more favorably treatment to these tobacco products than to the safer pharmaceutical alternative nicotine products which are governed by the FDA.

4) Sec. 907(d) by specifically stating that reduced risk tobacco products will not be regulated as a drug or device adds to the incentive to bring products within this standard rather than a pharmaceutical standard. The result is that tobacco companies have an incentive to retain toxins and other consumer product companies interested in the nicotine market have an incentive to add toxins.

Sec. 908. Tobacco Product Marketing Restrictions

1) Sec. 908(g) bans packages of under 20 cigarettes. This prevents the introduction of packages of 18 or 19 even if research shows this will help smokers to reduce intake. Experience from Germany and Finland would indicate slightly smaller packages actually do reduce smoking, apparently by impacting on people who smoke 'a pack a day'. It would be better to leave both package minimum and maximum sizes to health-based regulatory authority.

2) SEC 908(j) allows vending machines "where the retailer ensures that no individuals under 18 years of age are present or permitted to enter at any time". This would mean such things as that an owner or employee could not have a child be with them at any time, even when the establishment is closed. Such a rule is hard to enforce or interpret, and against social values. Would a single parent be forbidden from having a young child with them while cleaning a closed establishment on Sunday morning? Even if alternative child care was unavailable, or if the presence of the child was the only way that the worker had time to do her job and still make it to church on time? Would a tavern owner have to refuse permission for a young couple to shelter out of the rain if they were carrying a child? It would make far greater sense simply to end the use of vending machines rather than get caught in such massive interpretation problems.

Sec. 909. Tobacco Products Scientific Advisory Committee

1) Without clear limitations on obstructionist behavior the presence of a tobacco industry representative on this committee (Sec. 909 (b)(1)(C)) could greatly limit the functioning of the committee.

2) Sec. 909 (b)(1)(E) specifies that the Secretary shall appoint to this committee "a representative of the general public selected from pro tobacco organizations". It will be important to consider exactly what type of organizations are being considered here. The most prominent groups of 'public' pro-tobacco groups are actually set up and funded by the tobacco industry and run by professional public relations professionals. They would not appear to meet the specified criteria of being "from the general public".

Sec. 912. Authority to Assess and Use Fees

1) Sec. 912(b) specifies that the annual fee to be used for the funding of the regulation and control of tobacco products is set at $100 million annually. There is no flexibility given to this assessment. This leaves the assessment at risk due to inflation or other unforeseen events. In Canada a government promise of $10 million for tobacco control activities gave an incentive to the tobacco industry to engage in activities which would consume these resources, in order to protect themselves from the money being used in ways which could cause greater damage. The same incentive is built into this bill by leaving no flexibility on the funding side. If the tobacco industry can force the Secretary to spend $100 million a year on litigation, etc., it can apparently prevent a key element of this bill from effectively functioning.

Sec. 913 Preservation of State and Local Authority

1) State authority to act on a wide range of Chapter 9 issues, including labeling, is preempted (Sec. 913(a)(3)). This raises all the problems discussed in the review of the previous bills.

2) It appears possible to argue that a narrow reading of this section allows state action provided it does not deal with the same issues as are covered in this bill. For instance, if the requirements on labeling only deals with "warnings" it could be argued that states are not preempted from requiring a 'quit line'. At the same time this section clearly does greatly limit state authority, creating incentives for the tobacco industry to get the weakest possible measures from the federal government.

---

[1] S. 15(a), Tobacco Products Control Regulations, Canada Gazette Part II, vol. 123 No. 2, January 18, 1989.

[2] "Group says tobacco warnings weakened," The Globe and Mail, June 26, 1989, page 1.

[3] See note 1.

HEALTH SCIENCE ANALYSIS PROJECT

Policy Analysis No. 11

THE ROLE OF THE FOOD AND DRUG ADMINISTRATION IN REGULATING TOBACCO PRODUCTS

By

John Slade, M.D.
Professor of Clinical Medicine
Robert Wood Johnson Medical School
University of Medicine and Dentistry of New Jersey

May 11, 1998

HEALTH SCIENCE ANALYSIS PROJECT

Policy Analysis No. 11

THE ROLE OF THE FOOD AND DRUG ADMINISTRATION IN REGULATING TOBACCO PRODUCTS

By

John Slade, M.D.
Professor of Clinical Medicine
Robert Wood Johnson Medical School
University of Medicine and Dentistry of New Jersey

Table of Contents

The Health Science Analysis Project (HSAP) is an Advocacy Institute project, supported by grants from the Robert Wood Johnson Foundation, the American Cancer Society, and general contributions to the Advocacy Institute.

HSAP is directed by its Executive Committee. No grantor has editorial control over the scope of the project, or the content of the analyses it produces.

The material presented in this paper reflects the views and judgments of its authors, who are responsible for its content.

THE ROLE OF THE FOOD AND DRUG ADMINISTRATION IN REGULATING TOBACCO PRODUCTS

By
John Slade, M.D.
Professor of Clinical Medicine
Robert Wood Johnson Medical School
University of Medicine and Dentistry of New Jersey

EXECUTIVE SUMMARY

The regulation of tobacco products by the Food and Drug Administration holds enormous promise for public health gains but only if the agency has sufficient flexibility and resources to do the job well.

Despite their promise, so-called "low tar" cigarettes have not reduced illness rates from smoking, and many people have turned to these as an alternative to quitting. Lessons from the "low tar" experience speak to the form that FDA regulation should take.

Key recommendations for FDA authority are:

- The goal of tobacco product regulation is to reduce the overall burden of tobacco-caused illness and death to the greatest practical extent.
- Tobacco products should be regulated as drug-device combination products and not as a separate category.
- The definition of tobacco products should encompass all categories of traditional products and not just include cigarettes and smokeless tobacco products.
- Advisory Committees and similar bodies should not include representatives, consultants or grantees of the tobacco industry among their members.
- The FDA should take a stepwise approach to tobacco product regulation. It should first:
  1. Set interim product specifications based on the Advisory Committee process
  2. Learn about tobacco products in detail from tobacco companies and
  3. Develop appropriate tests.

Steps (2) and (3) will enable FDA to:

  -- Develop and implement further product specifications and
  -- Consider health claims for novel nicotine delivering products

- The FDA should scrutinize non-tobacco ingredients for tobacco products for safety, addictiveness, and palatability. The agency should forbid the use of any ingredient other than tobacco that contributes to harm or abuse liability.
- A substantial amount of work must be done before it will be clear whether and how nicotine itself should be regulated.
- Products for which health claims are to be made should demonstrate that they are substantially less dangerous than competing products and that they pose an acceptable risk to those who are not their intended consumers. Companies should present pre-marketing evidence to this effect and conduct post-marketing studies that confirm these expectations.
- Terms such as "light," "low," "mild," "low-tar," and "reduced delivery" should not be permitted.
- The FDA should have authority over labeling, advertising, and distribution of tobacco products.

- Preemption of a state's ability to regulate in this area should not be permitted except in relationship to regulations affecting the manufacture of tobacco products themselves unless FDA's authority to regulate products is limited or circumscribed.

THE ROLE OF THE FOOD AND DRUG ADMINISTRATION IN REGULATING TOBACCO PRODUCTS

By
John Slade, M.D.
Professor of Clinical Medicine
Robert Wood Johnson Medical School
University of Medicine and Dentistry of New Jersey

INTRODUCTION

Although tobacco products cause enormous harm to consumers, they have come under strikingly little regulatory oversight.[i] Nonetheless, the appropriate regulation of these products holds promise for reducing the enormous toll of illness and death caused by tobacco. At the same time, if the regulatory structure this country develops is too loose or subject to legal challenge, the public health will likely actually be harmed by the exercise.

The history of tobacco product innovation is filled with false promises and with public relations gimmicks which have masqueraded as public health advances. The death toll from tobacco has not been reduced by filter cigarettes, nor has it been reduced by so-called "low tar" cigarettes,[ii] even though these innovations have been hyped as genuine advances. Moreover, filters and "low tar" have actually helped sustain and grow the market for cigarettes, thereby actually making the epidemic worse.

The present situation presents what may be a unique opportunity to establish a rational regulatory structure for tobacco products. The public health potential for tobacco product regulation lies in at least four areas: it could contribute to reducing the new uptake of tobacco use by young people, it could facilitate stopping among those who want to quit by making information more available and possibly by making tobacco products less addictive, and it could create a regulatory environment in which the tobacco products which are sold are actually substantially less poisonous and do less damage, and it could foster the development of new treatment strategies by reducing the enormous competitive advantage of tobacco product development over treatment product development.

At the same time, there are potential pitfalls. The converse of the desired outcomes outlined above may also happen, especially if there are unsubstantiated claims for products purporting to be less dangerous. Tobacco product use may rise among the young and fail to decline among adults because of (perhaps misguided) impressions people have about improved safety. Quitting may become more difficult because of confusing messages about these products, and many people may continue to use products which are highly poisonous. Moreover, innovative treatments for tobacco dependence may be overshadowed by unduly favorable regulatory approaches to novel tobacco products.

Unfortunately, there are many unknowns, and so it is difficult to forecast what precise form the regulations should take. In this circumstance, the Food and Drug Administration should have broad authority over tobacco products as well as sufficient resources so it has the flexibility to approach this task in the manner necessary to protect the health of the American public. The 1996

Tobacco Rule issued by the FDA and its existing authorities appear to give the agency the flexibility to address current and emerging problems posed by tobacco product development and use. This authority needs to be affirmed and not weakened.

In August 1996, the Food and Drug Administration asserted jurisdiction over cigarettes, loose cigarette tobacco and smokeless tobacco.[iii] This action was the culmination of an investigation the agency had begun two and a half years earlier. It represented a substantial departure from the case-by-case approach the agency had used repeatedly since the early 1950s to regulate individual tobacco products which the agency determined from time to time fell within the scope of being a food or a drug.[iv]

The agency asserted jurisdiction over these products in 1996 because of the overwhelming evidence it had amassed that the manufacturers of these products intended that these products produce pharmacological effects and, indeed, nicotine addiction, in consumers. The agency found that these products were both drugs and devices and developed a regulatory approach which was suited to the combination drug-device nature of the products. While presently under review by the U. S. Court of Appeals (4th Circuit), the jurisdictional determination was upheld in Federal District Court in April 1997.[v]

On 20 June 1997, the major tobacco product manufacturers reached agreement with a number of states' attorneys general on terms which would settle the state Medicaid lawsuits. This agreement included a detailed outline of legislation on the FDA's authority over tobacco which would be acceptable to the industry. As discussed below, were the regulatory structure for tobacco products to be based on this document, the FDA would forever be at a major disadvantage in relationship to the regulated industry, and the public health would be severely compromised.

In July 1997, The Advisory Committee on Tobacco Policy and Public Health, led by C. Everett Koop, M.D., Sc.D. and David A. Kessler, M.D., issued a report on tobacco control policy which included a set of recommendations for the regulation of nicotine and tobacco products (see appendix). These recommendations continue to form a sound basis for policy development.

The next section of this paper reviews so-called "low tar" cigarettes because it is essential to learn from the false promises of "reduced risk" these products have offered over the last thirty years as we contemplate appropriate regulation of "reduced risk" products for the next thirty years. Following this is an overview of the major considerations involved from a public health perspective in those regulatory issues which are not addressed in detail by other papers in this series.[vi] The final section considers the most recent version of S-1415 available to the author in light of these major considerations.

"Low Tar" or "Light" Cigarettes

Making cigarettes less toxic has long been an appealing strategy. Unfortunately, the tobacco industry has usually settled for making its products *appear* less toxic instead of *actually* reducing their poisonousness.

There are numerous examples where tobacco companies have promised or implied "reduced risk," going back at least to the 1920s. However, it was only with the development of wide-spread public concern about lung cancer from smoking that health and safety became dominant concerns for cigarette designers. Filters in the 1950s and then "low tar" smokes in the 60s and beyond carried the promise of relative safety.[vii] At no time, unfortunately, have manufacturers been made accountable for their claims, and the very names "light" and "low tar," along with

the associated packaging and imagery, came to communicate relative safety.

Medical advice as recently as the early 80s was that, if the patient would not or could not stop smoking entirely, then he or she should at least switch to a "low tar" brand. This was based on clear evidence that the risk of tobacco-caused disease was related to the level of tobacco toxin exposure. By 1983, however, it had finally become generally known in medicine that this advice had been used by tobacco companies to provide cigarettes that were lower only in their delivery to machines while sustaining high toxin delivery to consumers. Furthermore, the nature of the marketing campaigns contributed to the tobacco industry successfully achieving its major intent, namely to undermine tobacco use cessation efforts by addressing health concerns with unfulfilled promises. These marketing efforts have been aided by the absence of any apparent restrictions by FTC to prohibit the use of claims such as "light", "low tar", and "reduced". Even food products must meet government-defined standards to warrant use of such claims and descriptors in labeling and advertising.[viii] "Light" cigarettes were not substantially less hazardous, they were just as addictive, and many people smoked them instead of quitting. (Indeed, we now know that consultants to cigarette makers actually viewed characteristics such as these as key advantages of the genre.[viii])

"Light" cigarettes are defined by manufacturers in relationship to the FTC cigarette test method, a way of measuring tar, nicotine and carbon monoxide yields from cigarettes in a standardized way. Unfortunately, this standardized test bears little relationship to how people actually smoke.[ix] Moreover, since the 1960s, cigarettes were specifically designed so that consumers would be likely to take in more smoke than the machines measured. This has been acknowledged in previously secret tobacco industry documents and confirmed by scientific studies. The actual doses that people derive from cigarettes are far more similar from cigarette brand to cigarette brand than is suggested by these test results. Moreover, the concept of "tar" as defined in the FTC test bears only a crude relationship to toxicity: the tars of different cigarettes can differ markedly in their toxicity.[x]

"Light" cigarettes have been an overall detriment to public health. The category has not resulted in substantial reductions in cigarette-caused disease. In fact, some measures of harm have increased. There has been a marked increase in adenocarcinoma of the lung in association with changes in manufacturing practices that increased the levels of tobacco-specific nitrosamines in cigarette smoke.[xi] Moreover, the relative risk of lung cancer among smokers is higher now than it was thirty years ago.

Not only have "light" cigarettes not delivered on their advertised promise in terms of their poisonousness compared to "regular" smokes, "light" cigarettes have kept people in the market who would have otherwise made more concerted efforts to stop. If only unfiltered, 70 mm cigarettes were being sold today, it is highly unlikely that there would be nearly as many people smoking as actually are.

In sum, the "low tar" segment of the market has sustained cigarette consumption at high levels and has not been associated with substantial reductions in risk of harm from tobacco use. This adverse experience could have been avoided had there been adequate regulatory oversight of the industry thirty years ago.

KEY ISSUES

Tobacco Products Should be Regulated as Combination Drug-Devices and not as a Separate Category.

Tobacco products should be regulated as combination drug-devices. The evidence amassed by the FDA demonstrates that cigarettes and smokeless tobacco products fulfill the statutory definitions of drugs and devices, and the FDCA gives the agency sufficient flexibility to regulate these products. Even the major tobacco manufacturers, in the 20 June agreement, accepted the drug-device designation. The establishment of a new category for tobacco products could limit the agency in unforeseen ways and set up a situation in which the industry will likely be able to substantially delay effective regulation by testing each attempted limit in court because of a lack of guiding precedent.

If a separate chapter is created but some tobacco products are excluded from the definition of regulated products, the agency may have difficulty eventually asserting authority over these other categories as it becomes appropriate (such as cigars) unless the new chapter provides a clear pathway for this. Moreover, the agency's existing regulations from August 1996 were issued under its authority to regulate devices. If tobacco products are treated in a separate chapter, provision would need to be made to immediately reissue these regulations under the new authority to avoid needless delays.

The absence of a scientific basis for a new chapter in the FD&C Act and absence of a jurisdictional record would invite endless legal challenges by the tobacco industry. This process would sap FDA's resources and lead to undue delays in implementation of life-saving regulations. Strikingly, when faced with matters of far lesser impact on health, FDA is able to act more freely in the interest of public health and consumer protection. For instance, the agency seized frozen orange juice falsely labeled as fresh a few years ago, and it routinely sanctions drug manufacturers whose product claims deviate only slightly from approved labeling.

Overall Standards by Which to Regulate Tobacco Products.

Since tobacco products cannot be made to be safe, and it is uncertain what the appropriate indication is for which they might be effective, it will be helpful for the agency to have standards for regulating tobacco products which are appropriate to the unique problems they pose.

The overall goal of tobacco product regulation is to reduce the overall burden of illness and death caused by tobacco products to the greatest practical extent. This standard uses as its vantage point the health of the entire population and necessarily considers each of the following groups:

- Those who presently use tobacco products and who will not stop doing so
- Those who presently use tobacco products and who intend to stop
- Those who have not started using tobacco products
- Those who have stopped using tobacco products and who are at risk of relapse
- Those who are exposed to tobacco smoke generated by others

The presumed rationale for "low-tar" cigarettes was to benefit people in the first category. Not only have "low-tar" cigarettes not provided any important health benefit to these people, they have harmed people in the other categories by providing a misleading excuse to avoid stopping, by making smoking appear less risky than it is, by sustaining addiction to nicotine, and by continuing to produce toxic pollutants.

Another way to state the guiding principle for tobacco product regulation is that these products should be no more harmful than necessary. This means that they should be no more toxic or addictive to users than necessary, that they should not unduly interfere with the desire to stop, that they should not be unduly attractive to prospective users, and that they should be no more toxic than necessary to those who are exposed to their smoke.

The expression of this standard will shift over time as more is learned about tobacco product design and as the epidemic of tobacco use evolves.

A different issue is raised when one considers what standard might be appropriate for tobacco products whose manufacturers want to make health claims (so-called "reduced-risk" products). A health claim for a tobacco product only makes sense if it looks in two directions at once, Janus-like.

On the one hand, a health claim has to be considered in relationship to the tobacco products with which the novel product would reasonably compete. In what ways does it provide a substantial chance of being substantially less toxic than the specific products which current consumers of tobacco products would be putting down in order to use the new one? This is the backwards-looking face of Janus which has received the most attention in discussions of this possible product category.

On the other hand, a health claim for a tobacco product also has to be considered in relationship to abstinence, since it is clear that many consumers would weigh in their minds using a novel product as an alternative to quitting altogether, and such products would likely tempt people who do not currently use tobacco products. Products in this category should be thought of as "nicotine maintenance" products: The manufacturer of one of these devices would intend that its customers continue to use the device indefinitely. This is the other face of Janus, looking forward.

Not only will the standard for products that make health claims have to weigh both comparisons to competing products on the one hand and abstinence on the other, the application of this standard will also change over time as product specifications ("performance standards") for the great bulk of tobacco products evolve over time in response to technological and scientific developments and to the evolution of the epidemic.

Legislation which sets standards for the agency to follow should provide the flexibility to accommodate to these dynamic features of the problem.

Definition of Tobacco Products

At a minimum, the definition of tobacco products should include all the traditional categories (cigarettes, cigars, pipe tobacco, cigarette tobacco, oral and nasal smokeless tobacco). While the agency can and should particularize its regulatory approach to fit the circumstances of each separate category, the omission of any of the traditional categories will create substantial problems down the road.

The clearest example of this is cigars. Except for the cigarette-like small cigars, these products are not covered by the FDA's present assertion of jurisdiction. Moreover, it is unlikely that the agency will ever be able to make as overwhelming a case for asserting jurisdiction over cigars as it has for cigarettes and for smokeless tobacco. Nonetheless, cigars are a substantial public health problem, and if they are unregulated, their danger to the public health will increase.

The National Cancer Institute has just issued a detailed report on cigars which concludes that cigar smoke is as toxic as cigarette smoke.[xii] Moreover, cigars deliver substantial doses of nicotine in a form which does not require inhalation. Despite their

risks, there are no federal requirements for warning labels on cigars (although such warnings are required on packages of cigars sold in Canada).

Cigar use is surprisingly high among the young. More than one in five high school students has smoked a cigar in the past month, including nearly a third of males and one female in ten.[xiii] Cigar use among high school students is now more than double the rate of smokeless tobacco use. Norman Sharp, President of the Cigar Association of America, has discounted these figures by suggesting that they represent the use of cigars to smoke marihuana.[xiv] This is not likely to be the case since young people readily distinguish between questions about smoking cigars and using cigar wrappers for marihuana, but if it were so, the industry would still have to face up to the fact of an enormous diversion of its product to people whom it does not want as customers.

Moreover, reducing access and appeal to cigarettes and smokeless tobacco will likely shift consumers to tobacco products which appear (because of history and the absence of any prior regulation) to be relatively safe.

The FDA's final rule on tobacco products requires that self-service displays be moved behind the counter. Applying this to only cigarettes and smokeless tobacco will leave cigars as self-service items.

The definition of tobacco products should not be so broad as to encompass novel tobacco products. Novel products such as Premier and Eclipse from RJR and the Accord system from Philip Morris have each been made (at least in part) to resemble conventional cigarettes, but these products fall outside the traditional understanding of "cigarette," and, even without a consideration of possible health claims, each raises important questions which should be addressed in a pre-market approval process as a new drug-device combination product. A number of patents describe potential tobacco products which would also fall outside any colorable definition of conventional product categories,[xv] and such products should also be subject to pre-market approval.

If the agency develops regulations category by category, it may also need the capacity to create new categories for novel products.

The August 1996 regulations promulgated by the FDA limit the definition of regulated products to those that contain nicotine. This limit was important for the FDA because of the terms of its jurisdictional analysis. The agency started with nicotine, determining that nicotine in these products was a drug, and then moved on to determine that the products containing nicotine were nicotine delivery devices. However, this limit need not be carried over into legislation. It would be useful for the agency to be able to regulate nicotine-free tobacco products since these products could be marketed in ways which also promote nicotine-containing products and since these products would presumably also be toxic and would therefore deserve oversight for that reason alone.

It is attractive to consider a definition which simply includes as tobacco products all products made from tobacco or any derivative of tobacco. While elegant and reasonable, an interesting anomaly appears if this definition is used. Specifically, nicotine replacement medications (e.g. patches, gum, inhaler, nasal spray), which only deliver pure nicotine to the user, rely on tobacco as their ultimate source of nicotine. If such a definition is used, there may need to be a hierarchy established whereby if a product is already regulated as a drug, it is not considered a tobacco product.[xvi]

Advisory Committee Membership

The FDA should have the guidance of an appropriate advisory committee of outside experts with knowledge and experience in relevant fields. The membership of such an advisory committee, and, indeed, the

membership of other committees that may be formed to implement various parts of a regulatory scheme, should not include representatives of tobacco product manufacturers or persons who have been consultants to or grantees of the industry.

There are two reasons for this.

First, the tobacco companies are committed to dogmas that are at odds with public health goals. These include: "Tobacco is not a proven cause of disease;" "Nicotine is not addictive;" and "Environmental tobacco smoke is not a proven cause of disease."[xvii] The continued attachment the companies have to misleading labels such as "light," "low-tar," and "mild," an approach which has greatly enlarged the public health problem caused by cigarettes, is a further indication that, while their perspective should be listened to and understood, these companies are incapable of constructively contributing to deliberations where scientific judgments in the interest of public health will be made.

Second, the tobacco companies have shown that they will bog things down and interfere with progress whenever and however they can. The experience of OSHA in its attempts to promulgate a rule on controlling ETS in the workplace, the experience of the Massachusetts Department of Public Health in its efforts to force ingredient disclosure, and the experience of the several federal agencies that worked on the various congressionally-mandated task forces on fire-safe cigarettes in the 1980s all demonstrate that the more directly the tobacco industry is involved in a process, the less is accomplished.

The frustration people of good will have with the industry has recently been expressed by recommendations that the Scientific Committee on Tobacco and Health made to the Department of Health in the United Kingdom last month. The Committee's top recommendations were:

> The Government should require of the tobacco industry:
>
> a. reasonable standards in the assessment of evidence relating to the health effects of the product it sells,
> b. acceptance that smoking is a major cause of premature death, and
> c. normal standards of disclosure of the nature and magnitude of the hazards of smoking to their customers, comparable to that expected from other manufacturers of consumer products.[xviii]

Until the day comes that industry behavior at least matches these recommendations, members of the industry should not have direct roles in official advisory deliberations about tobacco.

Overall Approach to Regulation

The regulation of tobacco products is uncharted territory. Past experiences with filters and so-called "low tar" products have been so adverse for public health that a deliberate, step-by-step approach is especially appropriate here.

It would be best if the FDA were to proceed with tobacco product regulation in the following order:[xix]

First:

1. Learn about tobacco products in detail, and then
2. Develop appropriate tests.

Then:

- Develop and implement performance standards (product specifications) and
- Consider health claims.

The agency will need to know about the design, engineering and manufacture of tobacco products and why they are made as they are. It will also need to know what things are no longer done, what other choices have been made, and why. This knowledge will permit the agency to move forward with confidence in the other steps.

The agency will need to establish testing criteria for tobacco products, especially standardized measures of the content and deliveries of specified constituents. Measures of "tar" alone are insufficient to assess toxic potential because "tar" has importantly different compositions from one product to another. The FTC test is not a sound basis for regulation as discussed above.

Once there is knowledge of the products and once there is an appropriate set of tests, the agency can develop performance standards, product specifications, for tobacco products in cooperation with the industry, members of the public health community, and independent scientists.

Product specifications (performance standards) will be one of the key benchmarks by which proposed health claims (claims of "reduced-risk") can be recognized. Until product specifications are in place and there is a clear understanding of what the range of conventional products is within this range, the agency may have difficulty making determinations of what constitutes a valid claim.

Finally, it is expected that there will be advances in science, advances in technology, and a continued evolution of the epidemic. These factors create a dynamic field on which the regulatory apparatus will operate and to which it must, in turn, respond appropriately over time.

Access to Information by the FDA

Any legislation must provide the FDA with an ongoing means to learn in detail about the products it is regulating. The agency must have a right of entry to production facilities and subpoena power to assure it access to all records pertaining to the design and manufacture of tobacco products.[xx] It may be especially important for the agency to be able to learn about the design choices which have been considered but not used and for it to learn about why things are the way they are.

There must be an ongoing sharing of information of this sort with the agency. Plans for new products, as well as planned changes in ingredients and processes for any existing products, should be communicated to the agency in a timely manner before they are implemented so the agency can review them and decide whether they are appropriate.[xxi]

Product Testing and Research

The FDA will have to develop tests of the content and yields of tobacco products which are relevant to the expected dosing that consumers receive when they use these products. The present FTC test falls far short of this goal because it has little ability to predict dose (because of smoker compensation) and because "tar" is such an imprecise measure.[xxii] The 20 June agreement envisions Congress mandating a 12 mg "tar" ceiling for cigarettes regardless of what FDA later does. It would be folly to pursue this course. The FDA is capable of developing appropriate measures, and establishing what amounts to an arbitrary performance standard based on a discredited test of an imprecise measure will only confuse the public and entrench a bad test.

Beyond this, in considering proposed health claims, the FDA will need to decide what surrogate markers are appropriate to study and will need to develop appropriate measures related to the potential for unintended consequences that these products will have (such as their use by novices and the substitution of these alternative products for

abstinence). The agency will need to help manufacturers design and develop appropriate post-marketing studies which will demonstrate whether the promise of these products is confirmed and whether or not there are acceptable levels of unintended effects.

The measurement and oversight tasks the agency will face must be built on a sound scientific base. This means that the agency will need access, either intramural, extramural, or both, to the scientific expertise and laboratory capability necessary to support the development and review of these measures. Since policy research of this sort is unlikely to be attractive to the NIH, the FDA itself should have an appropriate level of resources to carry out this part of its mission.

Regulation of Ingredients

The FDA should be able to regulate all ingredients in tobacco products (including ingredients in the tobacco component, in any papers, in any filter, and in any other components of each device[xxiii]) and it should be able to require disclosure of any ingredient which presents a health or an addiction problem.

The ingredients that are not derived from tobacco should be subject to immediate disclosure to the agency (including not only brand by brand lists of ingredients and amounts used but also the function(s) of various ingredients). Over a reasonable period of time, there should be an orderly review of whether each ingredient contributes to toxicity and addictiveness, based largely on data developed by the manufacturers. The agency should be able to set priorities on which ingredients are to be reviewed first, second, and so forth, according to its preliminary assessment of whether a given ingredient is likely or not to pose a hazard, and the review system should be arranged so as to not be an undue burden on either the agency or on manufacturers.

Among the factors the agency should be able to consider in regulating the non-tobacco ingredients of tobacco products are these:

- Toxicity of the ingredient as it is used
- Whether the ingredient contributes to addictiveness
- Whether the ingredient contributes to the palatability or acceptability of products in which it is used

It may be that there are ingredients which the agency determines should be used in every tobacco product in a given category for the benefit of public health. Legislation on ingredients should permit the agency to *require* that such ingredients be used.[xxiv]

Product Specifications (Performance Standards)

Cigarettes and smokeless tobacco products sold in the United States appear to be more poisonous than necessary. The yields of cancer-causing nitrosamines in comparable cigarettes sold in both Germany and Japan are substantially lower than those in U.S. brands without concomitant increases in yields of another carcinogen, benzo(a)pyrene. The moist snuff equivalent sold in Sweden (snus) has far lower levels of nitrosamines than moist snuff sold to Americans. Specifications should be established for each category of tobacco product to assure that these products are no more toxic than necessary.

The development of these specifications will be a difficult and complex process because of the technical and scientific issues that will need to be addressed. Moreover, the tobacco companies may be reluctant to have them set. The task should not be made more difficult by any procedural requirements which foster delay.[xxv]

There are a number of promising avenues which the FDA should explore in

developing these specifications to reduce hazard and addictiveness (without affecting nicotine content). These include:

- Using activated charcoal filters on cigarettes to reduce the levels of vapor phase toxins;
- Removing additives which contribute to toxicity;
- Requiring the use of additives which reduce toxicity or addictiveness;
- Setting a ceiling for yields of tobacco-specific nitrosamines (Commercial cigarettes in Germany and Japan have substantially lower nitrosamine levels than those sold in the U. S. It may also be possible to set this ceiling at "not detectable" according to the claims of Star Tobacco and Pharmaceuticals in Virginia);
- Improving the efficiency of combustion by increasing cigarette paper porosity and by reducing packing density of the cigarette rod;
- Reducing the addictiveness of tobacco products by eliminating ingredients which enhance nicotine delivery (ammonia generators, other alkalinizing agents, levulinic acid, glycerin) or which interact with its reinforcing qualities (acetaldehyde and acetaldehyde generators);
- Examining aerosol size distribution under various filtration systems and degrees of humectant loading to see if the proportion of respirable particles can be reduced;
- Exploring the extent to which ventilation affects deliveries of nicotine and other characteristics, including pH;
- Considering the removal of ingredients from the most toxic products which contribute generally to the consumer appeal of these products;
- Reducing or eliminating tobacco-specific nitrosamines from smokeless tobacco products;
- Taking steps to prevent blockage of ventilation holes;
- Making cigarettes fire-safe.

The guiding principle for developing these specifications should be that any non-trivial reduction in the toxic potential of tobacco products should be considered of practical importance. The companies will not be permitted to make claims based on these standards, and it will not be possible to measure long term clinical benefit before they are implemented. The result of the development of these product specifications will likely be a number of adjustments in tobacco product design and ingredients which, considered separately, might each be of little consequence, but taken together might have an important impact on the problem.

It is expected that, over time, these specifications will change because of new knowledge in science, new knowledge in technology, and the continued evolution of the tobacco epidemic.

The Regulation of Nicotine Itself in Tobacco Products

In the popular press, the regulation of nicotine has been focused upon as somehow being the centerpiece of FDA jurisdiction and the main goal of setting performance standards. As the rest of this discussion makes clear, this is a false impression.

It is not yet certain that nicotine levels should be reduced in tobacco products at all. There are a number of unanswered scientific questions to explore, such as what the threshold for nicotine dosing is for addiction in most people and how current tobacco users will respond to products which deliver less and less nicotine. Moreover, there is not yet enough treatment capacity for nicotine addiction, and there are insufficient alternative nicotine delivery devices available to deal with the practical consequences of nicotine reduction. While there are numerous preliminary steps which should be taken here,

the possibility of reducing or eliminating nicotine from tobacco products should not be foreclosed artificially. Nor should it be constrained artificially by extraordinary procedural limits. Rather, it should be a scientifically-based policy judgment based on the best evidence available about what the best approach is to reducing overall rates of illness and death from all tobacco products in the population. When and if a decision is made to go forward with this, there are sufficient protections for the industry in usual rulemaking procedures and in available judicial appeals.

Moreover, while it is expected that the reduction of nicotine to levels that are not addicting for most people will markedly reduce demand for affected tobacco products, such a policy would not be the same as banning that category of product.

Health Claims ("Reduced-Risk products")

The quest for a safer smoke has been a central theme of tobacco issues at least since the early 1950s. Uniformly, the history of this has been one of public relations gimmicks masquerading as public health advances.

The latest manifestations of this quest are novel products such as those from RJR (Eclipse) and Philip Morris (Accord). Both companies have made public presentations about the chemical compositions of yields from these products, and both companies have presented data from screening tests for carcinogenesis from these products. RJR has encouraged several academic researchers to conduct short-term human studies of Eclipse. These moves on the parts of RJR and Philip Morris are unprecedented for products which tobacco companies hope to sell to consumers.[xxvi]

At the same time, and as is more fully discussed elsewhere,[xxvii] the data so far presented for these products do not yet demonstrate compelling advantages over existing products. In the case of Eclipse, measured yields of several key toxic constituents are similar to or greater than those from an already marketed brand of ultra low tar cigarette.[xxviii] In the case of Accord, Philip Morris chose to compare this product with a cigarette which has four times the nicotine yield under FTC conditions despite the fact that consumers can pump up the yield from the control cigarette to even greater levels while the yield from Accord is, for practical purposes, fixed at a maximum of 0.2 mg per stick. Moreover, the toxicology work reported to date for both products does not address issues other than the potential risk of carcinogenesis, such as cardiovascular toxicity.

Besides these concerns, as discussed above, products for which manufacturers want to make health claims should not only show themselves to be superior to the products with which they would compete, they should also show that they are an acceptably safe alternative to abstinence. This is because these products are, actually, nicotine maintenance products.

This category of product can only be defined in relationship to conventional tobacco products, and these are highly uncertain comparisons until performance standards are established.

As described above, the FDA should only consider whether to permit health claims for novel tobacco products after performance standards have been established. These claims should be subjected to pre-market evaluation and approval by FDA, and the agency should establish post-market conditions for continued marketing of products for which claims are sought.

The pre-market approval process for making a health claim should be based on evidence standards set by FDA. Before approval is given for making a health claim for a tobacco product, a manufacturer should establish:

- that the product be substantially less toxic than competing products,
- that the product is unlikely to draw substantial numbers of people from the ranks of those who would otherwise quit (e.g. that it not substantially discourage quitting activity), and
- to the extent that it attracts people from the ranks of those who would otherwise quit, that it has an acceptable level of safety.

Once the product is on the market, the manufacturer should establish:

- that the product actually lives up to its promise of being less poisonous,
- that the product does not attract novices to its use,[xxix]
- that the product does not discourage quitting activity, and
- that the product has an acceptable level of safety in terms of overall toxicity and nicotine maintenance in relationship to those who use it instead of quitting.

In approving claims for products in this category, FDA will need to consider what disclosures the label should include about the continuing expected hazards of these products as well as what limits may be appropriate for advertising and distribution.

The Government Should Not Become a Tobacco Products Manufacturer.

The 20 June agreement envisioned that the federal government would actively facilitate the application of novel "reduced risk" technology by requiring cross-licensing of significant technology, by becoming the manufacturer of last resort for products which commercial manufacturers did not want to bring to market or by becoming a broker seeking out manufacturers for products that the industry did not want to produce. These ideas are, at best, premature at this time.

The essential role of government here is as regulator of this industry, and the clear establishment of this role is the central priority. If it also becomes business partner, or develops some other vested interest in particular products, its ability to regulate may be seriously compromised. This industry has never before been subject to effective regulation. Putting government in the business of "reduced risk" product manufacturer of last resort will lead to internal conflicts of interest and confusion of roles at a time when there is a fundamental lack of trust between regulator and regulated industry.

If a particular product is going to make an important contribution to public health, it will have a large market and will make its manufacturer a lot of money. It is unclear that there is an actual need for the sort of scenario that the 20 June agreement envisions.[xxx]

This is a question which might be productively revisited in ten or fifteen years, as experience accumulates with product development and the market's response in this area, and as trust develops between the parties involved.

Terms such as "Light," "Low-tar," or "Mild" should Not be Permitted.

The 20 June agreement preserves the terms "light," "low-tar," "mild" and the like when they are part of a brand name. By extension, those aspects of packaging and advertising that communicate reduced risk by color, design or other aspect, would also be preserved. This should not be permitted. So-called "light" cigarettes have made the tobacco epidemic worse. They have not lived up to their promise of reduced harm and they have kept more people in the franchise than would otherwise have remained smoking.

Preserving these names provides the tobacco product manufacturers with *de facto*

health claims for products which have been demonstrated to not live up to the promise implied in the names.

Good Manufacturing Practice

A provision requiring the FDA to promulgate a set of good manufacturing practice regulations was included in the 20 June agreement. It is not clear why this should be a priority for the agency.[xxxi] The existing FDA rule contains a provision that requires manufacturers to notify the agency if "serious adverse events that are not well-known or well-documented by the scientific community" occur in relation to the use of regulated products, including events related to contamination or to changes in ingredient or manufacturing process (#803.19(f)).

Along with regulations for good manufacturing processes come potentially elaborate waiver processes. There is the potential here for a relatively large amount of effort to be required for matters which are of little public health importance.

Labeling

As described in the companion paper in this series specifically on labeling, the FDA should have flexibility here to determine what labels should contain and how the information should appear. Particular attention should be paid to broadening the concept of the government-mandated label. Instead of the term "warning," the term "message" is preferred since it would permit the government to communicate a broader range of useful information to consumers on the package and so assist consumers in making decisions about the use of these products.

Advertising

Advertising functions as an extension of a product's label. Insofar as the regulation of advertising is related to public health, the FDA should be the lead agency, applying its "false and misleading" standard. Insofar as the regulation of advertising deals with matters of unfair competition among manufacturers of nicotine delivery devices, the FTC should be the lead agency, applying its "unfair and deceptive" standard.

The effect of any regulations the FDA promulgates to control advertising of tobacco products should be actively monitored by the agency and amended in accordance with experience.

Government-mandated messages in advertising should not be limited to "warnings."

Sales to minors

As more fully discussed in another paper in this series, distribution limits to reduce tobacco product sales to minors are an important element in an overall approach to tobacco product regulation. The FDA should be the lead agency for these distribution controls to facilitate a coordinated regulatory approach to the tobacco epidemic.

Preemption

The FDA's regulation of advertising, labeling, sales to minors, and ingredient disclosure should not be preemptive of state authority in this area. California already has its own separate requirements for labeling of cigars, and Massachusetts has disclosure requirements for ingredients and nicotine. In Canada, cigarette makers have been able to comply with rules that require them to make packaging different in each province.

At the same time, it is reasonable that those aspects of FDA authority that affect the actual composition or manufacture of products in interstate commerce be subject to preemption. While it might be argued that state action regarding the content and

composition of tobacco products might spur action by other states and by the FDA, if the FDA has sufficient authority and resources, end runs such as this should not be necessary. If, however, FDA's authority is limited or circumscribed, or if it does not have the resources to do the job, then states should be able to pick up where the FDA has failed. Therefore, assuming that the FDA is in a strong position, there should be preemption of regulation of tobacco products themselves which are in interstate commerce.

A potential loophole that this opens up is that companies may arise which manufacture and sell tobacco products wholly within the borders of a single state. This may be most likely to happen initially in a large state such as California, Texas or New York. In such a situation, the FDA would not have jurisdiction, and the only potential regulatory authority would reside with the state government. Similar situations have arisen from time to time with regard to drugs. States generally manage these by adopting appropriate federal statutory and regulatory language to oversee such intrastate operations.

CONCLUSION

The prospect of FDA regulating tobacco products holds great promise for public health. At the same time, if FDA is not given both the flexibility and resources it needs to do the job, the public health will be ill-served. The legacy of past decades, especially the lessons of the so-called "low tar" cigarette, contain many lessons which should inform the present policy discussions.

S-1415, TOBACCO PRODUCTS CONTROL ACT OF 1998

Staff Working Draft, 29 March 1998

Section 6, Definitions

The term "cigarette" is defined (page 20) in terms of the Federal Cigarette Labeling and Advertising Act with the following addition: "also includes tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette."

This definition is in striking contrast to the FDA's definition of "cigarette" which includes a requirement that the tobacco in the product be burned in normal use.

An effect of this new definition of "cigarette" would be to insure that products like Eclipse from RJR, which contain no tobacco leaf but only papers made from tobacco, are treated like cigarettes under the law. In adopting this approach, RJR would sacrifice the considerable tax advantage of Eclipse not being a cigarette in exchange for not subjecting the product to an approval process in order to market it. RJR may choose to simply put Eclipse on the market without special claims under this definition and to only seek approval if it chooses to make claims for the product. This approach is disingenuous since it is clear from public statements by RJR scientists that the product is intended to be offered as a product which is less likely to cause illness and death than products it would compete with.

The term "cigarette tobacco" (page 20) is taken from the FDA's definition and includes the requirement that the product contain nicotine. This requirement was necessary for FDA's purposes but is not necessary here and indeed is more restrictive than the definition of "cigarette" in the bill, which is taken from the FCLA. The requirement that "cigarette tobacco" contain nicotine is undesirable as previously discussed.

The term "smokeless tobacco" (page 23) is also taken from the FDA's definition and similarly includes the requirement that the product contain nicotine. As with the term "cigarette tobacco," this requirement is undesirable.

The term "tobacco product" (page 23) is limited to cigarettes, cigarette tobacco, little cigars, smokeless tobacco, roll-your-own tobacco, and fine cut products. The definition excludes cigars, pipe tobacco and nasal snuff. This definition is, essentially, limited to the products over which FDA asserted jurisdiction in August 1996 and is far too limited for public health purposes as discussed above.

Tobacco products should be defined in terms of all traditional tobacco products. Novel products should not be included. This approach allows oversight of the entire industry and requires companies to go through an approval process before marketing new categories of tobacco product.

Section 8, Notification if youthful cigarette smoking restrictions increase youthful pipe and cigar smoking

This section requires the Secretary to notify Congress if a consequence of this Act with its limits on cigarettes and smokeless tobacco results in an increase in cigar and pipe tobacco use among the young. This provision appears to excuse the omission of cigars and pipe tobacco from the definition of "tobacco product." However, as discussed above, cigar use among high school students is already at a level that is more than twice that of smokeless tobacco use. Cigar use is already a serious tobacco use problem among the young. In fact, it may be difficult for the Secretary to ever show that it has become **worse** as a result of this Act.

The fact that the drafters felt that this section was important to include suggests that

the drafters believed that if cigars and pipe tobacco ever became significant problems among young people, Congress would want to include these products under the Act.

The evidence of there being a significant problem with cigars is already at hand.

Title I—Regulation of the Tobacco Industry

Subtitle A—Jurisdiction of the Food and Drug Administration

Section 101. Amendment of Federal Food, Drug and Cosmetic Act of 1938.

(a) Definition of tobacco products.

This section defines tobacco products as including all products made or derived from tobacco intended for human consumption. This could include nicotine replacement medications since the nicotine in these products comes from tobacco if they were not already regulated as drugs.

(b) FDA authority over tobacco products.

This section establishes a new chapter, Chapter IX, in the FD&C Act for tobacco products. The following references are to the new proposed Chapter IX, Tobacco Products.

Section 901. FDA Authority Over Tobacco Products

(a)(1) excludes products regulated as drugs or products that make health claims

(b) includes products already regulated by FDA under the 1996 final rule as well as any products the Secretary deems subject to this Chapter.

(c) puts in place the FDA's final rule on tobacco products from 1996.

(d) limits the provisions of this chapter to tobacco products, prevents the chapter from being applied to tobacco leaf, and prevents FDA from entering tobacco farms without permission from the owner.

For the most part, these provisions provide reasonable solutions to defining the overall scope of what FDA regulates. The limitation on tobacco leaf being outside the agency's jurisdiction may be an issue if the agency determines that, for instance, a particular agronomic practice or curing method would promote the public health. However, if the technique in question results in tobacco leaf having a particular chemical composition, then FDA can set ceilings for those chemicals in finished products and leave it up to the manufacturers how they will obtain leaf having those characteristics.

Section 902. Adulterated Tobacco Products

This section outlines an appropriate range of situations which the agency can consider grounds for determining whether a tobacco product is adulterated.

Section 903. Misbranded Tobacco Products

The section appropriately authorizes the FDA to use its traditional authority to police labeling and advertising for "false and misleading" material.

Prior approval of labeling is authorized but prior approval of advertising is not.

Section 904. Submission of Health Information to the Secretary

This section requires reporting of information about tobacco products and documents relating to health, behavioral or physiologic effects of tobacco products as well as documents about reducing risk to health and market research. The agency is to be informed of the makeup of new products 90 days in advance and of changes in existing

products 60 days in advance of market introduction.

There seems to be a drafting error in (a)(2). As written, it states,

> A description of the nicotine content, delivery, and form of each tobacco product measured in milligrams of nicotine.

As written, it does not make sense. It may be intended to read:

> A description of the nicotine content, delivery, and form of *nicotine in* each tobacco product measured in milligrams of nicotine.

The documentation required to be submitted in this section will be helpful to the agency, but as described in an earlier section, this material will not be sufficient to provide the agency with what it will need to know to optimally regulate tobacco products. It will need right of inspection (authorized in Section 905) and subpoena power (not presently in this bill) to adequately learn what it needs to know to regulate this industry.

Section 905. Registration

This section requires the registration of manufacturers with the FDA. Each manufacturer must provide the agency with lists of all tobacco products it places into commerce along with labeling and representative advertising. The manufacturer must indicate that each product either complies with an applicable performance standard or that it is not subject to any performance standard. The agency is to be informed of new products, discontinued products and reintroduced products.

This section authorizes the FDA to inspect each manufacturer and requires that it do so at least every two years. As discussed above, this is an essential authority for the agency to have, but it should be strengthened with the provision of subpoena power to the agency, at least for a limited time period, say ten years.

At (j), new products are required to show that they are substantially equivalent (as described in section 910) to previously marketed products and that they comply with applicable performance standards.

Section 906. General Provisions Respecting Control of Tobacco Products

Subsection (d) authorizes the Secretary to impose limits on the sale, distribution, use, access, advertising and promotion of tobacco products. Appropriately, regulations in these areas are to be based on considerations of the risks and benefits to the population as a whole, including users and non-users.

The subsection prohibits the Secretary from requiring that the sale of tobacco products be contingent on prescriptions. An irony of this provision is that several nicotine delivery devices which are less hazardous than cigarettes (nasal spray and inhaler) are only available in this country by prescription. This provision both anticipates and forecloses a possible situation in the future in which it might well be appropriate for public health reasons to place a specific category of tobacco product on prescription. The provision places the burden on the public health community to undertake a change in the law at that time when actually the burden should be on the tobacco industry to make its case at that time to Congress that prescription is unwarranted.[xxxii]

The subsection requires that any limit on the sale of tobacco products to specific outlets be subject to a two year delay in implementation to permit Congress to review any such regulation. As discussed in the previous paragraph, this seems an unnecessary burden on the Secretary since the industry has

shown itself capable of getting favorable legislation in Congress to forestall regulatory action on much shorter time frames repeatedly in the past.

Subsection (e) deals with the establishment of good manufacturing practices for tobacco products. The subsection imposes limits on the Secretary in promulgating regulations in this area, requires oral hearings, and provides for appeals and waivers. It is not clear why these additional procedural hurdles are needed. This section would seem to have the potential to divert the attention of the advisory committee from more pressing business.

Subsection (g) requires that advisory committee proceedings be maintained except that trade secrets are required to be deleted. A better approach would seem to be the preparation of a public transcript with proprietary information deleted and an agency transcript containing proprietary information. The provision as written will result in the record of advisory committees having gaps which would be important for the FDA to have for its internal use.

Subsection (h) authorizes the Secretary to enter into contracts for research, testing and demonstrations of tobacco products and authorizes the Secretary to obtain tobacco products for these purposes. This is a sensible provision, although it is unclear why the Secretary is somehow not already able to do these things anyway, under the extensive research activities the Department presently undertakes.

Section 907. Performance Standards.

The section authorizes the establishment of performance standards for tobacco products. The product specifications may include reduction or elimination of nicotine yields from tobacco products, but nicotine may not be eliminated from the yield of a product without a two year waiting period to permit Congressional review.

The product specifications may also provide for reduction or elimination of "other constituents or harmful components of the product." It is not clear if this means that the specifications can be related to the yields in smoke as well as to their content in the product. The language could be clarified by changing it in the following way: "other constituents, *whether in the product itself or in smoke from the product*, or harmful components of the product."

There is no provision which would permit the agency to *require* a particular ingredient in a tobacco product. This might well be an appropriate thing to do under some circumstances, as discussed above, and it would seem wise to give the FDA the flexibility to do this.

The testing provision at (a)(2)(B)(ii) should place the burden for testing products to assure conformance with performance standards on the manufacturers, not on the Secretary.

The consultation provision for the development of performance standards at (a)(4) should include an authorization for the Secretary to conduct or contract for appropriate research in support of the development of these standards.

A strength of this section is that it specifically acknowledges at (b)(1)(B)(ii) that the prevention of both illness and injury are to be considered in developing these standards. This means that fire-safety can be considered.

The considerations the Secretary must take into account at (b)(1)(D) are appropriately broadly fashioned to address the general public health need.

The standards are to be promulgated under notice and comment rulemaking, taking any findings of the advisory committee into account as well. Any regulation which would eliminate an entire category of product or which would result in zero nicotine yields is

subject to a two year delay in implementation to permit Congressional review.

There is no specific requirement in this or other sections for the systematic review of ingredients in tobacco products which have been a feature of most other bills on this subject and which was included in the 20 June 97 agreement. The Secretary could accomplish much the same goals as the ingredient requirements of other bills under the performance standards, but the main disadvantage of doing it this way is that the manufacturers are not obligated to do the testing of ingredients for toxicity under conditions of use. The Secretary should be authorized to require the submission of specified toxicology data by the manufacturers concerning any ingredient other than tobacco itself which is of concern to the Secretary for public health reasons. This would place the burden on the manufacturers to demonstrate safety of its ingredients with some selectivity, unlike the all-encompassing provisions of other bills.

Section 908. Notification and Other Remedies

This section provides useful authority for issuing notification and for recalling tobacco products which are defective in ways that other tobacco products are not and which endanger the public health. The voluntary recall which Philip Morris conducted a few years ago illustrates the wisdom of having such a section.

Section 909. Records and Reports on Tobacco Products

This section establishes a reasonable mechanism for the reporting of "serious unexpected adverse experiences" associated with use of the product or any increase in a "serious expected adverse experience" by manufacturers.

Section 910. Premarket Review of Certain Tobacco Products

This section imposes controls on the introduction of any new category of tobacco product requiring the submission of data and review by the FDA and permitting review by its advisory panel.

The material the manufacturer must submit for review includes, at (b)(1)(G), "such other information relevant to the subject matter of the application as the Secretary may require." This is an essential element since the FDA may have questions relevant to public health issues about a particular product which are not addressed by the other required information.

The emphasis of approving an application is on finding that a given product is appropriate for the protection of public health with regard to the population as a whole.

The standard in (c)(4)(A) that whether the public health is protected be determined on the basis (where appropriate) of "well-controlled investigations, which may include one or more clinical investigations by experts qualified by training and experience to evaluate the tobacco product" is difficult to see applied in practice. The issues which will arise in considering these products are more complex than the determination of safety and efficacy for a drug because of the emphasis here on the effects of the new tobacco product on groups other than current consumers of tobacco products. It is likely that clinical trials will be of use but they should not be the only set of investigations considered in these applications.

Section 911. Judicial Review

This establishes procedures for judicial review, in the Court of Appeals of the District of Columbia or in a district court where the petitioner resides or does business, of

regulations issued under section 907 or of denials of applications for premarket approvals. The court can stay action pending disposition of the case, and the court's decision, if appealed, is appealed directly to the Supreme Court.

The section omits at (a)(2) an opportunity for a person to challenge the *approval* of a premarketing application, which would seem to be an omission which should be corrected. It may be that a public health group or another tobacco product maker might disagree with the FDA's approval of a premarketing application, and this section provides no remedy for such an affected party.

Section 912. Postmarket Surveillance

The Secretary can require postmarketing surveillance of tobacco products. This is a helpful provision.

Section 913. Reduced Risk Products

This section conspicuously omits the language found elsewhere in the bill which explicitly directs the Secretary to pay attention to the broad public health picture. The Secretary would seem to be required to permit health claims if studies are done which are focused only on the effects such products might have on those who already use tobacco products and who do not intend to stop. As written, this section is dangerous in its disregard for other populations. It opens the possibility of health claims being permitted for products which are threats to the public health by virtue of their appeal to novices and by virtue of their appeal to those who otherwise might stop using tobacco products altogether.

This section should conform with other sections of this bill which uniformly require the Secretary to take a broad public health view in all decision making about the regulation of tobacco products. This omission is perhaps the most serious weakness of the way this bill addresses the FDA's authority.

Section 914. Preservation of State and Local Authority

This section preempts state and local authority as it pertains to performance standards, premarket approval, adulteration, misbranding, registration, reporting, good manufacturing standards, and reduced-risk products. This section should not apply to products which do not enter interstate commerce. This section should be modified if FDA's authority in any of these areas is compromised, as it presently is in the case of reduced-risk products (with regard to the absence of a public health focus for review) and as it is in the case of performance standards (in which the agency does not have subpoena power to learn about tobacco products).

There is a provision which asserts that nothing in this chapter relating to tobacco products can be used to infer a limitation on liability under state law. This is an appropriate and necessary provision.

FDA can issue waivers for the things that are preempted by this section.

Section 915. Tobacco Products Scientific Advisory Committee

The nine member advisory committee established under this bill is to include two members representing the interests of the tobacco manufacturing industry. This is inappropriate as long as the industry continues its program of lies and doubletalk. Such members would not be able to participate constructively in the proceedings of this committee as more fully discussed earlier in this paper.

The inclusion of tobacco industry representatives on this committee is the second most serious weakness of the FDA section of

this bill, after the defect in the reduced risk section.

The transcripts of this committee are to be expunged of commercially sensitive material. This is unfortunate as the agency will have internal needs to use these transcripts. It would seem preferable that there be two sets of transcripts prepared. A public version without commercially sensitive information and an internal version containing this information.

Section 916. Equal Treatment of Retail Outlets

This section requires the Secretary to require retail outlets which mainly sell tobacco products to comply with advertising restrictions applicable to outlets which are accessible to individuals under the age of 18.

It may be that casinos will be regarded by tobacco companies as places where people under age 18 are not allowed and so will undertake extensive advertising in these places. While there may be rules against those under age from entering casinos, these rules are often observed in the breach. The practical issue is, as stated in the bill, the access young people have to an establishment, not the establishment's policy.

Subtitle B—Advertising

Section 142. Tobacco Product Labeling and Advertising

This section in general implements the FDA advertising rule with the several additions of the 20 June agreement.

A serious problem arises in (a)(1)(C) (page 33) in its sanctioning of terms such as "light" and "low tar." The mere provision of a disclaimer as required by the paragraph does not undo the harm that these terms have done and continue to do to the public health. Terms such as these should be treated as health claims and be subject to the same standards as other health claims.

Subsection (a)(1)(D) (page 23) permits the Secretary to review new advertising and labeling, but the provision is written so that the Secretary's review is concurrent and not prior to initial use of the material. The Secretary should be able to review new advertising and labeling before it is first used.

Section 143, Point-of-sale restrictions

As with Section 142, there is no provision for the Secretary to issue additional regulations about point-of-sale restrictions if the ones which would be embedded in law prove inadequate. This is a serious limitation.

Title III—Tobacco Product Warnings, Labeling and Packaging

Subtitle A—Product Warnings, Labeling and Packaging

Section 301-304: Warning Labels

Warning labels are considered in detail in another paper in this series. A point that needs emphasis, because of the limited way this bill grants authority to the Secretary, is that the format, size and locations of warning labels should be left within the discretion of the Secretary after appropriate notice and comment. The present bill permits the Secretary to change the wording but not the format, size and locations of the warnings.

In addition, the term used should not be "warning labels" but rather "messages." This change would permit the government to communicate a wider range of information on packages to consumers about tobacco products which manufacturers choose to not reveal. The interested reader is referred to the paper in this series on labeling for more detail.

Section 305—Tar, Nicotine and Other Smoke Constituent Disclosure to the Public

The section requires the Secretary to conduct a rulemaking procedure regarding the disclosure of tar and nicotine yields in advertising and on packages. The section applies only to cigarettes and not to other tobacco products since it is fashioned as an amendment to the Federal Cigarette Labeling and Advertising Act. The Secretary can establish the testing procedure to be followed, but the type, size and placement requirements for the disclosure of the information is limited by law.

The strength of this section is that the Secretary will be able to revise the testing of tar and nicotine in cigarettes. However, there are substantial weaknesses.

Tar is rapidly becoming obsolete as a concept.[xxxiii] Its composition varies from brand to brand, and, if Eclipse is treated as a cigarette, it is all but meaningless because most of the tar in Eclipse is glycerin. Federal law should not reach down to the level of detail that requires that tar be forever more the index which consumers have of toxicity of tobacco products. While it may yet have some utility, that usefulness will disappear in coming years. The Secretary should have the flexibility to determine what measures are the most appropriate ones to present to the public. This is not a question which should be imposed by Congress.

The Secretary should have the discretion to determine, with appropriate notice and comment, the size, location and form of the disclosure, just as the FDA has done for food labeling.

The Secretary should have similar authority to establish appropriate tests for all categories of tobacco products and to establish disclosure rules for them as well, including cigarette tobacco, smokeless tobacco and cigars.

A strength of this section is the provision (C) (page 87) which would permit the Secretary to disclose other tobacco smoke constituents to consumers through package inserts. (The section also mentions advertising inserts, but it is not clear what these are.) The section as written excludes smokeless tobacco since it limits its application to smoke, and it is unclear what other tobacco products besides cigarettes would be covered since the section amends the FCLAA. The public health would be best served if the section were modified to give the Secretary authority to prescribe disclosure requirements for both product content and smoke yields of all categories of tobacco products, whether smoked or not, as appropriate. In the case of cigarettes and cigars, for instance, it may be important to disclose both the content of the unsmoked product and the yield in smoke of certain constituents such as nicotine. In the case of smokeless tobacco, the contents of the market product are the most readily available measures of what consumers are actually exposed to. Another weakness of this section is its prohibition against the revealing of any of this additional information in advertising or on the packaging.[xxxiv]

Subtitle B—Testing and Reporting of Tobacco Product Smoke Constituents

Section 311. Regulation Requirement

This section gives FDA authority to issue regulations regarding the disclosure of tobacco product smoke constituents and ingredients. The section embeds tar in the required disclosures despite its limited utility and misleading nature and does not allow for the disclosure of such information as the nicotine content of cigarettes or smokeless tobacco products.

As discussed earlier, testing of tobacco products will be an important part of the establishment of performance standards for

these products. Disclosure to the public will actually assume a secondary, albeit a still essential, role as performance standards are developed. This section does not appear to have been written with this new, central use of test results in mind.

Given the nature of the regulatory task FDA will face and the importance of providing the agency with appropriate authority and flexibility, it would be appropriate for this section to not specify anything about what particular tests should be reported and to permit the agency to require tests not only of smoke yields but also of product constituents. The authority should extend to all categories of tobacco products.

Title IX—Public Disclosure of Tobacco Industry Documents

This title contains strong provisions to give FDA privileged access to the materials deposited in the industry's document depository. However, the documents that will be deposited there will not be the complete information that the FDA will need to know about how each product is made, what decisions have been made regarding the design and manufacture of each product, and what choices were not made in the design of each product. These are the sorts of information the agency will need as it prepares to develop performance standards for tobacco products. Provision should be made elsewhere in the Act for FDA to have inspection authority or otherwise to have access to the full records relating to how each product is made, what it contains, and why.

Title XXVIII—National Efforts to Reduce Youth Smoking

Subtitle D—Prevention of Tobacco Smuggling

This subtitle provides a number of tools which should be useful to deter smuggling. The inclusion of identification numbers on package labels and the indication of the country for which a package is destined should both be of great utility for law enforcement.

While it is beyond the scope of this comment to analyze the anti-smuggling provisions in detail, their inclusion in this bill is a demonstration that government is not a helpless bystander whose only option is to roll back public health protections should the black market for tobacco products become larger as a result of otherwise sound tobacco control policies.

NOTES

---

[i] USDHHS. *Reducing the Health Consequences of Smoking: 25 Years of Progress. A Report of the Surgeon General.* DHHS Publication No. (CDC)89-8411. Public Health Service, Centers for Disease Control, Center for Health Promotion and Education, Office on Smoking and Health, 1989.

[ii] Kenneth Warner, John Slade, David Sweanor. The emerging market for long-term nicotine maintenance. *JAMA* 1997;278:1087-92.

[iii] Food and Drug Administration. Nicotine in cigarettes and smokeless tobacco is a drug and these products are nicotine delivery devices under the federal Food, Drug, and Cosmetic Act: Jurisdictional determination.

Federal Register 28 August 96; 61(168):44619-45318.

[iv] John Slade. Nicotine delivery devices. In: C. Tracy Orleans and John Slade, eds. *Nicotine Addiction: Principles and Management.* New York: Oxford University Press, 1993, pages 3-23.

[v] Coyne Beahm, Inc. v U.S. Food and Drug Administration, 958 F. Supp. 1060 (M.D.N.C. 1997).

[vi] See separate papers on limiting sales to minors, advertising and labeling for full discussions of these issues.

[vii] Richard Kluger. *Ashes to Ashes: America's Hundred-Year Cigarette War, the Public Health, and the Unabashed Triumph of Philip Morris.* New York: Knopf, 1996.

[viii] See, for instance, The Nowland Organization, Inc. SHF cigarette marketplace opportunities search and situation analysis, volume II, Management Report, prepared for Lorillard, December 1976. Minnesota attorney general trial exhibit no. 17,994. (SHF is "super high filtration".)

[ix] U. S. Department of Health and Human Services. *The FTC Cigarette Test Method for Determining Tar, Nicotine and Carbon Monoxide Yields of U.S. Cigarettes.* Smoking and Tobacco Control Monograph 7. National Institutes of Health. NIH Publication No. 96-4028, 1996.

[x] For a more complete discussion, see J Slade. Tobacco product regulation: context and issues. Discussion paper for "Tobacco Dependence: Innovative Regulatory Approaches to Reduce Death and Disease," Georgetown University, 9 April 1998.

[xi] MJ Thun, CA Lally, JT Flannery, EE Calle, WD Flanders, CW Heath, Jr. Cigarette smoking and changes in the histopathology of lung cancer. *Journal of the National Cancer Institute.* 1997; 89(21):1580-6.

[xii] National Cancer Institute. *Cigars: Health Effects and Trends.* Smoking and Tobacco Control Monograph 9, National Institutes of Health, NIH Publication No. 98-4302, 1998.

[xiii] Office on Smoking and Health. Tobacco use among high school students—United States, 1997. *Morbidity and Mortality Weekly Report.* 3 April 1998; 47(12):229-33.

[xiv] Bruce Ingersol. FTC chief seeks cigar health warnings. *The Wall Street Journal.* 13 April 1998, A3.

[xv] See, for instance, Ron Davis and John Slade. Back to the future with electrically powered cigarettes. *Tobacco Control* 1993; 2(1):11-2, and ME Counts, WG Houck, Jr, KS Houghton, AC Lilly, Jr, PJ Lipowicz, JL Myracle et al. Electrical smoking article having continuous tobacco flavor web and flavor cassette therefor. US Patent 5,479,948, assigned to Philip Morris, Inc. 2 January 1996.

[xvi] A possibly interesting consequence of treating nicotine replacement medicines as tobacco products might be that they would thereby become exempt from the Controlled Substances Act, which contains an exclusion for tobacco products.

[xvii] The major tobacco companies have indicated they are committed to reducing tobacco use by youth. To the extent that this is so, though, it seems to be an end in itself rather than a means towards reducing illness and death caused by tobacco products.

[xviii] *Report of The Scientific Committee on Tobacco and Health.* Department of Health

(United Kingdom), London, March 1998, pages 9-10.

[xix] The Advisory Committee process may identify specific things which should be done immediately for interim product specifications to protect the public health, and so it may be appropriate for the agency to promulgate interim standards before it has complete knowledge of the products. However, the establishment of such interim specifications should not distract from the larger task of coming to know the products thoroughly and regulating them accordingly.

[xx] The agency does not have subpoena power for its other duties, but the tobacco problem is an extraordinary one. The information necessary to regulate these products does not exist outside of industry sources, and the agency must have the tools necessary to get the job done. It may be that subpoena power could be for a limited period, say 10 years, while the foundation for regulation is laid, to make up for the decades of cover-up the industry has engaged in.

[xxi] FDA has mechanisms to distinguish research findings of general interest from those that are strictly proprietary, and it routinely makes these distinctions with data submitted by pharmaceutical and food manufacturers.

[xxii] "Tar" is defined as the particulate matter from cigarette smoke minus water and minus nicotine. Tar in German and Japanese blended cigarettes is substantially lower in cancer-causing nitrosamines than is tar from blended cigarettes in the U.S. The way a product like Eclipse generates an aerosol renders the usual concept of tar all but meaningless since most of its tar is glycerin. As product testing comes to be tied to product regulation, it will become more detailed and specific. The dosing information that comes to be shared with consumers in the form of labeling and other disclosures can be more informative, and perhaps may make use of summary measures of toxicity related to the levels of specific constituents.

[xxiii] Eclipse includes a novel fuel element with a fiberglass insulator. A requirement that limited authority over ingredients to those related to tobacco, paper and filter would not include this fuel element and its component parts.

[xxiv] Both RJR and Liggett & Myers developed catalysts which apparently substantially reduced certain toxic emissions from cigarettes. There has been speculation in some tobacco industry documents about possible competition to tobacco products posed by nicotine antagonists. It may be that the incorporation of an antagonist into tobacco products could preserve all of the sensory characteristics of nicotine which the companies indicate is their only intention for nicotine while blocking its drug effects. Such an additive might substantially reduce the abuse liability of tobacco products while leaving all of the "taste and flavor" characteristics intact.

[xxv] Tobacco product manufacturers have resisted the introduction of hazard-reducing technology in the past (See Kluger's book, *Ashes to Ashes*, for several examples, such as a fire-safe cigarette from Philip Morris and a palladium-catalyst cigarette from Ligget & Myers). An excuse which has been suggested for this outrageous behavior is that the introduction of genuinely harm-reducing technology could cast a liability-enhancing pall over the industry's other products.

[xxvi] Limited clinical testing of Philip Morris brand cigarettes was published in the 1930s, and in the early 1950s, Lorillard sponsored a few studies on Kent designed to highlight its

lower nicotine yield. However, neither effort was on the scale of these present ones.

[xxvii] See *supra* note 11.

[xxviii] The publicly available testing on Eclipse relates to a product which RJR had in test market in 1996. This product carried a claim that it reduced environmental tobacco smoke by nearly 90% and had a short, cellulose acetate filter attached to it. The product which RJR is testing as Eclipse presently only claims to reduce ETS by 80% and is a non-filter product.

[xxix] The FDA already has requirements such as this in place for some other products. An especially instructive example is provided by the OTC cough remedy, dextromethorphan. This inexpensive and widely available drug is abusable, but it is only abused (mostly by adolescents) at a low rate. The manufacturers of dextromethorphan are attentive to abuse problems and, to date, the agency has been satisfied that the abuse level of this drug is at a level which does not require further restrictions on this drug.

[xxx] In contrast to this, there may be situations in which an "orphan drug" process may be appropriate for medications to treat some aspects of nicotine addiction. For instance, it may be difficult to find a pharmaceutical company sponsor for a drug that delivers pure nicotine by inhalation to the lung.

[xxxi] Unless this is the most expeditious way for the agency to obtain the information it needs on how products are made and what they contain, by analogy to Drug Master Files. However, it seems unnecessary to require an entire array of GMP regulations to learn how products are made and what they contain.

[xxxii] The industry has shown itself capable of getting legislation passed on short notice by Congress in the past to forestall regulatory action. In the 1960s, the industry went to Congress to stop the FTC from implementing labeling regulations. In the early 1970s, the industry obtained an amendment to the Hazardous Substances Act which prevented the Consumer Product Safety Commission from responding to a petition on cigarettes which had been filed by the American Public Health Association.

[xxxiii] One possible way out of this conundrum would be for FDA to define tar in a toxicologically meaningful way.

[xxxiv] One of the possible ways consumer information about toxic yields could evolve is that the Secretary might develop an index of poisonousness called, for instance, "soot". This measure would be based on the actual yields of specific toxic materials rather than on the arbitrary concept of tar. As written, Section 305 holds up tar as an important basic concept and discourages the development of more informative approaches to consumer education.

APPENDIX

REPORT OF THE TASK FORCE ON THE REGULATION OF NICOTINE AND TOBACCO PRODUCTS

FROM THE FINAL REPORT OF THE ADVISORY COMMITTEE ON TOBACCO POLICY AND PUBLIC HEALTH

Co-chairs:

C. Everett Koop, M.D., Sc.D. and David A. Kessler, M.D.

July 1997

SUMMARY OF MAJOR RECOMMENDATIONS OF THE TASK FORCE ON THE REGULATION OF NICOTINE AND TOBACCO PRODUCTS

BACKGROUND

"[N]icotine in cigarettes and smokeless tobacco has the same pharmacological effects as other drugs that FDA has traditionally regulated."[1] Indeed, it is acknowledged that nicotine is extremely addictive and that "the vast majority of people who use nicotine-containing cigarettes and smokeless tobacco do so to satisfy their craving for the pharmacological effects of nicotine; that is, to satisfy their drug-dependence or addiction."[2] Many would argue, therefore, that the regulation of nicotine and its delivery is itself the most essential element of tobacco control activities.

Other components of tobacco smoke are also toxic. The tar, carbon monoxide, and additives contained therein are dangerous to the health of those using tobacco and those around them.

RECOMMENDATIONS

Regulatory Policy

- FDA should continue to have authority to regulate all areas of nicotine, as well as other constituents and ingredients, and that authority should be made completely explicit.

- FDA should continue to have the authority to phase out nicotine and remove ingredients that contribute to the initiation of smoking and dependence on cigarettes and other tobacco products (including smokeless tobacco, pipes, cigars, and roll-your-own tobacco), and that authority should be made completely explicit.

- There should be no limitations on or special exceptions to FDA authority to regulate nicotine, other constituents, and ingredients of tobacco products and such a no-limitations policy should be made completely explicit.

---

[1] 61 Fed. Reg. 168, 44661 (1996).

[2] *Id.* at 44636 (comments of the American Heart Association, the American Lung Association, and the American Cancer Society).

- The FDA should continue to have authority to regulate further nicotine, other constituents, and ingredients as the evidence suggests. The best science, information, and health policy (and not an arbitrary deadline) should drive FDA regulatory timing and that authority should be made completely explicit.

- The FDA should have the authority to test nicotine levels by brand, based on the best science and that authority should be made completely explicit.

- Regulation of non-tobacco nicotine delivery devices (e.g., nicotine patches, nicotine gum, nicotine inhalers, etc.) should be done in a manner that does not make the development and sale of less hazardous systems difficult and that encourages maximum overall reduction in disease.

Research Policy

- FDA should have the authority and funding to conduct research on nicotine and other components of tobacco products.

- International exchange and scientific conferences on nicotine and other components of tobacco products should be convened among private industry researchers and public researchers (such as those from the FDA, the CDC, the NIH, and the WHO).

- Research should be conducted on the effects of nicotine in children and adolescents.

Fiscal Policy

- FDA should be adequately funded to carry out its regulatory, enforcement, public education, and research activities.

REPORT OF THE TASK FORCE ON THE REGULATION OF NICOTINE AND TOBACCO PRODUCTS

This report establishes public health benchmarks developed by the Subcommittee on Nicotine and Product Regulation. This compilation is not all inclusive, but rather a summary of the most serious concerns expressed by committee members to date with the advice and consent of nationally recognized experts:

I. Health Consequences of Nicotine Addiction, Withdrawal, Treatment, and Cessation Issues

With 50 million addicted tobacco users and other Americans who are impacted by smoking, the health policy developed through legislation, settlement, or regulation must address the needs of this population. Aside from compensation issues, these people will need help and funds from the industry should pay for their treatment. The FDA must have the authority to regulate nicotine, but not just in the context of future addicts. Any solution that does not address the needs of current users is inadequate. The costs and administration of a program to assist with this population must be coordinated with Federal, State, and Local agencies. It must be systematic and available throughout the country. Principles of a cessation program include:

- Multi-component program, utilizing all treatment options within the existing framework of nicotine replacement.

- A standard list of approved modalities, with reimbursement guidelines.

- A lifetime benefit, rather than a single or one time opportunity for help. Addiction to nicotine is a chronic disease, many individuals will need treatment more than once. A few will benefit from extensive help. There must be no arbitrary cap on number or cost of treatment that an individual may receive.

- An assessment of existing programs throughout the US, in order to maximize funds for coordinated effort.

- Quality control to ensure high standards.

- Adequate funding for research, particularly for children and special populations.

- Agency for Health Care Policy and Research guidelines provide a sound basis for describing for the range of services that should be actively supported initially, but additional modalities and interventions should be explored through clinical research.

- Both treatment and prevention services should be made available through state contracts.

II. Extent of Jurisdiction Over Nicotine, Other Constituents, and Ingredients

Much has been documented about the addictive qualities of nicotine, and the focus on the drug and its delivery device is the basis for FDA assertion of jurisdiction. Yet regulation of the myriad other constituents and ingredients has been less prevalent in the discussion of FDA authority. Full FDA authority in the regulation of nicotine is not sufficient. The authority to regulate, disclose, and if necessary prohibit other constituents and ingredients must be addressed in any public health policy. Tobacco additives, carcinogens, dyes, product enhancers, and preservatives all play a key role in the cigarette as a delivery device and must be scrutinized in addition to nicotine. Nicotine makes the product addictive, the toxins make it deadly, and the additives make it more consumer acceptable, like sweetening a poison. While the current FDA rules may not hold sway over each of these content areas, any regulatory scheme should include the consideration of these critical cigarette components. ETS and the OSHA regulations cannot be excluded in a comprehensive plan which assures protection of workers, children, and the public.

The authority to regulate cannot be construed as tantamount to regulating. Enforcement of regulation is a key component to any FDA action. Granting the FDA the right to regulate content, nicotine levels, and other ingredients must be coupled with the funds to do so. Ancillary FDA regulatory issues: labeling, disclosure of content, manufacturing, and marketing should be included in any public health policy. Other specific recommendations include:

- Explicit authority to regulate nicotine levels, other toxic constituents, and ingredients, including the authority to phase out nicotine and remove ingredients that contribute to the onset of smoking and dependence on cigarettes.

- Ability to test nicotine levels by brand based on the best science.

- Prohibition on use of marketing terms and brand names, such as "light, low, and mild" unless science supports claim and the public is proven not to be misled.

- Regulate nicotine in a way that is consistent with all other nicotine delivery systems (e.g., gum, patch, inhaler, etc.) All nicotine delivery devices, whether produced by tobacco companies or by pharmaceutical companies, should be evaluated and regulated by the FDA using a consistent set of standards.

- No limitations or special exceptions on FDA authority to regulate nicotine, other constituents and ingredients.

- Adequate funding for FDA research on nicotine to ensure appropriate regulation.

- Any burden of proof placed on the FDA regarding its authority to regulate should not be excessive; rather the lion's share of the burden of proof should rest with the tobacco industry in all areas of jurisdiction.

- Information exchange and scientific conference of industry and NIH researchers in a public national forum.

- Inclusion of pipes, cigars, roll-your-own cigarette tobacco, and smokeless in regulatory framework.

- Consideration of generic packaging for all cigarettes.

III. Timing of Jurisdiction Over Nicotine, Other Constituents, and Ingredients

Pragmatic consideration of FDA regulation roll out and enforcement should be addressed in a meaningful way. One option: to assign an arbitrary trigger for further restriction (a set number of years before agency can ban nicotine.) Yet another option: establish a standard of proof and mechanism of discovery necessary before FDA can take additional action. A realistic plan should be developed. The consensus of the committee:

- The best science, information, and health policy, and not an arbitrary deadline, should drive FDA regulatory timing.

- The FDA should take appropriate steps to protect public health and be able to *further* regulate nicotine, other constituents, and ingredients as the evidence suggests necessary.

- Jurisdiction by the FDA should not circumvent state and local communities from further assertion of regulation.

IV. Disclosure of Relevant Research

The need for full disclosure of both scientific and market data is necessary not only by the industry, but its associations, law firms, and service providers to the extent that such information will ensure complete and effective product regulation. Research on the health effects of the product, on why people initiate use, on the effects of marketing must be disclosed. All industry based research should be made available to the FDA for review. Data on ETS and its impact on the non smoker should be turned over as well. Penalties, both civil and criminal, for nondisclosure should be developed. A mechanism for document production must be adopted and could also serve as a trigger for additional FDA action.

- Research on nicotine levels is not enough - all science and information regarding pricing, additives, market strategy, addictiveness, toxicity, ease of use, attractiveness and consumer behavior must be made available to the FDA, and when appropriate, the public.

- Information includes all past, current, and future research.

V. Review of Regulatory Framework for All Nicotine Devices

The framework for regulation should bring to market less dangerous products and expose known science regarding "less hazardous" alternative delivery systems in full public view. But, in the broader context, a review of the requirements of all nicotine delivery devices, including pharmaceutical devices, is necessary to ensure the standard for cigarettes will achieve maximum overall reduction in disease rather than continue to give regulatory advantages compared to less toxic forms of nicotine delivery. State and local jurisdictional issues and antitrust considerations must be addressed in the context of the regulatory framework. The regulation of the tobacco industry should be on par with all other producers of regulated drugs. The regulatory framework must create an environment which yields less hazardous products and a reduced public health impact of tobacco use. Safety should be measured on the societal as well as the individual level.

- Equity and a consistent standard for all nicotine devices is necessary.

VI. International Implications Including Manufacturing and Market Issues

While international regulatory issues are not the primary purview of the FDA, consideration of the world market and the effects of US regulation deserves examination. Restricting Federal agencies from assisting tobacco companies internationally, reviewing funding and research support for the WHO, and considering compacts protecting developing countries from unfair and deceptive trade are beginning components of international regulation. Production

of tobacco abroad by domestic corporations should be addressed to both protect world health and ensure US regulation contributes to that end.

- Funding of a international information exchange whereby all documents associated with the domestic Federal regulation of smoking is shared with international community.

- No use of Section 301 of the Trade Act for tobacco.

Conclusion

The strongest health policy will treat currently addicted Americans, fund research in order to develop the less hazardous alternative nicotine delivery systems, give FDA immediate authority to regulate all areas of nicotine, other constituents, and ingredients, disclose all industry information regarding all aspects of the product including pricing and market data, build a regulatory framework that is equitable and consistent with all nicotine devices, and is mindful of the international implications of domestic regulation.

Through each of these components is the overarching need to fund each aspect of this policy. Without adequate funding: regulation, research, disclosure, prevention, and treatment will not be possible. Whether these issues are addressed by regulation, legislation, or settlement: the tobacco industry will have to pay for the damage its product has inflicted on the American public. In the context of this subcommittees charge, that means the industry must fully fund these policies. Anything less is not acceptable.

HEALTH SCIENCE ANALYSIS PROJECT

Policy Analysis No. 12

TOBACCO PRODUCT PACKAGING AND LABELING

By

Heather Selin, M.A., Policy Analyst
David Sweanor, LL.B., Senior Legal Counsel
Smoking and Health Action Foundation

April 14, 1998

HEALTH SCIENCE ANALYSIS PROJECT

Policy Analysis No. 12

TOBACCO PRODUCT PACKAGING AND LABELING

by

Heather Selin, M.A., Policy Analyst
David Sweanor, LL.B., Senior Legal Counsel
Smoking and Health Action Foundation

This paper was written while Heather Selin was a Policy Analyst at the Smoking and Health Action Foundation. She is now serving as a Visiting Associate at the Office on Smoking and Health at the Centers for Disease Control and Prevention. The views expressed in this article are her own and do not necessarily reflect the views of CDC.

Table of Contents

The Health Science Analysis Project (HSAP) is an Advocacy Institute project, supported by grants from the Robert Wood Johnson Foundation, the American Cancer Society, and general contributions to the Advocacy Institute.

HSAP is directed by its Executive Committee. No grantor has editorial control over the scope of the project, or the content of the analyses it produces.

The material presented in this paper reflects the views and judgments of its authors, who are responsible for its content.

TOBACCO PRODUCT PACKAGING AND LABELING

by
Heather Selin, M.A., Policy Analyst
David Sweanor, LL.B., Senior Legal Counsel
Smoking and Health Action Foundation

EXECUTIVE SUMMARY

This paper examines the packaging and labeling provisions in the June 1997 proposals negotiated between tobacco companies and state attorneys-general and in five tobacco Bills currently in the Senate: S. 1414 (the "Universal Tobacco Settlement Act") sponsored by Senators McCain and Hollings; S. 1530 (the "Placing Restraints on Tobacco's Endangerment of Children and Teens [PROTECT] Act"), sponsored by Senator Hatch; S. 1492, (the "Healthy and Smokefree Children Act"), sponsored by Senator Kennedy; S. 1638 (the "Healthy Kids Act"), sponsored by Senator Conrad; and S. 1648 (the "Preventing Addiction to Smoking among Teens [PAST] Act"), sponsored by Senator Jeffords.

Packaging and labeling issues have received scant attention in comparison with many other elements of the proposals and legislation. This is unfortunate, because there is clear evidence that package messages and other elements of package design have the potential to significantly reduce tobacco use. Furthermore, these design elements are important tools in the effort to promote informed consent among tobacco users.

An examination of the evidence on the efficacy of package messages, the experience of other countries with regard to package messages, and the history of tobacco package messages in the U.S., offers important guidance for developing an effective system of packaging and labeling regulations.

Key lessons include:

- Congress needs to delegate regulatory authority to an administrative body such as the FDA, while giving that authority broad powers to efficiently change messages and other package requirements on a regular basis, in order to communicate new knowledge about tobacco use risks, and to respond to loopholes;

- There should be as little discretion as possible given to tobacco companies with respect to the presentation of messages. Regulatory authority should include prescribing size, exact colors, font, design, placement of messages, and permit improvements as necessary to further public health. Otherwise competitive pressures within the tobacco industry will cause a 'race to the bottom';

- The packaging and labeling system should be based on research identifying the information consumers need. Warning/informational labels should be of sufficient size and legibility to communicate clearly; variety and creativity should be permitted in messages and formats; and

- Package health messages should be considered to be only part of a broader package-based information system that includes ingredient disclosure, removal of

misleading labeling, package inserts and, eventually, plain packaging.

The paper recommends a package warning label system similar to that used in Canada and Australia, which should include the following provisions (among others) as minimum standards. Regulatory authority should permit continuous improvements to the system based on the best available information:

- warning messages should cover at least 25% at the top of each main package panel (i.e., both sides), and be surrounded by a specified border, creating a total message area covering 40% or more of most tobacco packs;

- a series of eight or more rotating messages should appear in black-on-white and white-on-black formats, including "Cigarettes are Addictive," "Smoking Can Kill You," and "Tobacco Smoke Causes Fatal Lung Disease In Nonsmokers," Other messages, providing information on such issues as treatment and cessation assistance, should also be incorporated (Legislation should make clear that warnings are fully subject to change by the regulatory body as new information supports public health improvements.)

- one entire side panel should be used to provide toxic constituent information (tar, carbon monoxide yields, etc.); and

- tobacco cartons should also display warnings covering 25% of each panel area.

The paper analyzes and evaluates in detail current legislative proposals, examining the specific ramifications of proposed legislative language and structure, provisions for message content and format, rotation of messages, and preemption. It concludes that, while all of the legislation examined will significantly improve health information on tobacco packages sold in the U.S., there are potential important loopholes and significant areas for improvement in all of the legislation.

Two key issues emerge from this analysis. First, it is important to combine strong authority with regulatory flexibility to ensure that responsible regulatory bodies can optimize the effectiveness of tobacco packages to improve health. Second, state and local authorities should not be preempted from requiring improvements in packaging and labeling when federal authorities fail to act. In our conclusion, we recommend legislative approaches to achieve these goals.

TOBACCO PRODUCT PACKAGING AND LABELING

by
Heather Selin, M.A., Policy Analyst
David Sweanor, LL.B., Senior Legal Counsel
Smoking and Health Action Foundation

INTRODUCTION

This paper examines issues of tobacco package labeling, with specific reference to five current legislative proposals - S. 1414 (the "Universal Tobacco Settlement Act") sponsored by Senators McCain and Hollings, S. 1530 (the "Placing Restraints on Tobacco's Endangerment of Children and Teens (PROTECT) Act"), sponsored by Senator Hatch, S. 1492, (the "Healthy and Smokefree Children Act"), sponsored by Senator Kennedy, S. 1638 (the "Healthy Kids Act"), sponsored by Senator Conrad, and S. 1648 (the "Preventing Addiction to Smoking among Teens (PAST) Act"), sponsored by Senator Jeffords - which were introduced following proposals negotiated in June 1997 in response to tobacco litigation. The intention of the paper is to provide guidelines to effectively attain public health goals.

To do this we provide background on the rationale for and efficacy of package warnings, summarize the history of tobacco package warnings in the United States and current standards in other countries, examine the June, 1997 proposals and each of the above Bills, and give specific recommendations for improvements. Much of our analysis draws on the experience of other countries, and particularly Canada, as the proposed warnings are intended to be modeled on Canada's current system.

While this analysis concentrates on cigarette packages with less specific reference to other tobacco products, the basic principles of an effective warning system apply equally to all tobacco products. Similarly, an effective warning system is justified for all forms of tobacco products which are known to cause harm.

It is hoped that this analysis will inform discussions about the role of package-based health messages and facilitate measures that will most effectively prevent children from starting to use tobacco products and assist cessation among existing smokers.

BACKGROUND

There has been a considerable amount of government action concerning the delivery of public information and education on smoking and health (Walsh and Gordon 1986). The primary aim of health educators is to create a condition of informed consent for current and potential users of tobacco products.

Informed consent is necessary to enable and empower current and potential smokers to make knowledgeable decisions about their smoking behavior. This requires much more than simply knowing that 'smoking is hazardous'. Users should know which health problems are caused by tobacco use, the likelihood of contracting these various problems, the relative risk of contracting a tobacco-related disease compared with other health risks, the likely prognosis resulting

from such disease, and the potential impact of ending or adjusting tobacco use on these risks and problems.

The Concept of Informed Consent

Courts of law have been clear in articulating the principles of informed consent, and of the duty of product manufacturers to warn. A particularly clear statement of these principles is found in an Ontario court decision concerning oral contraceptives (Buchan v. Ortho Pharmaceutical 1986):

> Once a duty to warn is recognized, it is manifest that the warning must be adequate. It should be communicated clearly and understandably in a manner calculated to inform the user of the nature of the risk and the extent of the danger; it should be in terms commensurate with the gravity of the potential hazard, and it should not be neutralized or negated by collateral efforts on the part of the manufacturer. The nature and extent of any given warning will depend on what is reasonable having regard to all the facts and circumstances relevant to the product in question.

Because tobacco products are highly addictive for many users, and because most users start using tobacco at a very young age, the standard of warning for tobacco may be much higher than for other products.

The fulfillment of obligation to warn can be accomplished in a number of different ways (Daynard, 1990). But, as described below, package warnings are unarguably a cost- effective and highly utilized consumer education strategy targeted directly at all purchasers of tobacco products.

The Current Lack of Informed Consent Among Tobacco Users

Reviews by the Federal Trade Commission (US FTC 1981) and the US Surgeon General (DHHS 1989) of the public's knowledge of the health effects of smoking have shown that the level of knowledge among tobacco users in the U.S. generally has not met the definition of informed consent.

An American Cancer Society study (Martilla & Kiley 1993) asked Americans to choose the leading cause of death from a list of causes of death. The study found that only one in five Americans could correctly identify cigarette smoking as the leading cause of death (see figure 1). Studies in other countries, including studies of youth (Hill and Gray 1984, Canadian Cancer Society 1988, Canadian Council on Smoking and Health 1991, Health and Welfare Canada 1992, Health Canada 1996) have found a similar lack of informed consent about various health risks of tobacco use.

Table 1: Perception and Reality on Causes of Death In America

Cause	% believing to be largest cause	Actual Annual Death Toll
Car Accidents	28	49,000
Cigarette Smoking	21	434,000
Cocaine/Other "Drugs"	16	5,700
AIDS	12	31,000
Alcohol Abuse	12	105,000
Murders	7	22,000

From: Martilla & Kiley, Inc., Highlights from an American Cancer Society Survey of U.S. Voter Attitudes Toward Cigarette Smoking.

Most recently, research has found that smokers underestimate their personal risk of premature mortality and of developing cancer related to cigarette smoking relative to other

causes of cancer (Eiser et al. 1995, Schoenbaum 1997).

These studies indicate both a general lack of appreciation of the magnitude of the risks associated with tobacco use, and a resulting inability to make fully informed decisions about the use of tobacco products.

The Tobacco Package as a Message Medium

There are many ways to promote informed choice among current and potential users of tobacco products. Most current legislation proposes expansion of the public education campaigns that have been used for many years. Package-based information efforts can complement these other strategies, and reach many consumers that other strategies do not.

The potential public education value of package-based health messages is enormous because of the exceptionally large number of viewings to which cigarette packages are subjected. Approximately 500 billion cigarettes are consumed annually in the U.S. (Tobacco Institute, vol. 32, 1997). Since each of these cigarettes must be removed from a package, there are also at least 500 billion annual viewings of the package --every time a cigarette is lit. Package messages are viewed by both smokers and non-smokers when packages are on display at point-of-sale, while in the possession of the user, and when discarded.

The opportunity to send health messages targeted at tobacco users this many times, exactly when these users are consuming tobacco, should not be passed up as an educational tool.

Such messages need not be limited to warnings about health hazards. The provision of information on topics such as cessation methods, economic and social issues, and risk reduction behavior, is a valid component of informed consent. The form of presentation of the message, which can greatly enhance or detract from its actual wording, should also be a key focus.

Despite the reach and the of package messages, this educational tool has been underutilized. At present in the U.S., package messages are mandated only by federal law, which preempts further package warning initiatives at the state and local level or by federal agencies, despite the clear need for more effective warnings

The development of package warnings in the US(extensively reviewed in the 1989 Surgeon General's report (US DHHS 1989)), was strongly influenced by the tobacco industry. Their efforts offer both an explanation of the absence of and the justification for effective package warnings.

While the health risks of tobacco products are well established scientifically, their manufacturers do not acknowledge that these products have been proven to cause any disease, and have fought against the improvement of health information on packages.

At the same time, the tobacco industry's massive expenditure on product promotion and public relations has ensured that, over time, Americans have seen more positive than negative imagery surrounding tobacco. Stronger educational tools with broad reach, such as package messages, are all the more necessary as a result.

Guidelines for Effective Package Message Systems

Research and recommendations on the construction of an effective message system date back several decades. Selected summaries of the findings of this research are included below. It is important to note, however, that these are only guidelines, and that not all rules will apply uniformly to all populations. For example, the UICC recommends that messages should be undiluted by attributions to a particular source. However in some cases the attribution of a message to a very credible and

respected source could increase the believability and impact of the message.

These guidelines provide an indication of some minimum standards, and can serve as the basis for crafting messages. However, the best way to determine the most effective messages is to focus test several options on the population that will be reading them.

The report of) provides A good overview of what is necessary for effective package health warnings was offered by the U.S. Department of Health, Education, and Welfare (HEW) in 1965--about three decades before such warnings were implemented anywhere in the world. The report's recommendations have yet to be encompassed in law in the United States. They include:

1) Statute should require the warning to be prominent and conspicuous but should leave the precise location and size of the warning to regulation in light of the expertise and experience of the regulatory agency. There was specific attention given to the size and placement of the warning which became law. It was indicated that the warning message should be on the main (not side) panels, with the comment made that "... the specific provisions quoted are such as to make it unlikely that the warning will be noticed or remembered." Further, the Department said "10-point type, which is 2 points smaller than the type size used in typing this letter, is hardly calculated to invite the consumer's attention."

2) If the required warning is in effect negated or disclaimed on the label or in accompanying literature by words, statements, designs, or other graphic material, the warning requirement shall be deemed to have not been met. Further, there should be specific authority to prohibit or regulate statements which may give the consumer the misleading impression that a given cigarette is safer than others.

The International Union Against Cancer (UICC) has published guidelines on the development of effective health messages on tobacco products (UICC 1993). The UICC position makes it clear that it is not sufficient to simply have a warning system in place, but rather that the system be an effective one. The UICC believes that effective messages should:

1) Contain a clear and unequivocal message about the dangers of tobacco use in simple and stark terms. They should warn not only of the risk but of the degree of risk.

2) Be undiluted by any attribution (such as "Surgeon General's Warning"). Other dangerous products do not qualify their warnings, and attributions add to package clutter while suggesting to some consumers that the danger is merely an "opinion" of a health department, the Surgeon General etc. rather than a scientific fact.

3) Be prominent. That means:

- Warnings should be on the front and back of the pack, not on the side panels.
- They should be at the top of the pack, not at the bottom.
- They should cover a minimum of 25 per cent of the package face. Legislation should also specify the size of print.
- They should be in starkly contrasting colors. It is no good to design an effective message, only for it to be lost as part of the pack design. Black and white warnings offer the best safeguard, but specified colors, e.g. red or yellow warnings could prove even more effective in many markets.

4) In all cases, the legislation must specify the precise effect desired, otherwise the industry will use any loophole to reduce the impact of

the warnings. Legislation should, for example, avoid ambiguous phrases like "contrasting colors" which the industry will inevitably interpret to undermine the intended effect.

5) Apply to all tobacco products and all forms of packaging, and be at least as prominent in selling the health message as the industry's design will be effective in promoting the product.

Perhaps the most detailed analysis of the requirements for effective health warnings on tobacco products was conducted by the Center for Behavioral Research in Cancer (CBRC) in Melbourne, Australia (Health Warnings and Content Labeling on Tobacco Products, CBRC, 1992). The analysis, which is the basis for Australia's current warning system, aimed at moving toward "informed choice" and included the following recommendations:

1) That a panel be set aside covering not less than 25% of the surface area of the front of the pack for inclusion of a health warning and that this "boxed" area have a clear border.

2) That regulations specify the contents and other design features of this boxed area.

3) That the boxed area contain one of a comprehensive set of health warnings which shall be rotated with equal frequency.

4) That the position of the boxed area on the pack be specified in the regulations as being at the top of the front of the pack.

5) That the boxed area be either white or such color that provides strong contrast with no or minimal adverse effects on legibility.

6) That there be a minimum font size for the warnings.

7) That there be sufficient space between lettering and the border inside the boxed area to maximize legibility of the warning statements.

8) That the warning may run over one or more lines but no hyphenation of words be allowed.

9) That the initial set of twelve health warnings be short and pithy and be based on contemporary research with Australian subjects.

10) That the back of the pack should be given over entirely to the provision of more detailed health information about the harmful consequences of smoking.

11) That the design and content of back-of-pack information should be specified under the regulations.

12) That a national telephone network Quitline be established and the number be included on the pack.

As was mentioned at the beginning of this section, ongoing quantitative and qualitative research to answer particular questions about design, combined with focus testing on potential consumers will be necessary to ensure the continual improvement of messages. However, implementation of an initial message system should not be delayed to wait for further research. Enough is known to guide the development of a basic system.

Package Warning Systems Outside of the United States

There have been significant recent

advances in tobacco package warnings in many countries. Australia, Canada, the European Union, Singapore, South Africa, and Thailand have all implemented, or are in the process of implementing, rigorous warning systems. The most effective models for the United States to use in developing their own regime are the Canadian and Australian systems, which are closely related.

Canada's current warning system, implemented in 1994, (see Footnote 1, p. 12) set many precedents (Mahood 1995). Among these were the following requirements:

- the messages must cover at least 25% at the top of each main package panel (one side each in French and English);
- the messages must be surrounded by a specified border, effectively bringing the total message area to over 40% of many packs;
- each of eight mandated messages must appear in equal rotation on each brand half the time in black text on a white background with a black border, and the other half of the time in white text on a black background, surrounded by a white border;
- one entire side panel must be used to provide toxic constituent information (tar, nicotine and carbon monoxide yields); and
- every panel of tobacco cartons must display a black-on-white message covering 25% of the panel area, stating "Cigarettes are addictive and cause lung cancer, emphysema and heart disease."

Canada's system is described in more detail in the analysis of the settlement proposal and legislation.

Table 2 : Current Federal Health Messages in Canada

* Cigarettes are addictive
* Tobacco smoke can harm your children
* Cigarettes cause fatal lung disease
* Cigarettes cause cancer
* Cigarettes cause strokes and heart disease
* Smoking during pregnancy can harm your baby
* Smoking can kill you
* Tobacco smoke causes fatal lung disease in non-smokers

Australia's warning/message system is based on the work of the Center for Behavioral Research in Cancer (CBRC, 1992). It uses six rotating messages covering a quarter of the front of the cigarette packets (see figure 4). As in Canada, one side of the package is used to list tar, nicotine and carbon monoxide yields, and the messages must be in black and white (there are no white-on-black provisions).

Australia's approach differs from that of Canada in that each warning statement is accompanied with a more detailed health message on the opposite side of the package. Similarly, the list of smoke yields uses smaller print than in Canada but provides information on the nature of each ingredient. The provision of more detailed information is an additional step toward informed consent.

Efficacy of Package Warnings

It is important to consider package-based warning systems not only from the perspective of achieving informed consent, but from the perspective of efficacy in reducing tobacco use.

Evaluations of both the Australian and Canadian warning systems show that the warnings have had a measurable impact (Tandamar Research Inc. 1996, Borland et al 1996). Not only were the warnings read by smokers, smokers in both countries reported

that the warnings motivated quit attempts and reductions in consumption.

In Canada, packages were rated as second only to television as a source of information about the health hazards of smoking. They were also found to have a greater impact on youth than adults.

As mentioned previously, the impact of package warnings is significant because of their reach. For example, 19% of Canadian smokers reported that the warnings motivated them "a little" (8%) or "a lot" (11%) to make a quit attempt. While 19% may seem a small percentage, the number of smokers affected is huge simply because the package warnings reach every single smoker. Considered in the context of efforts to recruit smokers to smoking cessation programming, in which only an estimated 10% of smokers participate, package warnings offer impressive value for money.

The History of Warning Labels in the U.S.

Cigarettes

In 1964, shortly after the Surgeon General released the Report of the Advisory Committee on Smoking and Health (US PHS 1964) the Federal Trade Commission (FTC) promulgated rules to require prominent disclosure of pertinent health information on tobacco packages. But this regulation was preempted before it took effect by the Federal Cigarette Labeling and Advertising Act of 1965 in July, . Overall, the provisions of the law were less stringent than the FTC regulations they replaced. Section 5 of the law required that the statement: "Caution: Cigarette Smoking May Be Hazardous to Your Health" be placed in small print on one of the side panels of each cigarette package. Moreover, the law preempted other jurisdictions and agencies from requiring health messages on packages (section 7).

The 1965 law also required that the FTC transmit annually to Congress a report on the effectiveness of cigarette labeling, current cigarette advertising and promotion practices, and recommendations for legislation. In June 1967 the FTC submitted its first report to Congress. It recommended that the package label be changed to: "Warning: Cigarette Smoking is Dangerous to Health and May Cause Death from Cancer and Other Diseases" (FTC 1967).

Once again the FTC proposal was preempted by a weaker package labeling measure, the Public Health Cigarette Smoking Act of 1969 (Public Law 91-222). This Act (effective November 1, 1970) changed the health warning to read: "Warning": The Surgeon General Has Determined That Cigarette Smoking Is Dangerous to Your Health." The law also continued the prohibition on any other health warning requirements for cigarette packages.

In 1981 the FTC submitted to Congress the Staff Report on the Cigarette Advertising Investigation (FTC 1981). This report (p21) tentatively concluded that additional action designed to provide consumers with more information about the health consequences of smoking was necessary. The report recommended changing the size and shape of the warning and recommended the use of circle-and-arrow type warnings. While a small version of such warnings eventually appeared on smokeless tobacco advertisements, and large versions were recently adopted for point-of-sale warnings in some parts of Canada (see figures 1 and 2), such warnings have yet to appear on U.S. cigarette packages.

The current warnings in the United States were enacted by Congress as part of the Comprehensive Smoking Education Act (Public Law 98-474), which came into effect October 12, 1985. It required four rotating warnings. But it also left these more detailed messages encompassed within a statute rather than subject to regulatory control, retained the

same small type, and kept them on a side panel. Two decades after the Department of Health, Education, and Welfare had opposed such measures as insufficient to be noticed or remembered, they were still the basis of tobacco product warnings, and the law continued to preempt any other warnings from federal, state or local governments.

Smokeless Tobacco Products

Requirements for warning labels on smokeless tobacco products lagged behind those on cigarettes by over 20 years. By the mid-1980's the strong evidence that smokeless tobacco caused oral cancer and other conditions led the State of Massachusetts to adopt legislation requiring warning labels on packages of snuff, and caused 25 other states to consider similar legislation (Connolly et al. 1986).

Before it could take effect, the Massachusetts law was preempted by the Federal Comprehensive Smokeless Tobacco Health Education Act of 1986 (Public Law 99-252). This law, in using the ambiguous language "conspicuous and prominent," grants significant discretion to the tobacco companies regarding the prominence of required warning labels. As with cigarettes, this preemption clause prevents any Federal agency, state or local government from requiring on packages any other statements relating to the use of smokeless tobacco products and health.

THE JUNE 1997 PROPOSAL AND PROPOSED LEGISLATION

Packaging Requirements From the Proposed June '97 Agreement

Page 10 of the June 1997 proposals specifies that warnings based on the existing Canadian system will appear on tobacco packages. According to the proposals these warnings would cover "25% of the front panel of the package". The messages would be black text on a white background half the time, and white on black the other half. The listed package warnings are identical to the current eight warnings in Canada and add a ninth message, borrowed from existing U.S. messages: "WARNING: Quitting smoking now greatly reduces serious risks to your health".

While the text of the proposals describes the warning system as "Canadian-style," there are significant ways in which the proposed warnings differ from the system in Canada:

Message Placement and Size

The description of Canada's warning panel as taking up 25% of the package is technically incorrect. In Canada the "25%" rule is accompanied by a provision for a specified border, of between 3 and 4 mm, (Tobacco Products Control Regulations 1993) that is in addition to the 25% of each main panel required for the warning. This was done, in part, to prevent the manufacturers from redesigning packages to camouflage the health messages.

In addition, the bordered warning panel is required not only on the front, but on both main panels of the cigarette package. In Canada, the warning appears on one side in English and on the other in French in order to accommodate bilingualism requirements. (Every other country that has implemented significant warnings in the past five years – Australia, Singapore, Thailand, and South Africa – require a warning on both main faces of the package.) The result is that the Canadian health messages, borders included, actually cover from about 33% to over 40% (depending on package size) of each of the main package panels.

The June 1997 proposal does not

specify any borders around the proposed warnings, and would require the warnings on only one side of the package. As a result, despite referring to 'Canadian style warnings', the U.S. warnings would really cover slightly less than one third of the space covered by the Canadian warning system on a typical cigarette pack.

In addition to reducing the amount of package space used to inform the consumer of health risks, the requirement of a warning on only one of the main panels is a huge advantage at retail for the manufacturers. One value of conspicuous package warnings is to reduce the impact of huge retail package displays, a necessary part of reducing demand for tobacco by minors. If a warning is required on only one side of the package, manufacturers will urge or pay retailers to display packages with the warnings hidden.

Message Content

There is one potential improvement in the proposed warnings, which is the addition of a marker word, "WARNING," preceding the health message. However, while drawing attention to the warning, the addition of a marker word without a corresponding increase in the size of the warning panel will necessarily shrink the text size and thus the impact of the message. If the marker words are to remain, and we recommend that they do, then the size of the warning panel should be increased accordingly to accommodate them.

Absence of Ingredient/Emissions Information

A critical component of the Canadian warning system absent from the proposed settlement is the inclusion of 'toxic constituent' information on packages. Canada requires one complete package side panel be given over for this purpose. The failure to provide any information on tobacco or tobacco smoke ingredients on the package is in contrast to very strict US legal requirements for food labeling.

The Need for Tightly-Drafted Legislation and Regulations

The important role of legislation is to give wide regulatory authority to a body like the FDA, while ensuring that this authority must be used to further health objectives. Congress could achieve this goal by stipulating minimum standards which must be met, but authorizing the regulatory body to exceed these stated standards in the pursuit of public health goals (e.g., "the required messages must cover at least 25% of the overall package surface, or such greater amount as prescribed by regulation.")

As described in more detail in the analysis section, packaging and labeling rules, whether stipulated in legislation or by regulation, will have to be made very specific in order to avoid the warning-minimizing strategies the tobacco companies are driven to play by collective and individual competitive interests. As was witnessed in Canada with earlier attempts at package-based health messages, any discretion given to the tobacco industry will be used in ways which are adverse to public health. In Canada, companies interpreted the phrase "contrasting colors" to mean yellow on gold and white on silver.

The bills, in not specifying to the letter all components of the appearance of the warnings, subject the warnings to significant weakening in presentation by such things as choice of font, and even the choice of what constitutes "black" and "white" , which can come out as shades of gray. Due to past experience with liberal interpretations of the rules, Canadian regulations specify color and font.

An appropriate balance between what is specified in legislation versus regulation is debatable, but precedents that offer guidelines

do exist. A common approach is for legislation to simply set out the regulatory authority to mandate package messages in broad terms. For example, the legislation may stipulate that packages cannot be legally sold, imported or distributed unless they carry messages or meet requirements or specified by regulation. Regulations then set down the exact specifications, including text, format, placement, and rotation, and may be amended as necessary to deliver current information and maintain novelty to attract the attention of smokers.

Tobacco companies will undoubtedly argue for specifications in legislation, without regulatory authority to make changes. They will argue that they require such regulatory stability to operate, that regulatory authority would allow requirements to change "on a whim," that they will not receive sufficient notice to make changes, and that changes will be costly.

These arguments do not reflect the reality of the regulatory process. Contrary to being "whims," regulations, much more so than legislation, must be vigorously justified by evidence. If they are not, they will be challenged in court and will face repeal.

Regulations also are subject to a comment period, giving notice of potential changes to interested parties and allowing them to articulate concerns. In addition, it is quite rare for regulations to require immediate changes, particularly if the changes involve investment and planning by an industry. In Canada, with both phases of warnings required under former legislation, the industry was given ample notice of proposed changes in the form of information letters and draft regulations a minimum of a year in advance of implementation. In the case of the second and current phase of warnings, manufacturers were given notice of new proposals *four and a half years* prior to their implementation.

In addition, the industry's own actions belie their arguments. The June 1997 agreement proposes that one-third of packages would carry new warnings within 90 days, two-thirds within 120 days, and all packages within 180 days. This is an admission that manufacturers have the ability to completely implement a new warning system within six months.

With regard to the cost of changing package labeling, manufacturers routinely update package design and customize design for various markets. Changes that would be required by regulation would be unlikely to impose costs greater than those imposed by manufacturers on themselves through updated package design.

The current Canadian package warnings, and the draft regulations that will re-implement them in the near future,[1] should be referred to by those seeking to model them.

Overview of Proposed Legislation

The bills reviewed here contain almost identical proposals for package labels, and therefore are subject to similar critiques. Aside from minor differences in the proposed warnings text, the most significant differences are with regard to preemption and flexibility in regulatory authority to revise the warnings.

Bills S. 1414, S. 1530, and S. 1648 all preempt any labeling requirements for

[1]The warnings that currently appear on most Canadian packages were mandated by regulations under the *Tobacco Products Control Act* (*TPCA*) and were legally required from September 1994 to September 1995. On September 21, 1995, the Supreme Court of Canada struck down significant portions of the *TPCA*, including the provisions authorizing package messages.

On April 25, 1997 a new federal law, the *Tobacco Act*, came into force. It reinstates the legislative authority for package messages. While regulations reinstating the actual warnings have not yet been promulgated, they are expected to be issued in the near future. In the meantime, most manufacturers have voluntarily continued to print the previously mandated warnings on packages.

cigarettes and smokeless tobacco beyond those required by the legislation. Bills S. 1492 and S. 1638 are slightly advantageous in that they preempt state and local requirements but not other federal requirements. This means that a federal agency with authority to regulate aspects of tobacco, such as the FDA or FTC, could potentially require more stringent warnings.

All of the bills except S. 1414 provide some regulatory authority to alter the warning requirements. However, Bills S. 1530 and S. 1648 impose potentially significant restrictions on that regulatory authority. Bills S. 1492 and S. 1638 provide broad regulatory authority to amend the text, format, size and application of warnings.

Despite these differences, all of the bills suffer from various flaws from a public health perspective. The individual bills are discussed in detail below. As Bill S. 1530 was the first we reviewed, it is analyzed in the most detail. The analyses of the remainder of bills focus on their respective differences from Bill S. 1530. **Unless otherwise noted, it should be assumed that the merits and drawbacks of S. 1530 also exist in the other bills.**

S. 1530 ,the "Placing Restraints on Tobacco's Endangerment of Children and Teens (PROTECT) Act")

Bill S. 1530 (sec. 904) attempts to enact the text from the June 1997 proposal. The messages are virtually the same in text, size, colors and placement. The 25% coverage would apply to the upper portion of the "front panel" of cigarette packages and cartons, with some modified requirements for flip-top packages.

Definitions: Label Statement, Warning, Message, Text

A general discussion is in order here of the language used to describe the public health messages that could be required to appear on packages. This discussion applies to all five pieces of legislation analyzed here.

It is important for lawmakers to know and to be clear about the nature of the messages that particular legal language authorizes. Most of the language in the current legislation refers to "labels" or "label statements." Some have headings that contain the word "warning(s)." All of the bills that refer to regulatory authority to change the warnings at some point specify potential changes to the "text" of the statements.

All of this language poses potential limitations on the nature of the messages that could appear. The word "warning" is the most constraining, because it could preclude dissuasive messages which are not warnings per se. An example is, "Smoking a pack a day costs $xx every year. Think of what you could buy if you quit!". Other examples of messages which are not 'warnings' would be those providing information about quitting, such as the provision of a toll-free number.

However, even seemingly general language such as "label statement" or "message" could preclude desirable public health information presented in a visual format. The authority to alter the "text" of a statement implies that words, not pictures, are involved. It is important that the option of providing messages in visual rather than text format be left open. In addition to the old adage that, "a picture is worth a thousand words," studies have found that a visual on the package of blackened lungs tested favorably among youth as a dissuasive message (Health Canada, 1995). Providing visual information would also allow messages to reach the many Americans who are illiterate or who do not read English.

In addition to enabling implementation of visual information, language should be broad enough to allow textual messages, such as messages in Braille.

As the authors are not experts in

legislative drafting, we do not have definitive suggestions on the best language to use. However, one suggestion would be to include a general definition of a "message" or "label statement" that makes it clear that such a message or statement could be in visual or textual format. Also, rather than referring to changes in "text," it might be preferable to refer to changes in "content."

Message Content

The proposed statements (an extra statement, unique to S. 1530, is the fifth one listed here), to be rotated on cigarette packages, are as follows:

WARNING: Cigarettes Are Addictive.
WARNING: Tobacco Smoke Can Harm Your Children.
WARNING: Cigarettes Cause Fatal Lung Disease.
WARNING: Cigarettes Cause Cancer.
WARNING: If You Think Smoking Is Cool, You are Dead Wrong.
WARNING: Cigarettes Cause Strokes and Heart Disease.
WARNING: Smoking During Pregnancy Can Harm Your Baby.
WARNING: Smoking Can Kill You.
WARNING: Tobacco Smoke Causes Fatal Lung Disease In Nonsmokers.
WARNING: Quitting Smoking Now Greatly Reduces Serious Risks To Your Health.

The fifth warning here appears to be an attempt to incorporate a message that may appeal to youth more than a health statement. While the attempt is desirable, it is not clear why this particular warning was chosen. Warnings of this sort that use adults' perceptions of language that will resonate with youth can backfire. Message text, whether in a health message or another type of dissuasive message, should be determined based on focus testing for efficacy with both the target and other audiences. The basis for determining the text of messages is discussed in more detail elsewhere in this paper.

The statements to appear on packages of smokeless tobacco are as follows:

WARNING: This Product May Cause Mouth Cancer.
WARNING: This Product May Cause Gum Disease And Tooth Loss.
WARNING: This Product Is Not A Safe Alternative To Cigarettes.
WARNING: Smokeless Tobacco Is Addictive.

It should be noted that the first two smokeless warnings contain a qualifier – "may cause" rather than "causes" – that does not exist in the warnings for cigarettes. The medical and scientific evidence of the cancer risks from smokeless tobacco in the United States does not justify this weaker warning language. The warnings should read "This product causes mouth cancer" and "This product causes gum disease and tooth loss." If at some point in the future reduced risk products are introduced into the U.S. market, the warnings can be amended as necessary to reflect scientifically-evaluated reduced risk.

Message Placement and Size

Sec. 904(a)(2)(A) requires a warning statement to "be located on the upper portion of the front panel of the cigarette package (or carton)."

In addition to the problems discussed above with regard to a warning on only one side of the package, the specification of "front panel" could cause problems in the case of cartons. In 1989 Canada enacted regulations which specified that warnings be placed on the "principal display panel" of cartons (Tobacco Products Control Regulations 1989). The tobacco industry interpreted "principal display

panel" to be the small end panels of a carton. The current drafting of this bill would invite a similar interpretation. The Canadian government did not solve this problem until 1994, when new regulations were implemented requiring a health message on all panels of each carton.

There is a further potential loophole in Sec. 904(a)(2)(C) in dealing with flip top packages. The bill states that any flip top package (offered for sale on the date of enactment of this section) where the flip top is less than 25% of the panel would have the health warning reduced to the size of the flip top. This gives an incentive to introduce smaller flip top openings, and gives an advantage to such products. Concerns about not "breaking" the message when the pack is opened appear to take precedence over issues of informed consent. There is no apparent reason why the warning could not be printed through the break on the flip top.

Finally, as detailed above, there is no requirement for a border surrounding the warning panel. This detracts from the total size of the panel and from the visibility of the warning.

Message Format

Sec. 904 (a)(2)(B) specifies the type and color of the message. Once again, the language is not as precise as is needed.

Rather than specifying the typeface the bill states that the message must "appear in conspicuous and legible type". This granting of discretion to the tobacco industry could lead to liberal interpretations, as occurred in Canada in response to the 1989 regulations (*s. 15*) stipulating that warnings be "legible and prominently displayed in contrasting colors". The result was package labeling that the then-Minister of Health said could teach our military about effective camouflage (The Globe and Mail 1989).

The more recent Canadian regulations specify the exact font (17-pt Helvetica bold).

Other requirements for text format are also imprecise. While the marker word, "WARNING," is required to appear in capital letters, the case for the remainder of the warning is unspecified. The text in the bill uses upper-case for the first letter of every word, which may be harder to read. It should be noted that this is different than the messages described in the June 1997 proposals, in which only the first word in each sentence is capitalized. There are clear guidelines on use of case to maximize readability in various message formats. These should be considered, and then case should be specified so that the industry is not able to detract from the message's readability.

Marker words are used to draw attention to the warning. They could do this more effectively if they were in a color different from the black message text, such as red or neon yellow. Again, guidelines on the use of colors for this purpose exist and should be researched. Also, like any message, marker words can grow stale if overused. Consideration should be given to using a variety of marker words (e.g. "DANGER," "ATTENTION") and the regulatory flexibility granted to allow this.

For reference, the Canadian regulations specify that the first letter of the first word is capitalized, and all other words are in lower case. They also intentionally exclude a period at the end of each message, under the rationale that a period would unnecessarily take up more space and thus shrink the point size of the message.

There is both a loophole and confusing language in Sec.904(a)(2)(B). The loophole is that the Bill stipulates that the letters in the label statement must be "in contrast by typography, layout, or color with all other printed material on the package." Aside from the problems created by the impreciseness of the word "contrast," the use of "or" in this clause allows the manufacturer to choose

which of the three specifications – typography, layout, color – is in contrast, however the manufacturer defines contrast.

The confusing language is that the same sentence goes on to stipulate that the letters "be printed in an alternating black-on-white and white-on-black format." In effect, the color would be in contrast with all other printed material on the package if the package were any color other than black and white, but not in contrast if the package were black or white. At the very least, these two clauses of this sentence should be made clear and non-contradictory.

The solution to the above problems and other potential industry interpretations that undermine public health is to create greater certainty in the language of the legislation and regulations, and to ensure legislative flexibility to make changes as needed through regulation. To achieve this, Congress should set minimum standards in legislation, and authorize the regulatory bodies to exceed these standards as warranted to pursue public health goals.

Rotation

Language ambiguity also exists in Sec. 904(a)(4) with respect to rotation. While the intention seems to be to require all warnings to appear equally often, the language does not make this clear. Without a stipulation that all messages must appear an equal number of times there may be room for tobacco companies to make some messages less common. This could be remedied by simply adding that the messages must appear "in equal proportion on each brand of cigarettes".

This section also states that the Secretary "shall approve a plan submitted by a manufacturer. . .", as long as the plan provides the rotation required by the legislation. This is problematic in that it limits regulatory discretion to address loopholes in the legislation. For example, if a manufacturer found a loophole that allowed it to meet the legal requirements (which, as written, do not ensure equal rotation) while ensuring some messages are seen less often than others, the Secretary would have no choice but to approve the plan.

Another potential loophole under the current language is that it requires that all label statements "be displayed by the manufacturer or importer at the same time." It does not state that all label statements be displayed *on each brand* at the same time. One could envision Philip Morris concentrating the pregnancy warning on Marlboro packs and keeping it off of packages of Virginia Slims. Again, specifying equal appearance and rotation of all statements on all brands would solve the problem.

Plain Packaging

It should be mentioned that Bill S. 1530 implements a form of plain packaging by stating in Sec. 214(a) that "Except as provided in subsections (b) and (c), . . . any labeling or advertising for a tobacco product shall use only black text on a white background." Subsections (b) and (c) provide no exceptions for packaging.

While we suspect that this provision is unintentional, it is supported by the growing body of evidence suggesting that plain packaging would be an effective way of deterring adolescent tobacco use. For this reason, we recommend that it remain.

Products Not Addressed

This bill proposes messages only for cigarettes and smokeless tobacco. There are numerous other tobacco products – fine-cut tobacco, tobacco sticks, cigars and cigar substitutes and pipe tobacco – that warrant package health warnings.

A particularly strong case can be made for the need for messages on cigars, little

cigars, cigarillos, and any other cigar substitutes. A 1996 survey found that more than one-quarter of U.S. teens aged 14-19 had smoked at least one cigar during the previous year (Centers for Disease Control and Prevention 1997). Yet no health warnings currently appear on cigar packages or wrappings.

The U.S. has seen a massive increase in cigar promotion since 1992. As this promotion continues, youth experimentation with cigar smoking can be expected to remain high or even increase. Package messages are one means of balancing heavy promotion with health information to approach the standards of informed consent, and hopefully to discourage use.

Regulatory Flexibility

Sec. 904(d) gives limited authority to the Secretary to require changes in the text of the warnings. There is a one year delay before any change can become effective. In addition the Secretary may not bring forward any new labeling text during the first five years of the law coming into force "unless the Secretary can demonstrate extraordinary circumstances."

Sec. 904(d) limits in several ways the regulatory power given to the Secretary. The limits on changing the message text present one problem. How the Secretary establishes "extraordinary circumstances" is an open question, and being forced to wait five years to implement changes could mean that much important information is not conveyed on package messages. In fact, changes to messages would be recommended every few years at a minimum to prevent the messages from becoming stale.

Another limitation is that the regulatory authority is apparently limited to changing only the "text" of the messages. Changes to the size, color, placement, design, etc. would apparently require Congress to act. Since the method of communicating a message is a key component of overall communication, the Secretary is at a disadvantage. Among other things, the Secretary would apparently be unable to act on such things as the warning designs detailed in the staff report of the Federal Trade Commission (1981).

Ironically, the limitations on regulatory powers under Sec. 904(d) are imposed within a framework, established by Sec. 901 and 902, which gives broad regulatory powers and establishes a system for the use of these powers. Having established this broad regulatory authority in one section, the bill limits the ability to use it in another (Sec. 904(d)).

Regulatory authority to change message requirements is highly recommended, as described in more detail above, and is much broader in most countries. Australia, Canada, Singapore, South Africa and Thailand all rely on legislation to provide the authority to implement messages, but on regulations to specify those requirements. This provides an efficient mechanism to correct loopholes which undermine the intent of the legislation, change the messages to prevent staleness, or provide new information based on recent research.

Preemption

Sec. 904(e) preempts any other package message pertaining to the use of cigarettes or smokeless tobacco products and health. This continues the preemption first established under federal law in 1965 that prevents any other federal agency or state government from using the package to convey health information.

This is perhaps the most serious concern with this section of the legislation. Preemption was obtained by the tobacco industry in 1965 (U.S. Department of Health and Human Services in press) and has played a key role in preventing the strengthening of messages on tobacco products. The only

apparent possibility under this bill would be for other authorities to require 'non-health' statements (e.g. "Smoking a pack a day costs $1,000 per year").

Without preemption, states have the option to improve upon weak federal provisions. With preemption, states are effectively prevented from correcting mistakes made at the national level. The result is underinformed smokers across the country, despite political good intentions at the state level. The existence of preemption means that the tobacco industry only has to deal with Congress – by-passing state legislatures – to prevent improved labeling.

Canada has taken an opposite approach in dealing with labeling, entrenching in law the ability of subjurisdictions to act. Canadian legislation (Tobacco Act, s.16) states:

> This part does not affect any obligation of a manufacturer or retailer at law or under an Act of Parliament or of a provincial legislature to warn consumers of the health hazards and health effects arising from the use of tobacco products and from their emissions.

One advantage of the Canadian approach is that it ensures there are no legislated barriers to the adequate presentation of pertinent health information. In practice the Canadian law, and its 1988 predecessor, s.9(3) of the *Tobacco Products Control Act*, makes it much harder for the tobacco industry to fight effective federal markings. Any evidence of inappropriate influence at the federal level will result in a greater likelihood of different provinces moving unilaterally.

Fear of inconsistent national package messages may not be a justifiable reason to prevent state authority to require additional information. The concern over consistent packaging should be weighed against the concept of full disclosure of hazards. Few states would feel compelled to enforce additional labeling requirements unless there were federal neglect of the issue, and the existence of state power could ease the development of federal labeling requirements.

Even if some states chose to use labeling powers, this would not present a major problem for tobacco companies. Tobacco companies have shown themselves capable of efficiently manufacturing differently labeled products for markets much smaller than any U.S. state. For example Iceland, a country with only half as many people as the least populous U.S. state, has unique markings. In addition the U.S. manufacturing facilities of RJR make brands such as Camel, Winston and Salem with Canadian warnings for export to Canada despite these brands having a combined market share of only a fraction of one percent of the small Canadian market.

S. 1414, the "Universal Tobacco Settlement Act"

As with Bill S. 1530, this bill simply tries to implement the text of the settlement proposal. The stipulated messages are exactly as agreed upon in the June 1997 proposals. The warnings would be required on only one side of the package, would cover 25% of that panel and would not require a border. The language leaves room for interpretation, but Sec. 111(b)(2) gives discretion to the Commissioner in determining what is appropriate.

The language on rotation of messages is virtually identical to that of Bill S. 1530, with the exception that the FTC, rather than the Secretary of Health, would be responsible for approving manufacturers' plans. Like the S. 1530, S. 1414 states (Sec. 111(d)) that the government authority "shall approve a plan submitted by a manufacturer. . ." , thus limiting regulatory discretion as previously discussed.

This bill, unlike S. 1530, does not give

regulatory authority to amend either the content or format of the package messages. Sec. 114(c) simply empowers the FTC to implement the warnings stipulated in this bill. As such the limitations on effective package-based communication of effective information are even greater than in S. 1530.

The assignment in S. 1414 of regulatory authority to the FTC rather than the Secretary of Health and Human Services is, in our view, negative. Given that the FDA currently has regulatory authority over the product, it makes sense that regulatory authority over the package and, indeed, other aspects of tobacco regulation be assigned to the Secretary, who is responsible for the FDA. This will allow for more effective regulation and coordination of policy.

Bill S. 1414, in Sec. 103(a), contains the same, probably accidental, provision for plain packaging described above for S. 1530.

The federal and state preemption sections of this bill (Sec. 115 (a) and (b)) are virtually identical to S. 1530. S. 1414 prohibits federal, state or local action aimed at requiring any package-based health information other than that stipulated in the bill. In addition Sec. 115(c) stipulates that the message requirements do not relieve common law or State statutory law obligations. Since these obligations are affected by the other provisions of the Bill this subsection may be of little practical use.

Product Descriptors

S. 1414 is the only piece of legislation that implements the component of the June 1997 proposals dealing with product descriptors. While the June 1997 proposals require the disclaimer on advertising only, S. 1414 in Sec. 106(a) requires it on both advertising and labeling. However, regulatory authority for the FDA to regulate product descriptors is expressly granted in Sec. 106(b).

Addressing product descriptors is a positive component of legislation. However, as described below, it would be preferable to eliminate deceptive descriptors altogether.

Penalties

The penalties that apply to violations of labeling requirements (Sec. 114(a)) are extremely low (maximum $10,000) and are unlikely to deter violations given the financial resources of the industry. For comparison purposes, violations of the labeling provisions under Canadian law carry a maximum fine of approximately US$210,000, or maximum two years' imprisonment, or both.

S. 1492, the "Healthy and Smokefree Children Act"

Most of the language is virtually identical to Bills S. 1530 and S. 1414 and, thus, so are the potential inadequacies.

There are two additional messages specified for smokeless tobacco. These are better than the other four and, if message content continues to be specified in legislation rather than by regulation, should be incorporated in the other bills.

There is also an improvement in the size of the message on flip top packs. The exemption for a smaller message panel provided in Bills S. 1530 and S. 1414 for flip top packages in existence upon passage of the legislation is limited in S. 1492 to packages in existence June 1, 1997. This eliminates any advantage to companies introducing more brands in flip top packages as a way of achieving a smaller message panel.

One area of significant change is in the area of regulatory powers. Whereas S. 1530 and S. 1414 give little regulatory power, S. 1492 in Sec. 910 (e) gives the Secretary the ability "the[sic.] change the text or layout of any of the warning statements, or any of the labeling provisions". Also, in Sec. 912, general

regulatory authority is granted to the Secretary to "promulgate regulations to enforce the provisions of this chapter, or to modify, alter, or expand the requirements and protections provided for in this chapter if the Secretary determines that such modifications, alternations [sic], or expansion is [sic] necessary."

This is of great assistance in implementing effective messages. One question about the statement of authority referring specifically to changes to warnings is that it refers to the "warning statements". This could be interpreted as only allowing replacement messages which are also 'warnings', thus precluding a range of other potential valuable messages as discussed above.

S. 1492, like S. 1530, S. 1414 and S. 1648, preempts state and local action on package warnings. However, other federal requirements are not preempted.

S. 1638, the "Healthy Kids Act"

As with the other bills, Bill S.1638 is built around the messages used in the June 1997 proposals (Sec. 575), with the exception of the two additional messages on smokeless tobacco packages However, this bill carries significant advantages over those analyzed above.

The first is in breadth of regulatory authority. The bill provides specific authority (Sec. 575(a)(1)(C)) for the Secretary to authorize additional or altered warnings after an 18 month period following enactment of this subchapter. The criteria is that the Secretary determine that the new warnings "would be more effective in deterring the use of cigarettes". This language leaves some question as to the standard of proof for determining the effectiveness of new warnings. It would be very difficult to prove in the scientific sense the effectiveness of warnings prior to their implementation. Better language would be that the new warnings "could be expected to be more effective."

The bill also grants broad authority for the Secretary to change the text or layout of any of the warning statements or labeling provisions (Sec. 575(d)). However, there is a further stipulation that these changes can be made "if determined necessary by the Secretary in order to make such statements or labels larger, more prominent, more conspicuous, or more effective." This is an interesting stipulation and one that is positive for public health. In effect this means that minimum, rather than maximum, standards are being implemented and can be improved. Although it is generally assumed that broad regulatory authority will be used to progressively improve health measures, it could of course potentially be used to weaken previous measures. The wording of this section would seem to prevent this.

Another major improvement is with regard to placement of the message label. The warnings would be required to be displayed on both the front and rear panels (Sec. 575 (a)(2)) of the package. This doubles the exposure given to the messages and makes it harder for manufacturers to obscure the messages through product positioning. Requiring a warning on both main panels of the package is consistent with the requirements of Canada, Australia, Thailand and South Africa.

The language stipulating rotation of the messages reduces the size of a potential loophole present in the previous bills. Sec. 575(a)(4)(A) requires random distribution of the warnings "in all areas of the United States". This prevents the selective airing of warnings according to where they might do the least harm to tobacco sales. However, the Secretary is still required to approve a plan submitted by tobacco companies provided it meets the requirements described in the legislation (Sec. 575(a)(4)(C). This means that if unforeseen loopholes remain, the Secretary does not have the power to close them.

Bill S. 1638, in Sec. 728(a), contains the

same, probably accidental, provision for plain packaging described above for S. 1530 and found in S. 1414 and S. 1648.

Another advantage is that FTC authority over unfair or deceptive acts or practices is expressly retained (Sec. 575(d)(2)), as is common law and state statutory law liability (Sec. 575(e)(2)).

This bill also closes the "flip top loophole" in a manner similar to S. 1492.

Despite these significant improvements, other areas of this bill pose potential limitations to its public health impact. Again, preemption is a problem. State and local health messages are preempted (Sec. 575(e)(1)), although other federal requirements are not. This raises all the problems discussed previously. Because regulatory authority to improve the warnings is broad, the state preemption is less of a concern that with S. 1530, S. 1414 and S. 1648. However, no degree of preemption is desirable from a public health perspective.

S. 1648, the "Preventing Addiction to Smoking among Teens (PAST) Act

As with the other bills, S.1648 is built around the messages used in the June 1997 proposals (Sec. 905). There are important benefits to public health, but these health benefits are more constrained than those in S.1638.

Regulatory authority to make changes to the messages exists, but is constrained in three significant ways. There is a clear authority (Sec. 905(d)(2)(A)) for the Secretary to change the warnings text after a one year period after the final rule that makes the changes is published. Notably, there does not appear to be authority to change the format, positioning or size of the messages.

The second constraint is that the regulatory authority cannot be used for five years, unless the Secretary "can demonstrate extraordinary circumstances" (Sec. 905(d)(2)(B)). "Extraordinary circumstances" are undefined, but this is potentially an onerous burden to satisfy.

Finally, the Secretary is required to assess periodically "the efficacy of current labels and the public health benefits of revising such labels" as " scientific data regarding the effectiveness of warning labels in deterring youth smoking becomes available" (Sec. 905(d)(2)(C)). However, the assessment cannot occur more frequently more than once every three years. Also the language, in limiting the evaluation to issues of deterring youth smoking, suggests that evidence on improvements in labeling that would deter smoking only among adults *would not* justify revising the labels. This is a serious constraint that would prevent information that might contribute significantly to increased quit attempts by adults.

The potential rotation loophole described in S. 1530 remains in this bill.

Bill S. 1648, in Sec. 906(c)(1), contains the same, probably accidental, provision for plain packaging described above for S. 1530 and also found in S. 1414 and S. 1638.

This bill also closes the "flip top loophole" in a manner similar to S. 1492 and S. 1638.

State and local health messages are preempted (Sec. 913(a)(3)). Federal messages are not, but, as described above, the regulatory authority of the Secretary is constrained. This raises all the problems discussed in the review of the previous bills.

Other Labeling Issues

Warning labels are only one way in which the package contributes to or detracts from informed consent. Other important issues for consideration are described below.

Misleading Terminology

A critical packaging issue is the use of descriptive words in brand names. Words like "slim," "light," "mild," "low tar," and "smooth" are often used on tobacco packaging. There is substantial evidence that many smokers believe these descriptive names imply health or safety advantages of a particular brand (National Cancer Institute 1996). This misperception may deter quitting.

The June 1997 proposals give tacit support to the continued use of descriptive brand names by requiring a mandatory disclaimer in advertisements for brands using these terms. However, no such disclaimer is required on the package. In any case, this approach to descriptive brand names is insufficient to correct consumer perceptions of the meanings of these terms. Even with a disclaimer, the mere presence of the terms indicates that they have some meaning. Given the evidence on smokers' misconceptions about descriptive brand names and the effect that these misconceptions have on smoking behavior, it makes much more sense to eliminate the terms altogether.

As described above, Bill S.1414 is the only legislation that addresses use of product descriptors on packaging.

Plain packaging

An aspect of tobacco packaging which has received significant attention in recent years is the possibility of legislated 'plain' or 'generic' packaging for tobacco products. Bill S. 1492 proposes requiring plain packaging as a remedy if manufacturers repeatedly fail to meet their targets for youth smoking reduction. The concept behind plain packaging includes the ability to remove much of the image of tobacco products, thus severing the impact of past and present promotional efforts and making the product less attractive.

There is evidence that young people find plain packaging less attractive (Beede and Lawson 1992, Canadian Cancer Society 1993, Health Canada 1995, and additional research soon to be published from the U.S. and Canada) and that such packaging makes health messages potentially more effective (Center for Behavioral Research in Cancer 1992). In Canada the federal government has been examining plain packaging for tobacco products (Towards Zero Consumption 1994). The province of Ontario has regulatory authority to require plain packaging of cigarettes sold in Ontario. However as of yet, such packaging reforms have not been enacted in any jurisdiction.

Ingredient Disclosure and Emissions Yield information

Part of informed consent involves knowing the contents of products consumed. U.S. smokers are not given this information on the package or elsewhere. Consumers are notprovided any information on ingredients in cigarettes. The only ingredients of smoke provided to the consumer are tar and nicotine yields, and these are measured and reported in a way that misleads smokers about how much they actually inhale. A good package warning system should incorporate this information.

Package inserts

There are additional ways of using the package to convey information to the consumer. An ideal way to supplement warnings on the outside of packages is to provide more detailed information on inserts inside the packages. (Mahood, 1995) Inserts are cost-effective and are already used by manufacturers on a regular basis. They offer a way to provide a greater variety of messages and more information than is practical on the outside of the package.

Visibility of package messages at point of sale

Even if the language of legislation is crafted so that tobacco companies cannot effectively minimize the impact of health messages on the package itself, they will have an incentive to minimize how often and where these messages are viewed. Legislation should require the mandated messages not only to appear on packages, but to be visible to the purchaser while on display prior to purchase.

AREAS FOR IMPROVEMENT IN PACKAGE LABELING

It is important to note that the Canadian package messages can be greatly improved. Establishing a true condition of 'informed consent' requires much more than what is currently on Canadian packs. This is why the Canadian legislation allows for package inserts and changes to the content of messages, and why Canadian health groups are currently working to improve national warnings and facilitate the introduction of ancillary warnings in various provinces.

The June 1997 proposals aim for a standard set by Canada that is already four-and-a-half years old. The public health community in Canada has recognized from its experience that a higher standard needs to be set. It makes sense for the U.S. to implement that higher standard rather than rely on a system that is now considered out-of-date in Canada. To the same extent that Canada learned from the shortcomings of the EU regulations, the United States could improve upon Canada's current warnings.

An examination of research and experience from around the world leads to the following recommendations for improving requirements for package health messages:

1) As was recognized by HEW in 1965, there are clear advantages to having health messages dictated by regulatory/administrative means rather than having to rely on a Congressional amendment to make changes. The ability to efficiently change messages on a regular basis is necessary in order to prevent messages from becoming stale, to communicate new knowledge about tobacco use risks, and to respond to loopholes, Congress should set a legislative "floor" of strong messages based on current knowledge, but specifically authorize FDA or FTC to improve on and surpass these standards when scientific evidence shows that public health could be furthered by such changes. There should be similar flexibility for the administrating body to make decisions on overall size, design, wording, graphics, rotation, etc. as evidence shows the most appropriate strategies.

2) Legislative authority should be broadly stated and not restricted to "warnings" or "health messages". A wider range of potentially valuable messages will be necessary to achieve informed consent.

3) There should be as little discretion as possible given to tobacco companies with respect to the presentation of messages. Size, exact colors, font, design, placement, etc. should be precisely stipulated. Otherwise competitive pressures within the tobacco industry will cause a 'race to the bottom'. Ideally all of the detail should be left to regulations, and so does not need to be dealt with in legislation. However, if legislation is going to set specific conditions for messages it should be done in exact terminology.

4) Message content should be developed on the basis of what consumers do not know, and communicate that information to them in creative ways. To achieve informed consent it is not sufficient for a message simply to say, "Smoking causes lung cancer." In order to

communicate enough information for the consumer to make an informed decision, messages would have to say, "More than 85% of lung cancer is caused by smoking," or "Your chances of living for five years with lung cancer are less than 5%," or "Your chances of dying from smoking, if you keep smoking, are one in two."

Similarly, relative risk needs to be communicated. Rather than saying, "Smoking kills," it would be desirable to say, "Smoking kills 434,000 Americans every year -- more than alcohol, AIDS, car accidents, suicides and murders, ***combined***."

Creativity to content and design of messages should be applied. Tobacco companies employ scores of marketing and design specialists to ensure that package design appeals to the consumer. Use of comparable specialists should be made in the design of mandated package messages.

5) Messages should appear, at a minimum, on both of the main package panels. Otherwise the messages can be obscured simply by turning the packages around (e.g. at point of sale or in pictures). Having messages on only one side lessens the amount of information provided to smokers, such as that offered to consumers in Australia in the form of detailed messages. It would also encourage package redesign aimed at drawing attention away from the side with important consumer information.

6) Messages should encompass at least one-third of each side of the main package panels and be separated by a specified border from the remainder of the label. This is consistent with the Canadian and Australian warnings.

7) The law should allow for a variety of message formats to run simultaneously. To date, countries with package health warnings have used a standard form of presentation. There is potential to use many different formats and placements in order to increase novelty, allow post-marketing surveillance of effectiveness, successfully compete with attractive package design for attention, and reach different target groups. Some of the messages could, for instance, use the 'circle and arrow' format examined by the FTC in 1981. Others could simultaneously exhibit a different format and color scheme.

8) Package health messages should be considered to be only part of a broader package warning system that includes ingredient information, removal of misleading labeling, package inserts and, eventually, plain packaging. The legislation should at minimum provide regulatory authority to implement these measures in the future.

REFERENCES

BEEDE P, LAWSON R. The effect of plain packages on the perception of cigarette health warnings. *Public Health* 1992;106(4):315-22.

BORLAND R, CAPPIELLO M, HILL D. *Impact of the new Australian health warnings on tobacco products (Draft)*, Center for Behavioral Research in Cancer, prepared for Commonwealth Department of Human Services & Health, 29 February 1996.

BUCHAN v. ORTHO PHARMACEUTICAL (CANADA) LTD., Ontario Court of Appeal, January 17, 1986, 54 *Ontario Reports* (2d) pp.92-123.

CANADIAN CANCER SOCIETY. *Final report on a survey of Canadians' knowledge of and attitudes toward the harmful effects of smoking.* Canadian Cancer Society, Toronto. October 20, 1988.

CANADIAN CANCER SOCIETY. *Effects of plain packaging on the image of tobacco products among youth.* Canadian Cancer Society. January 6, 1993.

CANADIAN COUNCIL ON SMOKING AND HEALTH. *Awareness of health hazards due to smoking.* Canadian Council on Smoking and Health, 1991.

CENTERS FOR DISEASE CONTROL AND PREVENTION. Cigar smoking among teenagers – United States, Massachusetts, and New York, 1996. *Morbidity and Mortality Weekly Report* 1997;46(20):433-40.

CENTRE FOR BEHAVIOURAL RESEARCH IN CANCER. *Health Warnings and Content Labeling on Tobacco Products.* Center for Behavioral Research in Cancer, Anti-Cancer Council of Victoria, 1992.

CONNOLLY GN, WINN DM, HECHT SS, HENNINGFIELD JE, WALKER BW, HOFFMAN D. The reemergence of smokeless tobacco. *New England Journal of Medicine* 1986;314(16):1020-7.

CHRETIEN J. *Government action plan on smuggling.* Canadian House of Commons, February 8, 1994.

DAYNARD RA. Brief Amicus Curiae in the Supreme Court of the United States Concerning Thomas Cipollone. *Tobacco Products Litigation Reporter:* 3:179.

EISER JR, REICHER SD, PODPADEC TJ. Smokers' and non-smokers' estimates of their personal risk of cancer and of the incremental risk attributable to cigarette smoking. *Addiction Research* 1995;3(3):221-9.

FEDERAL TRADE COMMISSION. Advertising and labeling of cigarettes. Notice of rule-making proceeding for establishment of trade regulation rules. *Federal Register* 29:530-532. January 22, 1964.

FEDERAL TRADE COMMISSION. *Report to Congress Pursuant to the Federal Cigarette Labeling and Advertising Act.* Federal Trade Commission, June 30, 1967.

FEDERAL TRADE COMMISSION. *Staff Report on the Cigarette Advertising Investigation.* Federal Trade Commission, May 1981.

GLOBE AND MAIL, THE. *Group says tobacco warnings weakened,* June 26, 1989: 1.

HEALTH AND WELFARE CANADA. *Perceived health effects of smoking in Canada. Final report.* Health and Welfare Canada, September 10, 1992.

HEALTH CANADA. *Youth Smoking Survey 1994.* Minister of Supply and Services, 1996.

HILL D, GRAY N. Australian patterns of tobacco smoking and related health beliefs in 1983. *Community Health Studies* 1984;8(3):307-22.

HOUSE OF COMMONS STANDING COMMITTEE ON HEALTH. *Towards zero consumption: Generic packaging of tobacco products*, June 21, 1994

IMPACT RESEARCH. *Pack M.J. Inc. client study pack brand five-cigarette pack.* Impact Research, March, 1993.

LAWRENCE, C. *Summer campaign to confront smokers.* Minister of Health and Human Services, December 21, 1994.

MAHOOD G. Canadian tobacco package warning system. *Tobacco Control* 1995;4(1):10-14.

MARTTILA & KILEY INC. *Highlights from an American Cancer Society Survey of U.S. Voter Attitudes Toward Cigarette Smoking.* Martilla & Kiley Inc., Boston, MA. September 9, 1993.

NATIONAL CANCER INSTITUTE. *The FTC Cigarette Test Method for Determining Tar, Nicotine, and Carbon Monoxide Yields of U.S. Cigarettes: Report of the NCI Expert Committee. NIH Publication No. 96-4028.* National Cancer Institute, National Institutes of Health, US Department of Health and Human Services, August 1996.

NOVA SCOTIA COUNCIL ON SMOKING AND HEALTH. *Students and tobacco: The 1990 Nova Scotia Council on Smoking and Health survey.* Nova Scotia Council on Smoking and Health, 1990.

PRESIDENT'S CANCER PANEL. *Statement from the ad hoc committee of the President's cancer panel to consider the FTC test method for determining tar, nicotine and carbon monoxide levels in cigarettes.* President's Cancer Panel, National Cancer Program, National Cancer Institute. December 6, 1994.

SCHOENBAUM M. Do smokers under stand the mortality effects of smoking? Evidence from the Health and Retirement Survey. *American Journal of Public Health* 1997;87(5):755-9.

TANDEMAR RESEARCH INC. *Cigarette packaging study: The evaluation of new health warning messages*, prepared for Health Canada, March 1996.

TOBACCO INSTITUTE. *The tax burden on tobacco*, Volume 28, 1993. Washington, DC: The Tobacco Institute, 6.

TOBACCO PRODUCTS CONTROL REGULATIONS. *Canada Gazette Part II* 1989;123(2), January 18, 1989:s.15(a).

TOBACCO PRODUCTS CONTROL REGULATIONS. *Canada Gazette Part I* 1993;127(2),March 20, 1993:s.15(3)(a)(iv).

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES. *Reducing the health consequences of smoking: 25 years of progress. A report of the Surgeon General.* US Department of Health and Human Service, Centers for Disease Control, Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health. DHHS Publication No. (CDC) 89-8411, 1989.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES. In press report of the Surgeon General.

UICC. Health warnings/messages on tobacco products. *Tobacco Control Fact Sheet No. 2*, International Union Against Cancer, March 1993.