

To Issues Team

**HEALTH
SCIENCE
ANALYSIS
PROJECT**

Policy Analysis No. 1

**DISCLOSURE OF TOBACCO
INDUSTRY DOCUMENTS**

By

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EXECUTIVE SUMMARY

This paper analyzes the issue of the disclosure of tobacco industry documents, and demonstrates that a policy that maximizes disclosure could advance science, improve the public health and inform consumers.

ELEMENTS OF A DISCLOSURE POLICY

The authors identify 15 elements of a document disclosure policy, organized under three key questions, that are essential to ensure its effectiveness:

Which documents should be available?

- 1) A document disclosure policy should be constructed broadly to reach all relevant documents, rather than be limited to predetermined categories;
- 2) The policy should reach all documents that a) present scientific information, b) serve a public health, safety, or policy benefit, or c) are necessary to inform consumers and others of the true costs and benefits of tobacco use.
- 3) The disclosure policy should apply to all documents, in the United States or abroad, which are in the possession or control of: any tobacco company who sells into the domestic market and its corporate parents and related companies; all tobacco trade associations; all tobacco industry attorneys and other tobacco company agents.

4) Within the policy the term "documents" should be broadly defined to include all forms of documents, document indexes and document summaries, including those maintained on electronic media.

5) The obligation for disclosure should be ongoing.

6) A policy should maintain the work-product, attorney-client and trade secret privileges for the tobacco industry, but such claims for privilege should be weighed against the public's need for disclosure, and should be reviewed carefully with respect to whether they are truly privileged.

Who should review the documents?

7) Claims of relevance and privilege should be reviewed by a full-time panel of experts comprised of scientists, representatives of the public health community and individuals involved in public policy who are well-versed in tobacco related issues and whose decisions are subject to an appeal on an abuse of discretion standard by a specially constituted court of three judges

8) The panel should be within the Department of Health and Human Services, appointed by the Secretary, and be given sufficient staff and resources to conduct their

review. It should be entitled to subpoena documents or testimony to ensure complete disclosure. It should also be able to assess significant and ongoing penalties against the tobacco companies for failing to disclose documents in a timely manner, for knowingly asserting artificial claims of privilege, or for otherwise impeding the operations of the panel.

9) Determinations on privilege and relevance should not be binding upon any other Court or agency, but should only pertain to the immediate release of the documents.

Who should have access to the documents?

10) The documents should be made available in a public depository to be run by a government agency (e.g., National Library of Congress, National Library of Medicine, Department of Health and Human Services).

11) Access should be constrained only to the extent necessary to preserve the documents, and the use of such documents should not be restricted.

12) The documents should be made available on the Internet, CD-ROM or other similar technology.

13) The depository should accept and incorporate other relevant documents such as those in the public domain or those documents or indices donated by plaintiffs involved in lawsuits against the tobacco industry.

14) Resources should be made available to analyze and categorize the documents.

15) The cost for the creation and maintenance of the document depository should be borne by the tobacco industry and closely related entities.

EVALUATION

The paper compares five Senate bills proposing comprehensive tobacco legislation against these 15 elements. S. 1638, the "Healthy Kids Act," comes closest to meeting our standard as it:

- Broadly defines the categories of documents (including paper, electronic, video and audio communications) that would be disclosed, and leaves the door open for additional documents and information to be obtained by the Secretary of Health and Human Services if they are important to public health;
- Does not interfere with the rights of courts or parties to lawsuits to obtain documents;
- Requires disclosure from manufacturers of tobacco products, tobacco trade organizations, and any organization primarily funded by the tobacco industry; and
- Makes the documents available to the public, including electronically.

Despite its strengths compared to the other bills, S. 1638 also has several important weaknesses. The bill:

- Does not require that future documents be released;
- Does not allow for the formation of a scientific panel to assist the Secretary in deliberations regarding the public health significance of documents;
- Does not address the obtaining of documents located outside the United States;
- Does not suggest a mechanism for monitoring the industry's compliance; and
- Does not provide for the review and categorization of the documents obtained.

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INTRODUCTION

Both Congress and the President have made the development of comprehensive legislation to regulate tobacco a legislative priority for this year. To date, five bills have been introduced in the Senate to accomplish this purpose. One important element included in each of these bills is a mechanism to disclose internal tobacco industry documents. The importance of such a component cannot be minimized and is often called for by public health scholars and advocates when discussing a national tobacco policy (Campaign for Tobacco Free Kids 1997; Burns, et al. 1997; Koop and Kessler 1997).

The extent of internal industry documents is unknown, but potentially enormous. To date, most internal industry documents have been brought to public attention through their discovery as part of a lawsuit or by whistleblowers. For example, Attorney General Hubert H. Humphrey III, of Minnesota, has filed suit against several tobacco companies alleging that they have committed both antitrust conspiracy and consumer fraud (*Minnesota v. Philip Morris* 1998a.). As a result of the discovery process of this suit, Minnesota has obtained over 33 million pages of internal tobacco industry documents.

Legislation mandating document disclosure may be necessary, as the tobacco companies have not willingly disclosed documents until ordered as part of a legal action. For example, when Congressmen Henry Waxman and Ron Wyden made

documents from Brown and Williamson Tobacco Company public, the company filed suit in several states in an attempt to subpoena reporters and seal the documents. Brown and Williamson also attempted to prevent the public disclosure and use of documents that were made available by a whistleblower (Todd et al. 1995). Although Brown and Williamson was unsuccessful in all of these attempts to prevent public disclosure of their documents, they certainly did nothing to facilitate the process.

Furthermore, in legal proceedings the tobacco companies have been recalcitrant when it comes to document disclosure (See e.g., *Minnesota v Philip Morris* 1997). In many cases the tobacco companies will assert claims of privilege in order to shield particular documents. The three main legal privileges at issue in these cases are attorney-client, work-product and trade secret. The tobacco companies have overused, and allegedly abused, these claims of privilege.

The tobacco industry's intense efforts to withhold documents may be changing, as recent events in Minnesota suggest. In February 1998, after three weeks of trial in Minnesota, the tobacco industry requested that the court lift a protective order and open the documents produced in the lawsuit to the public, and as a result many of the documents produced in that case are now available to the public. Nevertheless, it is clear that the documents would not have been disclosed without the persistence of the State of Minnesota in its lawsuit. Therefore, if any national legislation is formulated to eliminate

lawsuits against the tobacco industry, the importance of the document disclosure provisions will be magnified. Furthermore, it is clear that relying on litigation alone to discover documents will result in an uneven discovery process.

In this paper, we analyze a number of issues related to tobacco industry document disclosure in an effort to inform any future policies governing disclosure. First, we describe the significance of document disclosure and who can potentially benefit from disclosure. Second, we outline the important elements of a document disclosure policy. Third, we evaluate the five proposals currently before Congress and compare them against our standards.

SIGNIFICANCE OF DOCUMENT DISCLOSURE

Factors for Disclosure

We start with the basic premise that the tobacco industry, as large multi-national corporations who sell dangerous products into the general market, are in possession of documents which should be released. The need for these documents arises from three primary motivations. First, document disclosure will maintain a free flow of scientific information. Second, document disclosure will provide information which can lead to improvements in public health and public policy. Third, document disclosure helps to ensure that consumers of tobacco products are informed of the risks that they may be facing by either beginning or continuing to use tobacco products.

Free Flow of Scientific Information

Progress in science depends upon the free exchange of scientific information

(Rosenberg 1996). When scientific research involves matters of health and safety, the consequences of restricting the flow of scientific information include increased morbidity and mortality (Chalmers 1990; Rosenberg 1996). Concealing scientific information also calls the scientific process into question and increases the public distrust of properly conducted scientific research.

The tobacco companies have funded and promoted scientific research, and then withheld the results of the research if it proved unfavorable to the industry position that tobacco is not harmful (Bero, et al. 1995; Hanauer, et al. 1995). Similarly, the industry has promoted the dissemination of research that supports its claim that tobacco is neither harmful nor addictive and has mounted campaigns of scientific misinformation in order to confuse the public (Glantz, et al. 1996- ch 2-5, 9).

Public Health and Public Policy

The refusal of the tobacco industry to disseminate information has also slowed the public health and public policy responses which could reduce the morbidity and mortality related to tobacco. For example, recent disclosures of tobacco industry documents have revealed that tobacco companies:

- knew that nicotine was addictive before this was general knowledge in the scientific community (Slade et al. 1995);
- had an internal research program aimed at developing a "safer" cigarette (Glantz et al. 1996 - ch 4, 5); and
- marketed cigarettes to youth.

These disclosures have had significant policy implications. The disclosure regarding nicotine addiction supported the Food and Drug Administration's (FDA) assumption of jurisdiction over tobacco products. The

disclosures about the research program aimed at developing safer cigarettes has significant implications for the future regulation of the industry. Lastly, the disclosures related to marketing strategies aimed at youth refutes the tobacco companies' public claims that they do not market to youth, and provides evidence from which the FDA can act to control the promotion of tobacco products to children. Furthermore, all of the disclosures mentioned above have damaged the corporate image of the tobacco industry and served the valuable public health function of keeping issues of tobacco safety in the news media.

Consumer Information

The tobacco companies have argued that smoking is an adult activity and that consumers can freely make the choice to smoke. This claim is based upon the assumption that consumers are making fully informed choices. However, the tobacco companies prevent this from occurring by withholding information from consumers. It is consumers who have suffered as a result of any fraudulent statements that tobacco was not harmful, and it is consumers who have suffered from any conspiratorial behavior which has kept safer products off the market. A thorough document disclosure program will improve consumers' ability to make informed choices about their personal habits, and provide them the information they need in order to decide whether to pursue legal action against the tobacco companies.

Similarly, employers, health care providers and insurers also have an interest in receiving information about the health effects of tobacco products. Governmental bodies also have an interest in preventing activity that would disrupt free markets. Information provided by the tobacco companies will inform these entities and help them decide

whether to initiate actions for potential tobacco industry wrongful behavior.

Factors against Disclosure

In the next section, we rebut the following arguments against a document disclosure policy:

- all the necessary information is already available, documents will be disclosed without the need for legislation;
- disclosure would impinge on tobacco industry privileges; and
- the cost of a document disclosure program is prohibitive.

Information is Already Available

One argument against legislation requiring the release of documents is that such a program will provide no new information, but will simply confirm what is already common knowledge (Kluger 1996). This is unlikely to be true and is belied by the fact that many of the documents made public so far have provided new information about the tactics of the tobacco industry. For example, although tobacco companies have publicly claimed that they do not market their product to youth, internal industry documents have revealed that the industry was definitely concerned with the youth market (See e.g., *Minnesota v Philip Morris* 1998b). In addition, through disclosed documents it became public knowledge that the tobacco industry attempted and failed to produce safer cigarettes, rather than remove their product from the market (Glantz et al. 1996 - ch 4, 5). Finally, the publicly available evidence on the addictive properties of nicotine and the harmful effects of tobacco did less to stimulate tobacco control policy advances than disclosures about the tactics the tobacco industry used to refute these findings and

manipulate both researchers and policy makers.

Tobacco industry documents that have not yet been made public are also likely to provide information that is directly relevant to other policy decisions. For example, indoor air policies are likely to be influenced by internal industry documents. The limited number of available documents related to environmental tobacco smoke have already revealed that the tobacco companies influenced the dissemination of research on environmental tobacco smoke and launched campaigns to influence the regulation of environmental tobacco smoke (Barnes et al. 1995).

In short, the information necessary to influence public health is far broader than whether tobacco is harmful. It also includes documents regarding how tobacco is harmful and what policy measures can be taken to reduce death and disease related to tobacco.

Documents Will be Disclosed Without the Need for Legislation

With the recent success of the litigation against the tobacco companies, there is the perception that most of the relevant documents either have been or will be released through the process of the litigation. This is a faulty assumption for three reasons. First, documents that have been released in the course of the litigation may not be complete. Second, the documents produced in the course of litigation may not be in a form usable or accessible for public health and public policy professionals. Third, relying on the documents already disclosed will provide no mechanism for continuing disclosure of tobacco industry research.

There is no reason to believe that the cache of incriminating industry documents has been exhausted by the disclosures that have been made to date. The documents that have been produced have not been thoroughly

reviewed, and many documents have still not been released pursuant to court orders. It is also not clear that all of the remaining documents will be released by continuing litigation. For example, the continuing discussions of granting the tobacco industry some form of immunity make the prospect of future litigation uncertain.

In addition, there is a high likelihood that the information deemed relevant to lawyers in a case will be different from those that are relevant to public health and public policy researchers. Furthermore, the documents that are being used in the various court cases are not easily accessible to outsiders. For example, the documents are scattered around the world from many different cases and have no consistent cataloging or indexing scheme.

Finally, so long as the tobacco companies stay in business they are likely to keep documents which will be relevant to public health and public policy. Relying on documents which have already been produced in litigation will not reach future documents.

Document Disclosure Requirements Would Impinge Upon Tobacco Industry Privileges

A criticism of a universal document disclosure program is that it would place an unfair burden on the tobacco industry. The tobacco industry is an integral part of the United States economy and society. As such, it is entitled to the same protections as other companies. Although attorney-client, work-product, and trade secret privileges should be maintained, they do not present an argument against document disclosure, but rather that the document disclosure be conducted carefully.

The tobacco industry should have the right to maintain the confidentiality of documents that are work product, or represent private attorney client communications. However, it is not always easy to determine

which documents are deserving of these privileges. For example, the crime-fraud exception releases documents from the protection of the attorney-client privilege. This exception is based upon the premise that the attorney client privilege extends to defending actions which may have already occurred, but not to perpetuating or assisting with wrongful actions. Therefore, any communication which is conducted in furtherance of a crime is not protected by attorney-client privilege under the crime-fraud exception. The tobacco industry and its attorneys have allegedly been working in furtherance of conspiracies, which would make many of their communications not privileged (see, e.g. *Minnesota v Philip Morris* 1997). Similarly, there is evidence that the tobacco companies have routed scientific research through attorneys in an attempt to protect it from disclosure (Bero et al. 1995; Hanauer et al. 1995). But a communication that is otherwise not privileged cannot be made privileged simply by sharing it with an attorney (see, *Upjohn Co. v. United States* 1981). Therefore, many of the scientific documents which the industry claims are privileged have been ordered disclosed by courts (see, *Minnesota v Philip Morris* 1997; *Burton v. R.J. Reynolds Tobacco Co.* 1997; *Sackman v. Liggett Group, Inc.* 1997). There is also precedent for overriding the privilege where there is a compelling public interest, such as protecting the public health from the harmful effects of tobacco (see, *Sackman v. Liggett Group, Inc.* 1997, *supra.*, applying New York law).

The same is true for the work-product privilege. Few would disagree that attorney notes written while developing a defense to a particular claim in a particular lawsuit should be protected. However, courts have deemed that reports on studies that are claimed to have been created in anticipation of litigation but were conducted in the ordinary course of

business are not protected by the work-product privilege. Thus, the work-product privilege will not apply to medical studies which were conducted by the tobacco industry to determine the safety of cigarettes or for which the attorney's role in the research was incidental (see, *Burton v. R.J. Reynolds Tobacco Co.* 1997). In addition, the crime-fraud exception is also applicable to the work-product privilege. Thus, many of the documents sought by the public health community could be obtained without removing the privilege. Nevertheless, given the past abuses of asserting privileges by the tobacco companies, the work-product privilege should be narrowly construed in the case of the tobacco companies to only cover the very core of work-product, i.e. those documents specifically prepared in defense of a particular lawsuit, and not those documents generated in anticipation of litigation.

Similarly, a balance can be struck between the need to maintain proprietary information through trade secret privileges and the need to protect the public health. We feel that this balance should favor the public health, but tobacco industry information which does not implicate the public health and for which the release would cause substantial economic harm to the industry can remain confidential. The patent laws will still provide protections to the tobacco companies from competitors. At the same time, however, documents which the industry claims contain trade secrets can be reviewed to determine whether they impact the public health, and if so, the trade secret designation can be removed.

Cost

The last of the criticisms against a required document disclosure policy is that it would be expensive to construct and to maintain. Given the high cost to society of

death and disease related to tobacco, estimated at more than \$100 billion per year (Bartlett et al. 1994), the relative cost of constructing and maintaining the document depository is comparatively negligible. Furthermore, if producing the documents results in improved public health programs and improved policy measures to reduce death and disease related to tobacco, the costs will be easily recouped through societal savings. Finally, because of tobacco industry recalcitrance and previous misbehaviors in withholding documents, a rational argument can be made that it should bear the costs related to the depository.

ESSENTIAL ELEMENTS FOR A POLICY ON DOCUMENT DISCLOSURE

Our starting assumption in developing a policy is that there are internal tobacco industry documents that are potentially important to public health and the development of sound tobacco control policy, which have not been disclosed and are unlikely to be disclosed through the course of the litigation. Thus, documents relevant to these goals, unless there is an overarching reason for preventing disclosure, should be available for public review. Similarly, a document that does not significantly impact the public health and is from a privileged class should not be released. With this in mind we propose that the following 15 elements, which we have organized under three key questions, be addressed in a document disclosure policy.

Which documents should be available?

1) A document disclosure policy should be constructed broadly so that it will reach all relevant documents, and not be self-limiting to reach only predetermined categories which

may be either incomplete or incorrectly construed.

2) The policy should reach all documents that meet the following criteria: a) documents which present scientific information, b) documents which serve a public health, safety, or policy benefit, or c) documents which are necessary to inform consumers and other market participants of the true costs and benefits of tobacco use.

3) The obligations for disclosure should be of all documents, whether located in the United States or abroad, which are in the possession or control of: any tobacco company who sells into the domestic market and its corporate parents and related companies; all tobacco trade associations; all tobacco industry attorneys and other tobacco company agents.

4) Within the policy the term "documents" should be broadly defined to include all forms of documents, document indexes and document summaries, including those maintained on electronic media.

5) The obligation for disclosure should be ongoing.

6) A policy should maintain the work-product, attorney-client and trade secret privileges for the tobacco industry, but such claims for privilege should be weighed against the public's need for disclosure, and should be reviewed carefully with respect to whether they are truly privileged.

A policy that includes these elements should result in the release of those documents that will have the most dramatic impact on public health and public policy. Some documents which should be released include, *but are not limited to:*

- Scientific and health-related research on the effects of tobacco products on tobacco users;
- Scientific and health-related research on the effects of nicotine on tobacco users;
- Research and policies regarding the manipulation of nicotine levels in tobacco products through manufacturing, agricultural or other means;
- Scientific and health-related research on the effects of all additives and constituents in the manufacturing process (such as pesticides and herbicides)
- Scientific and marketing research regarding less hazardous tobacco products.
- Scientific and health-related research on the effects of environmental tobacco smoke;
- Research related to tobacco product safety;
- Policies regarding the development of and use of scientific research including publication;
- Documents regarding youth smoking;
- Documents regarding the advertising and marketing of tobacco products especially as it relates to youth and other specially targeted groups; and
- All information regarding tobacco industry involvement in or the influence of policy through the use of campaign contributions, abuse of the Freedom of Information Act process, and the financing or support of outside organizations to influence policy.

Moreover, a policy based upon the proposed elements will also have the benefit of not releasing information which is irrelevant to public health. Some of the documents that are not likely to be released under such a process would include:

- Personnel files;
- Manufacturing processes which are not relevant to the public health;

- Accounting information related to the normal day-to-day operations of the company; and
- Research and development that contains proprietary information and does not impact upon the public health.

Our proposed elements would not disclose documents that are protected by work product, attorney client, or trade secret privileges, if they do not significantly impact the public's need for disclosure. Conversely, our elements do allow for the release of documents for which the need for disclosure outweighs the benefits of the privilege.

Who should review the documents?

7) Claims of relevance and privilege should be reviewed by a full-time panel of experts comprised of scientists, representatives of the public health community and individuals involved in public policy who are well-versed in tobacco related issues and whose decisions are subject to an appeal on an abuse of discretion standard by a specially constituted court of three judges.

8) The panel should be within the Department of Health and Human Services, appointed by the Secretary, and be given sufficient staff and resources to conduct their review. It should be entitled to subpoena documents or testimony to ensure complete disclosure. It should also be able to assess significant and ongoing penalties against the tobacco companies for failing to disclose documents in a timely manner, for knowingly asserting artificial claims of privilege, or for otherwise impeding the operations of the panel.

9) Determinations on privilege and relevance should not be binding upon any other Court

or agency, but should only pertain to the immediate release of the documents.

The expert panel provides a means for monitoring tobacco industry compliance with any proposed policy by having experts review the actions of the industry. In addition, by placing the responsibility for review within a federal agency, the panel would be able to conduct the investigations necessary to complete its tasks and have sufficient rulemaking authority to design the rules necessary for an effective and efficient review of the documents. For example, the panel could require the automatic disclosure of all documents, including indices and summaries, which have been produced in legal actions against the tobacco companies, and in Congressional and regulatory investigations of the industry and for which there are not claims of privilege which have either been upheld or are still unresolved. By requiring the automatic disclosure of documents already produced in litigation, the panel is less likely to be overwhelmed by industry documents.

Who should have access to the documents?

10) The documents should be made available in a public depository to be run by a government agency (e.g., National Library of Congress, National Library of Medicine, Department of Health and Human Services).

11) Access should be constrained only to the extent necessary to preserve the documents, and the use of such documents should not be restricted.

12) The documents should be made available on the Internet, CD-ROM or other similar technology.

13) The depository would be able to accept and incorporate other relevant documents such as those in the public domain or those

documents or indices donated by plaintiffs involved in lawsuits against the tobacco industry.

14) Resources should be made available to analyze and categorize the documents.

15) The cost for the creation and maintenance of the document depository should be borne by the tobacco industry and closely related entities.

Providing for the disclosure of documents has only limited value unless access to the documents is ensured. Guaranteeing access to the documents for the public health community, academics, and consumers is particularly important as these groups may not be able to otherwise obtain the documents. The elements we propose are essential because they ensure not just that the documents will be available, but that they will be in a usable form.

Admission of Liability

Many public health commentators have argued that there is a need for the tobacco companies to admit past wrongdoing and to admit the hazardous nature of their products (Burns et al. 1997; Warner 1997). Although such admissions could advance the public health and have other societal benefits, we do not include this provision among our proposed elements, for two major reasons. First, to compel admissions, especially those which could implicate the criminal laws, could violate various individual's constitutional right against self-incrimination. Second, any compelled admission would lack the sincerity necessary to fully achieve the public health benefits of such an admission. Ultimately the documents will be able to speak for themselves.

EVALUATION OF CONGRESSIONAL PROPOSALS

At the time of this writing there are five comprehensive legislative proposals before Congress to address issues related to tobacco. These bills are: S. 1414, the "Universal Tobacco Settlement Act," introduced by Senator McCain (and others); S. 1492, the "Healthy and Smokefree Children Act," introduced by Senator Kennedy (and others); S. 1530, the "PROTECT Act," introduced by Senator Hatch (and others); S. 1638, the "Healthy Kids Act," introduced by Senator Conrad (and others); and S. 1648, the "PAST Act," introduced by Senator Jeffords (and others). Each of the bills contains provisions which would require the tobacco industry to disclose documents to the public. In the following sections we compare these five bills against our list of essential elements. The key provisions of each bill are summarized in Table 1 (at the end of the paper).

Which documents should be available?

In contrast to our elements, which would require the disclosure of documents based upon their potential impact to the public health, all of the bills before Congress recommend that specific categories of documents be made available. We feel that limiting the release of documents merely to document "types" will inevitably be restrictive and result in the non-disclosure of important documents. In general, S.1414, S.1492 and S.1530 require the release of documents related to health research, addiction or dependency, safer or less hazardous cigarettes, studies of the smoking habits of minors, and the relationship between advertising or promotion and youth smoking.

Furthermore, the disclosure of many documents called for in these three bills is dependent upon the resolution of pending

court cases. S.1648 and S.1638 define the types of documents to be released more broadly to include all documents related to research on the health effects of tobacco products, manipulation of nicotine and reduced risk tobacco products, and marketing. Each of the five bills, however, allows for the disclosure of documents that are not specified in the bill upon action by the Secretary. S.1638 allows for the release of documents relating, referring, or pertaining to "such other matters as the Secretary (of Health) may prescribe." The remaining bills allow for the release of "all other documents determined appropriate under regulations promulgated by the Secretary." The bills do not clarify the criteria that the Secretary would use to make these decisions, as opposed to the scientific integrity, public health, and consumer information criteria we suggest.

The proposals differ slightly in the amount of time that the tobacco companies and their agents would be allowed to have before disclosing the documents. Although all the bills mention that tobacco companies and selected tobacco trade organizations must release documents, only S.1638 requires that "any entity primarily funded by persons who manufacture a tobacco product" must release documents. S.1648 is also the only one which addresses the international component of the document disclosure provision. In this bill, information regarding "imported" cigarettes will also need to be disclosed to the Secretary. None of the bills addresses the issue of documents which may be located in foreign jurisdictions.

Of the bills, S.1638 uses the broadest definition of "document" and includes not only paper and electronic documents that can be printed, but also audio and video.

S.1648 requires the tobacco industry to release documents on an ongoing, annual basis. S.1414, S.1492 and S.1530 allow for the release of specified future documents and S.1638

seems to allow for additional disclosures as required by the Secretary of Health and Human Services.

Most importantly, only S.1638 requires that decisions regarding whether documents should be protected from disclosure by legal privileges be made on the basis of their importance to public health. S.1414, S.1492 and S.1530 propose that decisions regarding attorney-client, work-product and trade secret privileges be based on American Bar Association / American Law Institute Model Rules and Uniform Trade Secrets Act, not on the relevance of the documents to public health. S.1648 relies upon the Freedom of Information Act with respect to rules for the public disclosure of confidential trade secret information, and allows for the release of confidential information pertaining to an ingredient, substance or compound if it is in the interests of the public health. (S.1648 is silent with respect to the attorney client and work-product privileges, and does not provide a public health exception for other documentary information.) The proposed mechanisms for reviewing the documents are compared in the next section.

In summary, S.1638 would most likely allow for the disclosure of as many documents as our proposed elements, because it most easily allows for the release of documents not in specified categories and clearly provides a public health exception to claims of privilege. However, S.1638 does not meet all of the essential elements because it lacks provisions requiring the disclosure of documents in the future and one which attempts to address documents located outside the United States.

Who should review the documents?

The five bills before Congress differ most with each other and with our proposed elements in their recommended procedures for

document review. S.1414, S.1530 and S.1492¹ propose that the documents be reviewed for claims of privilege by a panel of three federal judges, while S.1638 and S.1648 call for review by the Secretary of Health and Human Services. The decisions of the judges' panels will be final and shall be binding upon Federal and State courts. Under S.1492 there is a rule of construction which states that the judges' panel is not to interfere with the discovery rights of other courts or parties to other litigation involving tobacco products. But for S.1414 and S.1530, it appears that once a document is deemed privileged by the judges' panel, this decision will hold for other lawsuits, even if they are for a different

¹ S.1492, in addition to the judges panel would establish a Tobacco Oversight and Compliance Board to oversee compliance by the tobacco companies with the entire act through a review of the industry documents. The board will consist of five members with expertise related to tobacco and public health. Tobacco manufacturers will be required to submit to the board all documents in their possession relating to: any health effects, including addiction, caused by the use of tobacco products; the manipulation or control of nicotine in tobacco products; and the sale or marketing of tobacco products to children. The manufacturers will also be required to submit all documents produced or ordered to be produced in the case *State of Minnesota vs. Philip Morris, Inc.*, including documents protected by attorney-client privilege. The board will have the power to subpoena additional information.

The board will publish an annual report describing whether the tobacco manufacturers are in compliance with the disclosure provisions of the act and whether they have attempted to conceal information related to adverse health effects, addiction, marketing to children, or efforts of the industry to circumvent regulation of their product. It is not clear whether any penalties will be assessed if the tobacco industry is not found to be in compliance with the act. The board will make the documents that are submitted to it available to the public except those which are entitled to protection as trade secrets, unless the board determines that disclosure is necessary to protect the public health. It is unclear how the disclosure requirements of the board are to be read consistently with the provisions regarding S.1492's provisions for a document depository.

purpose, or if there is additional evidence which suggests that the document be released.

Both S.1638 and S.1648 require that privileged documents be presumptively released to the Secretary of HHS for review. Because S.1648 treats the evaluation of claims of trade secret as an internal matter, it is unlikely that it would guide other evaluations. S.1638 allows the Secretary to subpoena additional information and states that the Secretary's decision is not binding upon the courts.

S.1414, S.1530 and S.1492 provide that the judges' panels can assess fees for bad faith assertions of privilege and may assess other sanctions as well. S.1530 is the only one that mentions specific penalties for failure to comply with the decision of the judges' panel. In it, if a tobacco product manufacturer is found to have failed to produce documents for the depository, they will be assessed a civil penalty not to exceed \$15,000 per document not disclosed and \$1,000,000 for all documents adjudicated in a single proceeding. In addition, because the S.1648 and S.1638 require disclosures to the Secretary any failure to disclose will likely be governed by Federal laws which will likely use federal enforcement procedures which govern the failure to disclose to agencies. Thus, it appears that each of the bills has an enforcement mechanism.

In summary, none of the proposed bills suggest a presumptive release of documents to a panel of scientists / public health representatives, followed by judicial review if necessary. However, S.1638 states that decisions about document disclosure will be made by the Secretary of HHS based upon whether disclosure of such information is necessary for the public health. S.1638 also does not hold that determinations of privilege will be binding upon the courts. As a result, S.1638 may result in a program that satisfies our proposed elements.

Who should have access to the documents?

S.1648 is the only bill that fails to state explicitly that the disclosed documents will be available to the public. S.1648 states that the Secretary of HHS must release information on any ingredient, substance, or compound in a tobacco product if it is in the interest of public health, but the bill does not state that other documents must be disclosed to the public. S.1648 does include a provision which indicates that the documents will be available from the Secretary pursuant to the Freedom of Information Act.

Both S.1530 and S.1414 require that a public depository be established and maintained by the manufacturers of tobacco products, Tobacco Institute, and Council for Tobacco Research. S.1492 and S.1638, similarly to our proposed elements, require that the depository be run by a government agency. All four bills require that the Depository be open to the public, including litigants, public health groups, and any other individuals that have an interest in the documents. Only S.1638 mentions that the documents will be available electronically. Electronic access, as we propose, would facilitate public use of the documents.

It appears that funding for the document disclosure provisions under each of the four bills will be provided by the manufacturers of tobacco products, Tobacco Institute, and Council for Tobacco Research. This is consistent with our elements.

None of the bills provide for resources to analyze and categorize the documents. It is possible that because under S.1648 and S.1638 that the documents will be produced to the Secretary of Health and Human Services, that the Secretary could undertake such a review.

CONCLUSION

S.1638 comes closest to meeting our proposed standard for document disclosure as it maximizes the disclosure of documents that are relevant to public health. S.1638 broadly defines the categories of documents that would be made available to the public, and leaves the door open for additional documents to be disclosed at the discretion of the Secretary of Health and Human Services. Furthermore, the Secretary's decision about whether to release privileged information will be determined by the importance of the documents to public health. The Secretary has the power to subpoena additional information, which may be necessary in order to obtain documents. In addition, the Secretary's decision will not be binding in courts and, thus, will not interfere with the rights of courts or parties to litigation to access the documents. S.1638 uses the most generous definition of document to include paper, electronic, video and audio communications. In addition, S.1638 requires disclosure from manufacturers of tobacco products, tobacco trade organizations, and any organization primarily funded by the tobacco industry. The documents will clearly be available to the public, and will be available electronically.

Despite its strengths compared to the other bills, S.1638 also has several important weaknesses. First, it does not require that documents produced by the tobacco industry in the future will be released to the public. Second, it does require the formation of a scientific panel to assist the Secretary in deliberations regarding the public health significance of documents. Such a panel could provide the expertise necessary to judge the value of documents on a broad range of topics from laboratory research to policy, marketing, and economic analyses. Third, S.1638 does not attempt to address the issue of tobacco industry documents not located in the United States. Fourth, S.1638 does not suggest a

mechanism for monitoring the tobacco industry's compliance with the act, nor a specific proposal for penalties that would force the industry to comply. Last, S.1638 does not provide for the review and categorization of documents.

REFERENCES

- Barnes, D. E., P. Hanauer, J. Slade, L. Bero, S. A. Glantz. (1995). Environmental tobacco smoke: the Brown and Williamson documents. *JAMA* 274(3): 248-253.
- Bartlett, J. C., L. S. Miller, D. P. Rice, W. P. Max. (1994). Medical care expenditures attributable to smoking—United States, 1993. *MMWR* 43(26): 469-472.
- Bero, L., D. E. Barnes, P. Hanauer, J. Slade, S. A. Glantz. (1995). Lawyer control of the tobacco industry's external research program: the Brown and Williamson documents. *JAMA* 274(3): 241-7.
- Burns, D., N. Benowitz, G.N. Connolly, K.M. Cummings, R.M. Davis, J. E. Henningfield, D. R. Shopland, K. E. Warner. (1997). What should be the elements of any settlement with the tobacco industry? *Tobacco Control* 6(1): 1-4.
- Burton v. R.J. Reynolds Tobacco Co.* (1997). 170 F.R.D. 481 (D.Kan., 1997).
- Campaign for Tobacco Free Kids. (1997). Core Principles for Consideration of the Resolution of Current Outstanding Tobacco Issues (Press Release), National Center for Tobacco Free Kids.
- Chalmers, I. (1990). Underreporting research is scientific misconduct. *JAMA* 263: 1405-1408.

- Glantz, S. A., J. Slade, L. A. Bero, P. Hanauer, D. Barnes. (1996). The Cigarette Papers. Berkeley, University of California Press.
- Hanauer, P., J. Slade, D. E. Barnes, L. Bero, S. A. Glantz. (1995). Lawyer control of internal scientific research to protect against products liability lawsuits: the Brown and Williamson documents. JAMA 274(3): 234-240.
- Kluger, R. (1996). A Peace Plan for the Cigarette Wars. The New York Times Magazine: 36.
- Koop, C. E. and D. A. Kessler (1997). Final Report of The Advisory Committee on Tobacco Policy and Public Health, The Advisory Committee on Tobacco Policy and Public Health.
- Minnesota v Philip Morris*. (1997), case no. C1-94-8565, County of Ramsey Second Judicial Circuit, "Order With Respect to non-Liggett Defendants' Objections to the Special Master's Report Dated September 10, 1997", December 16, 1997.
- Minnesota v. Philip Morris*. (1998a). case no. C1-94-8565, County of Ramsey Second Judicial Circuit, "Second Amended Complaint", January 6, 1998.
- Minnesota v Philip Morris*. (1998b),), case no. C1-94-8565, County of Ramsey Second Judicial Circuit,, "Order With Respect to non-Liggett Defendants' Objections to the Special Master's Report Dated February 10, 1998", March 7, 1998.
- Rosenberg, S. A. (1996). Secrecy in medical research [editorial]. NEJM 334(6): 392-394.
- Sackman v. Liggett Group, Inc.* (1997). 920 F.Supp. 357 (E.D.N.Y. 1996) (vacated 167 F.R.D. 6 (E.D.N.Y. 1996) reinstated in part 173 F.R.D. 358 (E.D.N.Y. 1997)).
- Slade, J., L. Bero, P. Hanauer, D. E. Barnes, S. A. Glantz. (1995). Nicotine and addiction: the Brown and Williamson documents. JAMA 274(3): 225-233.
- Todd, J. S., D. Rennie, R. E. McAfee, L. R. Bristow, J. T. Painter, T. Reardon, et al. (1995). The Brown and Williamson Documents: Where Do We Go From Here? (editorial). JAMA 274(3): 256-259.
- Upjohn Co. v. United States*. (1981). 449 U.S. 383, 395-396 (1981).
- Warner, K. E. (1997). Editorial: Dealing with Tobacco – The Implications of a Legislative Settlement with the Tobacco Industry. American Journal of Public Health 87(6): 906-909.

**HEALTH
SCIENCE
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Policy Analysis No. 2

**TOBACCO CONTROL
RESEARCH**

By

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University of Vermont

April 14, 1998

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TOBACCO CONTROL RESEARCH

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EXECUTIVE SUMMARY

An effective national tobacco policy must be firmly grounded in a comprehensive, ongoing research program. This paper assesses the current status of tobacco control research, describes the necessary components of a tobacco control research agenda, and assesses five major legislative proposals with regard to fulfilling that agenda.

Major Findings:

1. Tobacco/nicotine research has been one of the best examples of research directly benefiting public health.
2. Despite the fact that tobacco use causes 20% of all US mortality, the National Institutes of Health (NIH) currently expends only 1.1% of its budget on tobacco research. There is little coordination of tobacco research efforts at NIH, and many other agencies (e.g. the Food and Drug Administration (FDA)) also underfund tobacco research. There is no indication this is improving. This lack of funding has impeded the growth of tobacco research in the past few years.
3. Currently proposed legislation only minimally addresses these problems.

Major Recommendations:

1. Legislation should distinguish between biomedical research in general, research on tobacco-related diseases, and research on tobacco use (i.e. research on the causes,

prevention and treatment of tobacco use but not research on the consequences of tobacco use).

2. Tobacco settlement/excise tax funds should increase tobacco control research to \$200 million per year in the first two years, \$400 million per year in the following two years and \$600 million per year thereafter.

3. Funds should go not only to NIH institutes but also to FDA, the Centers for Disease Control (CDC), the Occupational Health and Safety Administration (OSHA), the Environmental Protection Agency (EPA), the Federal Trade Commission (FTC), and other agencies.

4. A panel of tobacco control experts should advise the Secretary of DHHS on the allocation of funds across agencies.

The paper includes a chart comparing five major legislative proposals on key tobacco control research issues, and an addendum listing examples of important tobacco control research priorities.

TOBACCO CONTROL RESEARCH

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INTRODUCTION

This report deals with "tobacco control research," which is defined as "research on the causes, prevention and treatment of tobacco use." "Tobacco use" includes cigarettes, cigars, pipes, smokeless tobacco, cigarette substitutes, etc. This definition does not include research on the mechanisms, prevention or treatment of the health consequences of tobacco use. The definition does include:

- research on the neurobiological, behavioral and psychosocial events that initiate or maintain or predispose to tobacco use/dependence or to promote cessation of tobacco use;
- epidemiology of tobacco use/dependence;
- interventions to prevent tobacco use, to help tobacco users abstain, or to help mitigate the harmful effects of tobacco use including health services research on implementation of these interventions; and
- modeling and evaluating policy initiatives (e.g. taxation) for tobacco control, and other areas.

Tobacco control research has been an excellent example of science informing policy. In the 1950's, for example, tobacco use was not thought to be harmful, nicotine was not thought to play a role in tobacco use, tobacco use was not thought to be an addiction, nicotine was not thought to act directly on receptors in the brain, and there were no treatments for cessation of tobacco use. Now, due almost exclusively to scientific research, we know that smoking is harmful, that

nicotine is the major promoter of tobacco use, and that tobacco use is often a true addiction, and we have several FDA-approved treatments for tobacco use cessation.

Continuing research is important for tobacco control for several reasons. First, tobacco control policy is best based on a scientific understanding of the forces that initiate, maintain and prompt cessation of tobacco use. Recent advances in understanding the genetics of smoking, nicotine receptors in the brain, beneficial effects of nicotine, and economic effects on smoking, among other areas, need to be continued so that they can concretely assist prevention, treatment and policy efforts. Second, only ongoing epidemiological research can examine whether we are making progress in tobacco control. Third, although many proposed tobacco control policies appear face-valid, only objective research can evaluate their impact. Fourth, the tobacco industry has been very effective at innovative measures to circumvent tobacco control policies (e.g. ads at sporting events and smokeless cigarettes); thus, research is needed into the impact of these industry measures. Fifth, although prevention interventions work, their impact is small and more powerful interventions are needed. Sixth, tobacco control policies appear to be influencing mostly the less dependent, less troubled smokers; thus, the remaining future smokers will be more and more those who are heavily nicotine dependent or who have psychological problems. We need research on how to treat such smokers.

DESCRIPTION OF CURRENT TOBACCO CONTROL RESEARCH FUNDING

Current spending on tobacco control research totals approximately \$200-\$300 million per year. It is funded and conducted primarily through the following institutions:

National Institutes of Health

The only empirical analysis of tobacco research at NIH was a recent report by the Society for Research on Nicotine and Tobacco and the data and conclusions that follow are drawn from that report. The analyses in the report used NIH's CRISP computerized data base and found that in 1995 NIH expended \$92 million per year in extramural research focused on nicotine/tobacco of which about \$70 million of this is tobacco control research. In contrast, the budget for extramural and intramural research on alcohol at the National Institute on Alcoholism and Alcohol Abuse is near \$200 million and the budget for non-nicotine research at the National Institute on Drug Abuse is near \$400 million. This \$92 million represents 1.1% of the NIH extramural research budget. Thus the NIH expends 1% of its budget on a behavior that, according to several sources accounts for 20% of all mortality in the US. To make matters worse, this report found that tobacco research funding has increased only slightly over the last 10 years. A prior study that found the amount of published nicotine research has stopped growing in the last 10 years¹. Thus, the recent low level of funding for tobacco control research appears to have resulted in fewer scientific advancements to assist in tobacco control.

This report found that only 50% of tobacco/nicotine research at NIH was in traditional investigator-initiated research grants. Typically such grants comprise more than 75% of an institute's budget. The small

percent for investigator-initiated research was due to the funding of large contracts for clinical trials. This can be problematic, as most of the breakthroughs in medical and psychological science have come not from institute-directed contracts but via investigator-initiated research.

At NIH tobacco research has been spread across 18 institutes. No single institute has been designated as responsible for tobacco research. There has been almost no intramural research on tobacco. There has been no plan coordinating research across institutes. NIH has had few tobacco experts. For example, assignment of tobacco control grant applications to NCI vs NHLBI vs NICHD vs NIDA is often whimsical. The report concluded that nicotine/tobacco research at NIH is underfunded, uncoordinated, and has no current prospects of improving.

Other Governmental Agencies

Several other governmental agencies deal with tobacco control: i.e., the Food and Drug Administration, the Center for Disease Control and Prevention, the Federal Trade Commission, the Occupational, Safety and Health Administration, the Environmental Protection Agency. When this author contacted all these agencies, with one exception, none were conducting any substantial tobacco control research. This is problematic as the missions of these agencies in regard to tobacco clearly require scientific information.

The one exception was the Office on Smoking and Health at the Center for Disease Control which spent approximately \$11 million in 1997. This agency directly surveys tobacco use and analyzes data from other national surveys. The agency has two chronic problems, slow turn around time (e.g. the smoking rates for 1995 are just now being released), and the lack of prospective, longitudinal, cohort surveys. Rapid

turnaround time is important to tobacco control to quickly assess the effects of tobacco policies and of industry activities. Prospective surveys are important, as we must follow individuals over time to understand how tobacco use/dependence develops in children, how smokers develop motivation to stop smoking, and other long-term processes.

State Funds

Several states have used tobacco excise taxes to fund nicotine and tobacco research. Although these funds have produced significant advances, the California experience shows us these funds can be diverted to other uses. Also, since these funds are restricted to scientists who reside in the state, in smaller states they often do not fund a breadth of research.

Nonprofit Organizations:

Exactly how much nonprofit foundations fund tobacco research is unclear. In fact, much of the innovative applied research and policy research on tobacco now comes from foundations and the states.

Pharmaceutical Companies:

The amount pharmaceutical companies spend is typically deemed confidential information, but this author estimates they spend at least \$25 million per year. Although the majority of this is spent on drug development per se, a substantial minority of the funds goes toward neurobiological and behavioral studies of nicotine dependence, surveys on smoking cessation, etc. This author foresees no dramatic increases or decreases in the amount of pharmaceutical-based research in the near future.

In summary, the major problems for tobacco control research at this time include:

- inadequate funding at NIH and other governmental agencies relative to the amount of mortality and morbidity due to tobacco and the large proposed changes in tobacco policy
- lack of advocacy for smoking research within NIH and a lack of coordination across NIH institutes and between NIH and other concerned government agencies
- within NIH, overuse of large contracts at the expense of investigator-initiated research

EVALUATION OF PROPOSED LEGISLATION

S. 1530 - "PROTECT Act," Sponsor: Sen. Hatch

Description: Section 521 of this bill describes a 25 year "NIH Trust Fund for Health Research" and Section 101 defines research and the amount of allocation. Section 101(c)(2) proposes \$2.15 billion for the first year and then increasing amounts until \$4.0 billion in the 5th year and for the remaining 20 years. In comparison, in 1995, NIH expended \$92 million on nicotine/tobacco research. Section 101(c)(3)(B) defines research as "biomedical and behavioral research into the causes of tobacco use, diseases and conditions associated with tobacco use and other substance abuse dependencies, and the development of therapies for such diseases and conditions."

Section 521 specifies that 2% of the yearly amount go to the NIH Directors Office, 2% for the NIH Revitalization Act, 1% for health communications, 10% for national cancer research and demonstration centers, and the remainder (85%) to NIH institutes in the same proportion as their percentage of federal NIH budget for each of the 25 years. Section 521(d) has NIH, in collaboration with

FDA, CDC, SAMSHA and ONDC prepare a "National Tobacco Research Agenda" on "tobacco-related illnesses and diseases and conditions related to other abuse substances" within 1 year of the act. The section lists several areas to be included and calls for a "special emphasis on youth tobacco use." Areas include research on "factors that are related to. . . the development of tobacco-related diseases, research "of the same type" for "other abused substances such as illicit narcotics" and research on "brain development in the early years of life."

Analysis: The bill is vague in regards as to whether the Trust Fund is to fund only tobacco-related projects or all types of biomedical research. Although Section 101 defines research only in regards to tobacco, Section 521 designates funds for the Office of Dietary Supplements, the Office of AIDS, etc. In addition, the act has the money divided across institutes in proportion to current funding, which would not make sense since NIH institutes are based on diseases, some of which are highly related to tobacco and some of which are not.

Even if the bill is interpreted to support only tobacco research, the definition of tobacco research includes research for "tobacco-related diseases;" thus, much of the funds may go to investigating diseases themselves independent of any tobacco related issues. In addition, the bill provides for research on "other abused substances." The intent of this may be to allow research on basic mechanisms of drug dependence as this might help understand nicotine dependence; however, the vague way its worded, it could be used to allow funding of unrelated research; e.g. behavior therapies for cocaine dependence.

In summary, as written, the bill is unclear enough that it could recapitulate the problems NIH had in making sure that AIDS research monies were actually spent on AIDS-related areas.

The amount of funding proposed may or may not be adequate. If the all \$2-4 billion per year is used for tobacco research, this would be a 20-40 fold increase over current NIH spending on nicotine/tobacco (\$92 million per year). If so, it would be prudent for the Secretary to spend a large amount of this money in training grants, as this amount of funding probably exceeds the present pool of expert tobacco researchers. If the total is for generic research, and we assume that NIH continues to expend 1% of its budget on nicotine and tobacco, this would be an extra \$20-40 million, or an increase of only 20-40% over current NIH spending. This would be quite inadequate.

The bill provides for the development of a national tobacco research plan to define needs but does not include language directing the NIH director to report on how the NIH is or is not fulfilling the plan.

S. 1492 - "Healthy and Smoke Free Children Act," Sponsor: Sen. Kennedy

Description: Sections 101 (B) 2821-2826 describe a "National Biomedical, Basic and Child Development Research Board." The 9 voting members of the board have "expertise in biomedical research, basic research, child development, and medicine" and have 6 year terms. The board "shall award grants . . for the expansion of basic and biomedical research and to provide graduate training with respect to such research" but may delegate all or some of this authority to DHHS, Education, NSF or "any other Federal agency." The Board may give grants directly to federal agencies or to universities, research centers, foundations, etc. The graduate training may be for both graduate students and postdoctoral fellows under NSF/NIH programs, for loan forgiveness programs, for equipping postdoc labs and to "enhance the teaching capabilities of fellows seeking careers in academic teaching settings." The amount for this research and

training is 50% of 57% (ie. 28.5%) of the extra revenues from the \$1.50 excise tax, or approximately \$8 billion per year.

Another 10% of the 57% (5.7%) goes to "children's research, training and demonstration projects." These are not tobacco-related research funds.

The bill also provides funds for "reduction and addiction prevention research" to discourage tobacco use and assist in quitting to be allocated by the Secretary of DHHS. The amount is \$100 million in 1998 and then increases annually based on the Consumer Price Index (CPI).

Evaluation: This bill uses tobacco excise tax for two types of research. The first is presumably for generic biomedical research. For this research, the bill does not use the current NIH structure to allocate tobacco control research funds but sets up a separate DHHS board to allocate the funds not only to NIH but other federal agencies, etc. I could not find provision as to how board members are chosen, whether these are governmental or independent scientists, etc. This is important, as these board members will have to decide if tobacco control should receive a disproportionately large share of the funds or if tobacco control should receive none since there is a separate fund for tobacco research (see below). A conservative estimate is to assume that about 1% (NIH's current allocation to tobacco research) or \$80 million per year of this fund would go toward tobacco research (currently, NIH expends about \$92 million).

The second type of research is for research to discourage use and encourage cessation. How this \$100 million is to be spent is not specified and it will be up to the Secretary of DHHS to determine how much of this is spent on basic research understanding tobacco use/dependence, applied prevention/treatment research, policy research, and other categories.

Thus, a conservative estimate is that the total amount of funding would be an extra \$200 million per year; essentially, tripling the current NIH budget. This is a significant improvement of current policy; though more is needed to meet the nation's needs regarding tobacco control research.

S. 1414 - "Universal Tobacco Settlement Act," Sponsor: Sen. McCain

Description: Section 516 establishes a "National Cessation Research Program" to develop interventions to "discourage tobacco use and to help users stop." The Secretary of DHHS controls the \$100 million per year for this fund.

Evaluation: This bill appears to provide research monies only for applied prevention and treatment research and not for basic science research on the causes of tobacco use nor on policy research. How it will be administered is not defined. The amount is equivalent to doubling the NIH budget on nicotine/tobacco research. There is no funding of non-NIH agencies nor mention of a transagency board.

S. 1648 - "PAST Act," Sponsor: Sen. Jeffords

Description: Section 2851 directs the Institute of Medicine to develop a research agenda for research on tobacco use, and health consequences from tobacco. It specifically calls for consideration of research in prevention, addiction, health services, surveillance/ epidemiology and prevention/ treatment of tobacco-related diseases. Section 2852 establishes a National Tobacco Task Force, set up by DHHS, to include the Surgeon General, representatives from OSH, AHCPR and NIH, and outside representatives from public health and tobacco organizations. The Task Force is charged to "coordinate and advise tobacco-related

research activities," disseminate research findings to the states and report on research annually to the Senate. Section 2853 sets up a Tobacco Settlement Trust Fund of from \$1.45-3.45 billion per year for research funds for 10 years to CDC for surveillance/epidemiology and to "develop tobacco control and prevention strategies." Section 2854 directs \$2.5 billion per year for 1999 to 2008 to NIH for research on the "causes of tobacco use, disease and conditions associated with tobacco use and the development of treatments." The bill specifies that 40% of the funds go to NCI and 30% to NIDA.

Evaluation: Using the IOM to generate a report on tobacco funding is an excellent idea, as the IOM has often served as a good faith broker in such situations. Sections of the bill lead to confusion as to whether the intent is to fund only research on tobacco use (ie. on prevention, treating and understanding tobacco use) or this research plus research on the consequences of tobacco use (e.g. cancer, heart disease, etc) or not. This vagueness can allow NIH to spend 80% on basic research on cancer, atherosclerosis, etc and only 20% on tobacco use. Another concern is that \$2.5 billion per year (see p 172) for NIH research is simply too much money to be spent all at once on tobacco use research. There are simply not enough qualified researchers to spend this amount of money wisely. Thus, some mechanism to slowly ramp up funding over time, through a trust fund or other means, is needed. During this time, training grants could be used to increase the number of qualified researchers. In addition, no research money is allocated to FDA, OSHA, FTC, and a number of other agencies that need research support. The idea of a task force to foster coordination not only across government agencies but with representation from non-governmental private organizations is a very good one. In addition, having the Task Force do some technology transfer of research results

to the states is an excellent use of this group.

The FDA needs to be added to the Task Force. FDA may have been omitted because they traditionally do not do research; however, this should be outweighed by the factor that they are the one agency that has the greatest need for research findings. The bill should not specify to NIH the percentages to go to institutes. This should be left to the Task Force, who has more expertise and can respond to any changes on a year to year basis. In fact, this allocation could be dependent on the Institute's performance with the prior year's allocation.

S. 1638 - "Healthy Kids Act," Sponsor: Sen. Conrad

Description: Section 121 establishes a "NIH Trust Fund for Health Research" to receive 21% of funds from the settlement and tobacco excise taxes. Of these funds, 2% goes to fund the Director's Office, 2% to the National Center for Research Resources (2%), 7.5% for cancer research, 7.5% for tobacco research (see the description of Section 601 below), 1% for CDC prevention programs (unspecified as to whether on tobacco or not), 1% to AHCPR (unspecified as to whether on tobacco or not) and the remainder (79%) to NIH for general research.

Section 601 directs the DHHS Secretary to expand research on how tobacco causes disease, methods of reducing negative effects of products, addictive effects of nicotine, prevention and treatment of tobacco-related diseases and pharmacological treatments for smoking cessation. Section 602 provides for research on reasons that people begin and stop using tobacco. This would be funded, not by the funds described above, but rather by 10% of the 15.5% of the settlement/taxes (after taking out \$500 million for other projects.) Section 603 provides for CDC to undertake monitoring of tobacco use, specifically mentions research on price effects,

and provides funds from the same pot as the 602 money comes from (i.e. 5% of the 15.5%).

Evaluation: This bill specifically defines the different types of tobacco research; i.e. it earmarks monies for research on tobacco diseases (Section 601), tobacco use (Section 602) and monitoring (Section 603). Interestingly, addiction research, research on less harmful products and treatment outcome research, which is often thought of as on tobacco use research is not in Section 602 but is in Section 601. The bill does not contain an advisory board nor provide monies for non-NIH agencies to fund research.

CONCLUSIONS

Recommendations for legislation concerning tobacco control research are as follows:

1. The bill should make a clear distinction between biomedical research in general and research on tobacco/nicotine *per se*. Furthermore, it should make a distinction between tobacco control research (see above for definition) and research on the consequences of tobacco use.

2. Tobacco control research should be increased slowly but methodically. The recommended goal is to double the NIH budget in the first two years (to \$200 million per year), \$400 for million per year in each of the following two years, and then \$600 million in the third year, and then increase by the CPI thereafter. This slow increase is necessary as there is currently a limited pool of excellent tobacco/nicotine researchers. Initial monies could be heavily weighted to training grants to train students and non-tobacco researchers in how to do tobacco/nicotine research. \$600 million per year would still represent only

about 5% of the NIH budget.

3. Research funds should go both to NIH and other federal agencies. It is imperative to give FDA money to research the predicted and actual effects of nicotine regulation of new tobacco industry products, etc. It is imperative to give CDC money to be able to quickly track changes in youth and adult smoking due to industry activities and to federal, state, and local policies. It is also imperative to give the FTC, EPA and OSHA money to do independent studies of the actual contents of tobacco products and the actual effects of secondhand smoke.

4. A panel of tobacco control scientists should advise the Secretary of DHHS on how to allocate money to both NIH institutes and to non-NIH agencies. The board should also be charged with preparing a National Tobacco Research Agenda and updating this at least every three years. The board should not have control in how each federal agency/institute spends the money, but it should report to the Secretary on the appropriateness of use of the funds (e.g. how much is going to investigator-initiated research, how much to policy research, and other key criteria).

The table on the next page compares and evaluates the five pieces of legislation on fulfilling the above recommendations:

Table 1

	<i>S.1530</i>	<i>S.1492</i>	<i>S. 1414</i>	<i>S.1648</i>	<i>S.1638</i>
Distinguishes between biomedical and tobacco control research	Unclear	Yes	Yes	Yes	Yes
Funds to \$200-600 million per year	Unclear	Barely	No	Yes	?
Funds to non-NIH agencies	No	Yes	No	No	No
Trans-agency advisory board	Yes, but no power	Yes	No	Yes	No

ADDENDUM: EXAMPLES OF IMPORTANT TOBACCO CONTROL RESEARCH NEEDS

1. Epidemiology of tobacco use/dependence within the last 6 months
2. Experimental research on the predicted effects of proposed federal, state and local policy initiatives
3. Field research/evaluation of the actual impact of federal, state and local policies on tobacco use
4. How nicotine dependence develops, why teenage tobacco use is not declining and what to do about it
5. Prevention and treatment of tobacco use among disadvantaged populations including the poor, the less educated, certain ethnic groups and those with psychiatric and alcohol/drug problems
6. Neurobiological, behavioral and sociocultural causes of or predispositions toward nicotine dependence
7. New behavioral and pharmacological treatments for smoking cessation, especially among youth
8. Advisability of programs or products to reduce tobacco intake in those unwilling or unable to abstain
9. Addictiveness of and harm from cigar use
10. Regular assessment of the toxin content of all tobacco products, assessment of accuracy of smokers perceptions of harm from "light," low tar/nicotine cigarettes
11. Neurobiological and behavioral effects of tobacco and nicotine exposure during pregnancy on the child
12. Whether reducing the nicotine content of cigarettes would decrease smoking initiation, prevalence or toxin exposure

NOTES

¹ Hughes, John R and Anthony Liguori. (1997). "Bibliographical analysis of research on smoking cessation therapy." Tobacco Control 6:111-114.

**HEALTH
SCIENCE
ANALYSIS
PROJECT**

Policy Analysis No. 3

**INTERNATIONAL INTERESTS
IN U.S. TOBACCO LEGISLATION**

By

John L. Bloom, J.D.
Tobacco Policy Consultant

April 14, 1998

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The author also serves as Manager of International Issues for the National Center for Tobacco-Free Kids. This article was written in his capacity as an independent policy consultant, and he is solely responsible for the views expressed.

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INTERNATIONAL INTERESTS IN U.S. TOBACCO LEGISLATION

by John L. Bloom, J.D.
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EXECUTIVE SUMMARY

U.S. tobacco policy will have significant effects on tobacco control efforts worldwide. International concerns should be carefully weighed as Congress considers tobacco legislation and should be addressed to the extent possible. A responsible U.S. policy should include the following measures:

Support for tobacco control efforts internationally. Supporting international tobacco control efforts is one of the most cost-effective public health strategies in the world. Nevertheless, the U.S. has no major public or private programs in place to help promote tobacco control abroad. New legislation could correct this serious oversight. Funding in the range of \$300 million per year should be divided between public sector and private sector strategies. Private sector funding should be used to create an independent nongovernmental organization to coordinate and fund private sector efforts. Four of the five bills introduced in 1998 include these provisions, but only S. 1415 provides adequate funding for international efforts.

End U.S. government support for tobacco interests overseas. The recently passed Doggett Amendment now prohibits the departments of Commerce, State and Justice from using government funds to promote tobacco products, and prohibits employees from opposing tobacco control measures in other countries. Any comprehensive bill should strengthen the Doggett Amendment to make public health considerations of primary

importance in U.S. tobacco trade policy and require HHS to make a public health finding before the U.S. takes any action against tobacco-related laws in other countries.

Restrict harmful U.S. tobacco company behavior. Numerous proposals are under consideration to restrain U.S. tobacco company marketing, sales, manufacturing and labeling practices overseas. Such proposals are subject to objections that they will be difficult to enforce. Several proposals appear to address concerns about U.S. jurisdiction and enforcement to the extent possible. While it is unclear whether these provisions would have a strong effect directly, they uphold important moral principles and could stimulate tobacco control efforts in other countries.

Other proposals. Other important proposals would retain current FDA authority over tobacco product exports; stop international tobacco smuggling of U.S. exports; protect the interests of foreign parties whose right to sue tobacco companies in U.S. courts could be lost as part of a legislative trade-off that only benefits U.S. parties; provide tax incentives for U.S. tobacco firms that observe minimum public health standards in their overseas operations; assess a fee on tobacco companies to support international tobacco control efforts; and require tobacco companies to develop company-wide programs to ensure compliance with public health and anti-smuggling laws in the U.S. and abroad.

INTERNATIONAL INTERESTS IN U.S. TOBACCO LEGISLATION

by John L. Bloom, J.D.
Tobacco Policy Consultant¹

"It bothers me that we want to stop American kids from smoking, yet we don't seem to have the same degree of concern about Asian or African kids."

- Senator John McCain, (R-Arizona)²

INTRODUCTION

Fewer than five percent of the world's 1.1 billion smokers live in the United States. How will U.S. tobacco policy affect the other 95 percent? This is one of the most important and least discussed questions raised by the ongoing debate over U.S. tobacco policy. From a global perspective, the ultimate measure of U.S. tobacco policy is how well it advances public health worldwide.

This paper focuses on specific legislative provisions that may directly address international public health interests. Examples of these provisions include measures to reform U.S. tobacco trade policy, allocate significant funds for international tobacco control efforts, prevent international smuggling of U.S. tobacco products, and require U.S. companies to observe minimum public health standards in their overseas operations.

U.S. tobacco policies aimed primarily at the domestic market also may provide substantial benefits for other nations. For example, innovative and effective tobacco control laws in the U.S. can serve as models and precedents in other countries. Disclosure of tobacco industry documents, admissions and concessions by U.S. tobacco companies, media attention, funded research and other

advances resulting from strong U.S. legislation also would be of tremendous value internationally. These potential benefits will not be explored in detail in this paper, but the international interest in these issues should be considered as they are debated in Congress.

Because a strong U.S. tobacco policy has direct and indirect benefits for the rest of the world, the international public health community has a legitimate interest in seeing that U.S. policy is as strong as possible, and that international interests are not unnecessarily compromised in the legislative process. Public health leaders outside the U.S. have spoken out forcefully on the importance of including provisions to address international concerns as part of any national tobacco legislation. As the proposed settlement between state attorneys general and the tobacco industry was being negotiated in June, 1997, tobacco policy advocates from 19 countries issued a joint statement urging rejection of any agreement that did not take steps to address international concerns and suggesting numerous provisions for inclusion. The proposed settlement did not include any measures to support international tobacco control efforts.

Concern about U.S. tobacco policy was high at the 10th World Conference on Tobacco or Health in Beijing, China in August, 1997. Delegates passed a number of resolutions, including one urging the U.S. government to ensure that any tobacco control policy does not impede tobacco control efforts in other countries.

The Advisory Committee on Tobacco Policy and Public Health, chaired by former

Surgeon General C. Everett Koop and former Food and Drug Administration Commissioner David Kessler, also addressed international concerns in its final report to members of Congress on U.S. tobacco policy. The report suggested a number of specific actions for Congress and the President, including tobacco trade policy reform; creation of a nongovernmental International Tobacco Control Commission governed by public health leaders; and proactive support by the U.S. of tobacco control efforts internationally.

The Problem

Tobacco is expected to kill about 500 million people alive in the world today, including more than 200 million of today's children and teenagers.³ The total will exceed deaths from HIV, malaria, tuberculosis and maternal conditions combined.⁴ By 2030, based on current smoking rates, tobacco will kill about 10 million people annually, with more than 70 percent of those deaths occurring in developing nations.⁵

Two of the top three global tobacco companies are American. In all, U.S. companies supply about one-fifth of the nearly six trillion cigarettes smoked in the world each year.⁶ U.S. companies exported about eleven billion packs of cigarettes from U.S. plants in 1997,⁷ and manufacture more cigarettes overseas than in the United States. In 1996, more than 70 percent of cigarettes sold by Philip Morris,⁸ and 57 percent of those sold by RJR Nabisco,⁹ were sold overseas. Philip Morris alone made \$4.6 billion in profits on its international sales in 1997,¹⁰ and has increased its international sales by 80 percent since 1990, compared to a 4.7 percent increase in the U.S.¹¹

U.S. tobacco companies have used political influence to defeat tobacco control laws in many nations.¹² U.S. companies also have launched aggressive advertising campaigns designed to appeal to traditionally

nonsmoking women and children. U.S. marketing efforts typically associate smoking with the United States, affluence, sex appeal, freedom and liberation. In many markets, American companies reach youthful audiences through television and radio advertising, product placement in movies and other methods outlawed in the United States.

Historically, the U.S. government and U.S. tobacco companies have worked in partnership to expand the global cigarette trade. Using threats of trade retaliation under Section 301 of the U.S. Trade Act of 1974 ("Section 301"), the U.S. forced Japan, Taiwan, South Korea, Thailand and China to open their markets to U.S. cigarettes. Each of these countries had previously maintained an exclusive domestic monopoly over cigarettes. Tobacco use by young people and traditionally nonsmoking women has surged in each of these countries since their markets were opened. Econometric analysis shows that tobacco use rose by about 10 percent more after U.S. companies entered the market than it would have had the markets remained closed.¹³ These elevated smoking rates are expected to result in millions of additional deaths in these countries in the future.¹⁴

At least part of this increase is the result of the marketing wars touched off by aggressive marketing by U.S. companies entering previously closed markets. As Greg Connolly, an international tobacco control expert, has observed, "when the multinational companies penetrate a new country, they not only sell U.S. cigarettes, they transform the entire market. They transform how tobacco is presented, how it's advertised, how it's promoted. And the result is the creation of new demand, especially among women and young people."¹⁵

The Public Health Response

Despite the steady flow of data showing that tobacco will cause more death

than any single disease,¹⁶ there are no major programs in place by any U.S. public or private agency to help address tobacco use internationally. The World Health Organization allocates about \$60,000 per year to tobacco control from its regular budget, and provides the equivalent of one full-time position. In addition, several nations provide extrabudgetary resources to WHO totaling about \$500,000. The United States contributed about \$75,000 to these efforts in 1997.¹⁷

The World Bank and several nongovernmental organizations have developed tobacco control programs with an international dimension that are regarded as helpful but modest in relation to the magnitude of the problem. There is no well-funded organization, agency or project, public or private, focused exclusively on advancing tobacco control internationally.

Several nongovernmental organizations spend several hundred thousand dollars per year on international tobacco control efforts. While this amount compares favorably with governmental efforts, it has proven insufficient to have a meaningful impact on global tobacco consumption.

How International Interests Can Be Advanced Through National Legislation

It is often said that the U.S. cannot, by itself, solve the tobacco problem for the entire world, and that other countries must confront tobacco addiction as the U.S. and some other developed nations are doing. This is undeniably true.

It is equally true that there are legislative measures the U.S. can take that could have significant health benefits for the rest of the world. The role played by U.S. interests in creating this global health problem increases the moral obligation to help address it. Thus, while the U.S. cannot solve the tobacco problem worldwide, there are steps it can and should take that are consistent with

U.S. domestic policies and with the nation's position as a world leader and supporter of public health.

Special attention to supporting tobacco control in developing nations is justified as part of any policy because tobacco use is rising in these countries as it declines in developed markets. Developing countries also are in greater need of assistance because their legal and public health systems are least equipped to deal with the sophisticated marketing and lobbying tactics of transnational tobacco companies, because they have greater difficulty mounting effective public education and cessation programs, and because they can least afford the resulting increases in medical care costs and lost productivity from tobacco-related death and disease.

Specific policy measures designed to benefit other nations fall into three categories:

- *Supporting tobacco control efforts internationally.* Measures in this category include technical assistance and funding to support public education, research, policy reform and cessation programs in other countries analogous to those planned and underway in the United States.
- *Ending U.S. government support for tobacco interests overseas.* U.S. officials have a long history of supporting tobacco industry marketing, promotion and lobbying efforts overseas. There is a need to strengthen and extend the current prohibition on use of government funds for these purposes, and to adequately train diplomats and trade policy personnel in compliance.
- *Reducing harmful U.S. tobacco company behavior overseas.* These measures aim to prohibit, tax, regulate or otherwise restrain harmful U.S. tobacco company behavior overseas, such as marketing aimed at children, selling cigarettes without

adequate warning labels, enhancing the addictiveness of tobacco products through the use of additives, and making misleading health claims. While this approach appears to address important concerns most directly, it raises difficult questions about jurisdiction, enforcement and evasion that will be discussed in "Controlling Harmful U.S. Tobacco Industry Behavior Overseas," below.

Status of Legislation

As of early April, 1998, eight "comprehensive" bills have been introduced in Congress:

- S. 1415 as amended and passed by the Senate Commerce Committee on April 1, 1998. This bill includes strong international provisions that are the subject of ongoing negotiations with Senators from tobacco-producing states.
- S. 1889, introduced by Senators John Chafee (R-Rhode Island), Tom Harkin (D-Iowa) and Bob Graham (D-Florida). This bill includes strong international provisions, although not as many as S. 1415.
- S. 1638, introduced by Senator Kent Conrad (D-North Dakota) on behalf of the Senate Democratic leadership. This bill also includes strong international provisions.
- H.R. 3474, introduced by Congressman Vic Fazio (D-California) on behalf of the Democratic leadership of the House of Representatives. This bill contains international provisions identical to S. 1638.
- S. 1648, introduced by Senator James Jeffords, (D-Vermont). This bill contains

no international provisions due to jurisdictional concerns, according to Senator Jeffords' staff.

- S. 1530, introduced by Senator Orrin Hatch (R-Utah). This bill does not address international issues.
- S. 1492, introduced by Senator Edward Kennedy (D-Massachusetts). This bill does not address international issues due to jurisdictional concerns, according to Senator Kennedy's staff.
- S. 1414 as proposed in 1997 by Senator John McCain (R-Arizona). This bill follows the June 20, 1997 proposed settlement between state Attorneys General and the tobacco industry and does not address international concerns.

This paper will focus special attention on the bills introduced so far in 1998, of which four out of five include significant international provisions.

SUPPORTING TOBACCO CONTROL EFFORTS INTERNATIONALLY

Significant funding to support international tobacco control efforts is perhaps the most concrete and effective international provision that could be included in tobacco control legislation. Supporting a level of tobacco control activity that is appropriate to deal with the worldwide problem is a tremendous undertaking. The World Health Organization, World Bank and many other public and private organizations are providing some assistance to developing nations for tobacco control programs, and aspire to provide much more. However, funding from these organizations has never exceeded more

than a few hundred thousand dollars per year, an amount easily dwarfed by the multi-billion dollar marketing efforts of the tobacco industry.

The proposed settlement between the Attorneys General and U.S. tobacco companies did not include any earmarked funding for international activities. It was reported by participants that the tobacco industry, and BAT Industries in particular, took a very hard line against such funding. BAT, the parent company of U.S. tobacco company Brown & Williamson, does more business in developing nations than any other tobacco company.

The impasse in negotiations over funding for international tobacco control was reportedly resolved by including an additional \$50 million per year in unallocated funds to the Department of Health and Human Services, with the expectation that the department would use the funds for international tobacco control purposes. Despite this informal agreement, it seems likely that the tobacco industry will use what influence it has to oppose significant funding for international tobacco control efforts, and to impose harmful limitations on any international funding that is provided.

Legislation Should Support Public and Private Sector Approaches

Tobacco use is a complex problem that must be addressed in many ways, both domestically and internationally. Debates over whether to fund public education, cessation or research, and whether to provide funding through nongovernmental organizations, federal agencies or multilateral agencies such as the World Health Organization (WHO), World Bank and UNICEF, miss the point. All of these approaches and channels should be funded to make a meaningful difference.

Support for nongovernmental organizations (NGOs). NGOs tend to be more entrepreneurial, less bureaucratic, and less subject to political interference than most governmental bodies. They often are able to produce results more quickly and to work more easily with other private sector actors, including the media, the business community, the religious community and private universities and research institutions. U.S. NGOs receive significant government support for their work addressing HIV/AIDS and other public health issues, international development, emergency relief and democracy-building. NGOs should play an equal if not greater role in international tobacco control, complementing the equally important work of federal and multilateral government agencies.

No major NGO is focused exclusively on international tobacco control. There are, however, NGOs in every region that could deliver effective tobacco control programs with appropriate funding and oversight. Some are already working on tobacco control, but without appropriate funds; some are working on other public health issues and could integrate tobacco control programs if funding were available. To put significant funding to work effectively, there is a need for an independent NGO to focus intensely on this issue and to serve as a focal point for NGO efforts. Such an entity should focus on private sector approaches and fund activities on the basis of the best data without any bias toward any single organization, individual or approach.

Proposals to create such an entity are included in most pending bills. The proposed NGO, called the American Center on Global Health and Tobacco, or ACT, is modeled after the National Endowment for Democracy, which is funded by Congress to support democracy-building activities overseas. This proposal is included in S. 1415, S. 1638, S. 1889, and H.R. 3474.

Under all of these bills, ACT would be required to maintain a small staff and to work primarily through established NGOs and public health experts in the U.S. and abroad. ACT would be governed by an independent board including leaders of U.S. public health organizations. ACT also would maintain an International Advisory Council of experts in relevant fields from around the world.

Support for international agencies. WHO, UNICEF, the World Bank and regional development banks play decisive roles in advising and funding health programs and policies in developing countries. Their potential to stimulate strong tobacco control efforts worldwide should not be underestimated. Historically, these agencies have been politically constrained by fears that tobacco industry allies in Congress would reduce their overall funding if they took serious action to address tobacco use internationally. Rather than restraining these agencies from fulfilling their missions, the U.S. should provide substantial funding and strong support for their international tobacco control efforts.

Support for U.S. federal agencies. All federal agencies involved in health issues, diplomacy and economic and trade policy have a role to play in assisting and stimulating effective tobacco control efforts overseas. Relevant HHS agencies include CDC, FDA, the National Institutes of Health, the Surgeon General, the offices of the Secretary and Assistant Secretary for Health, and the Substance Abuse and Mental Health Services Administration. Relevant agencies outside of HHS include the Department of the Treasury through its involvement with the World Bank system, and the Department of State, which has expertise in developing and negotiating international agreements and also oversees the Agency for International Development and the U.S. Information Agency. All of these

entities can play important roles if they are provided the resources and the mandate to do so.

Avoiding Pitfalls in Legislative Drafting

Minimizing political interference and bureaucracy. There is widespread concern that tobacco industry allies will attempt to sabotage any new programs by attaching unnecessary limitations on the activities that can be funded and imposing bureaucratic procedures designed to stifle action and delay progress. Legislators and advocates should guard against any proposals or amendments that would impose limitations on these programs that are not imposed on other analogous programs. Any appointments to public or private advisory boards or commissions should be strictly limited to qualified candidates with relevant expertise and a demonstrated commitment to international tobacco control.

Flexibility of health agencies to work in different ways in different countries is especially important in international work. For example, similar public education activities may be most effectively delivered through NGOs in some countries, through government agencies in others, and through both channels in many other countries. For this reason, Congress should allow public and private health agencies to coordinate their activities with as few constraints as possible. As a general rule, public health will be best served if Congress provides funds and fiscal oversight to legitimate and responsible public health authorities and allows those authorities to develop appropriate strategies, tactics and coordination.

Nowhere is the concern about potential political interference greater than in the provisions creating ACT, the independent NGO. ACT will only be as effective as its staff and Board of Directors. A qualified, strategic, nonpartisan Board free of political influence is

critically important. There are several options for accomplishing this:

- Providing for appointment of the original Board by the Secretary of HHS. This is consistent with the U.S. Constitution, which vests the Executive Branch with the power of appointment, and also places responsibility with the agency with relevant expertise. This is the approach taken by S. 1638 and H.R. 3474.
- Legally creating ACT prior to passage of the legislation, with an initial board of widely respected nonpartisan public health leaders. This could prove to be a less controversial approach than one that directly involves Congress or the Administration in the appointment process.
- Specifying in the legislation an initial Board that is acceptable to Congress.

None of these options guarantee that an ideal board will be selected. However, these approaches would minimize partisan influence to the extent possible.

It is also important that future Board appointments be filled by the existing Board, just as they would be in any other NGO. Continued political involvement in the appointment process would be contrary to the independent, nonpartisan mission of ACT. For the same reason, funding for ACT should not be subject to annual appropriations. Congress should retain complete fiscal and legal authority over ACT, but should rely on ACT's independent Board for substantive oversight, intervening only if significant problems arise.

Funding should be appropriate in light of the magnitude of the problem. The amount of funds that could be justified in addressing tobacco use worldwide is quite large. Billions

of dollars are needed for effective community-level programs, mass media and cessation, to name just a few components of a comprehensive global effort. While allocating billions of dollars per year may be justified as a matter of policy, it is not politically realistic. However, it would be reasonable and appropriate for Congress to allocate at least two percent of new revenue raised by any tobacco bill to public and private international tobacco control efforts. This would provide at least \$300 million per year in the case of legislation that raises \$15 billion. These funds should be placed in a trust fund account with no artificial spending deadlines. To minimize political and governmental interference in the affairs of ACT, the independent NGO, its funding should not be subject to annual appropriations.

Evaluating Proposals To Support Tobacco Control Internationally

Four of five bills introduced in 1998 include funding to support international tobacco control through public and private sector efforts. (S. 1415, S. 1638, S. 1889 and H.R. 3474.) Each bill provides funding to HHS for governmental and multilateral agency programs, and provides separate funding to create ACT. Significant points about these proposals include the following:

- In all bills except S. 1415, funding for international efforts is unjustifiably low. S. 1638 and H.R. 3474 provide about \$60 million per year; S. 1889 provides \$100 million per year. Both amounts are much less than one percent of revenue raised by these bills. S. 1415 provides a separate financing mechanism – a licensing fee on worldwide tobacco product production by U.S. companies – that is intended to provide significant funding, including \$150 million per year for ACT.

- S. 1415 includes specific language making ACT funds subject to annual appropriations. This language should be removed.
- S. 1638 directs that governmental funds "shall be focused on preventing the use of tobacco products by minors." While this provision does not absolutely prohibit funding programs geared toward helping addicted adults quit smoking and preventing tobacco use by women and other traditionally nonsmoking populations, it could prove to be a serious impediment depending on how it is interpreted by Congress, the Administration and the courts. This language should be deleted.

ENDING GOVERNMENT SUPPORT FOR TOBACCO INTERESTS OVERSEAS

One of the first principles that should govern U.S. tobacco policy is "do no harm." Implementing this principle in U.S. foreign policy, and particularly in trade policy, has proven much more difficult than implementing it domestically.

The U.S. government has a long history of serving as an advocate for U.S. economic interests abroad. Advocacy efforts include promoting U.S. products and companies, objecting when other countries threaten to impose regulations opposed by U.S. companies, and, in extreme cases, threatening other countries with trade sanctions for discriminating against U.S. products. Until recently, no distinction was made between tobacco and other products, and the public health implications of a pro-tobacco trade policy were considered to be irrelevant. Health officials were not consulted

in policy deliberations, and U.S. trade officials made policy decisions based largely on information supplied by tobacco industry lobbyists.

In recent years, the U.S. government has shown more sensitivity to health concerns. It has avoided overtly promoting U.S. tobacco products, and has agreed not to oppose "nondiscriminatory" tobacco control laws in other countries. This position also has been adopted by Congress through the Doggett Amendment to the FY98 Appropriations Act for the Departments of Commerce, State and Justice, the Judiciary and Related Agencies.¹⁸ The Doggett Amendment provides that:

None of the funds provided by this Act shall be available to promote the sale or export of tobacco or tobacco products, or to seek the reduction or removal by any foreign country of restrictions on the marketing of tobacco or tobacco products, except for restrictions which are not applied equally to all tobacco or tobacco products of the same type.

On February 17, 1998, the Clinton Administration issued a directive to all diplomatic posts with guidelines very similar to those articulated in the Doggett Amendment.

Despite this progress, a difference of perspective remains between U.S. health and trade officials. Health officials' chief concern is whether any tobacco-related government action is likely to add to, or reduce, disease and death caused by tobacco. Trade officials tend to focus on the motives of foreign trade officials and on the impact of a given action on U.S. business interests. The principle of nondiscrimination between domestic and imported products is so central in trade policy circles that most trade officials would view a regulation passed with a degree of protectionist intent or impact to be

illegitimate, even if it also were likely to protect public health and save countless lives. They would urge that alternative approaches be used to achieve the desired public health goals, without serious regard to whether those approaches are politically feasible. Health policy experts, on the other hand, would be more likely to say that concern for human life is a higher value, and that a law that protects public health is justified regardless of the motives of the politicians who passed the law. Congress and the Clinton Administration have not yet adopted this position.

As a result of this difference in values and perspective, neither the Doggett Amendment nor the Administration's directive would prevent the U.S. from taking action against another nation, through Section 301 of the Trade Act of 1974 or otherwise, if the Administration believes the other nation is discriminating against U.S. tobacco products. Thus, when public health and traditional rules of international trade collide, as they sometimes do, tobacco industry interests would continue to prevail.

Against this backdrop, national tobacco legislation could achieve a major advance by unequivocally giving health policy experts within HHS authority to decide whether a government action is consistent with U.S. health policy, and making this consideration of primary importance in tobacco-related trade deliberations.

In an administration sympathetic to the tobacco industry, HHS could be pressured by the White House to quietly agree to harmful tobacco trade policy actions. Thus it is important that any legislation require the Secretary of HHS to make a finding that may be publicly scrutinized before any tobacco trade action may proceed. Such a finding will shed some daylight on the process and provide an opportunity for public health groups and the media to understand what is going on within the administration and to object if appropriate.

Pending Legislation

Four of the five tobacco policy bills introduced in 1998 adopt similar provisions to directly address government support of tobacco interests. (S. 1415, S. 1638, S. 1889 and H.R. 3474.) These proposals each would:

- Extend the Doggett Amendment to all government agencies and make it permanent; and
- Prohibit any government action opposing foreign tobacco laws without a written determination by HHS that the foreign law is not a reasonable protection of public health.

By giving HHS the final word in deciding whether tobacco-related trade actions may proceed, and by forcing the issue into public view, these provisions are likely to provoke opposition from trade policy officials within the Clinton Administration and by the tobacco industry.

This proposal raises several technical questions: How would this law be enforced if government officials violated it? How would disputes over interpretation be resolved? Who has standing to sue for injunctive relief? What are the penalties for violation? What is the process for investigating complaints? The bill could be improved through specific provisions to address these issues. For example, it should allow any U.S. citizen to seek injunctive relief and to recover legal costs if successful. In the absence of specific provisions to deal with these issues, they would be resolved through the administrative and political process. For example, Members of Congress could ask for a GAO or Inspector General investigation and report on alleged abuses.

CONTROLLING HARMFUL U.S. TOBACCO INDUSTRY BEHAVIOR OVERSEAS

A central question facing any comprehensive tobacco control policy is whether, and how, U.S. legislation can help reduce the harmful behavior of tobacco companies overseas. Measures discussed thus far do not directly accomplish this objective.

The moral and public health rationale for requiring U.S. companies to fundamentally reform their marketing, labeling, manufacturing, lobbying, sales and other business practices overseas is overwhelming. The question is how this objective can best be accomplished.

Ultimately, international law must be brought to bear on this problem. Efforts are now underway by the World Health Organization and supportive governments to develop an International Framework Convention on Tobacco. This project deserves full support and substantial funding from the U.S. However, developing international law can be a slow process and participation by governments is entirely voluntary, meaning that many governments may never participate. The immediate opportunity is to bring about some level of reform among U.S. companies in the interim through application of U.S. law.

Legal Issues

Any restraint on overseas conduct by U.S. companies must address legal concerns relating to jurisdiction, enforcement and evasion.

Jurisdiction. U.S. jurisdiction over U.S. nationals and U.S.-incorporated companies operating abroad is well-established, provided that U.S. law and foreign law do not directly conflict. The jurisdiction issue becomes

complicated, however, because much of the offensive marketing in foreign countries is conducted by foreign subsidiaries of U.S.-based tobacco companies, not by the U.S. companies themselves. These subsidiaries are legally distinct entities usually incorporated in the host nation. U.S. jurisdiction over these companies is more limited than it is over U.S.-based companies or over individual U.S. citizens. However, there is strong precedent for holding the U.S. parent company responsible if it is shown to be involved in the prohibited action. For example, if executives of the parent company in the U.S. approved, ordered or assisted in the prohibited conduct of a foreign subsidiary, the parent company could be held liable. This is the approach taken by the Foreign Corrupt Practices Act (FCPA), which makes it an offense under U.S. law for U.S. companies to bribe foreign officials or to engage in other prohibited acts.

Enforcement. There is no realistic way for the U.S. to enforce U.S. law in another country. Thus any enforcement scheme must provide: (1) a mechanism for collecting information about violations that involve U.S. companies or U.S. nationals, and (2) a range of penalties that can be imposed on the parent company in the U.S. Potential enforcement mechanisms include a "bounty" or reward, for information leading to a successful action against a U.S. tobacco company, and the ability of nongovernmental entities to bring action in U.S. courts for injunctive relief and penalties, and to recover legal costs and a portion of fines imposed on tobacco companies as a result of their successful actions, similar to provisions of the False Claims Act.

A common refrain among enforcement agencies is that an unenforceable law is worse than none at all because it undermines respect for law. However, there are many examples of laws — the Foreign Corrupt Practices Act and many traffic and tax laws to name a few — that are considered worthwhile even though

only a small percentage of violations are punished. In all of these cases, the principle upheld by the law, and the deterrent value of the threat of punishment, justifies keeping the law on the books.

Evasion. If the benefits sought by the law are easily denied through evasion, the law may be of little value. For example, if restrictions could be avoided through minor adjustments in stock ownership of the companies, changes in corporate board structure, changes in domicile of a corporation, asset sales and other transactions, the value of the restrictions may be significantly diminished.

The creativity of corporate lawyers and accountants in devising strategies to evade any law should never be underestimated. At the same time, in evaluating any proposal, it is important to consider that sometimes the greatest value of a law is in the precedent it sets, the moral principle it upholds, and its exhortative and deterrent value. As the Foreign Corrupt Practices Act demonstrates, these benefits may be achieved even if a law can be evaded or is difficult to enforce.

Policy Arguments For and Against Unilateral Restraints

The main argument for unilateral restraints is that, as a world leader and the top exporter of tobacco products, the U.S. has an obligation to do what it can to ensure that its tobacco companies meet minimum standards of conduct abroad, both as a matter of public health and to avoid creating ill-will toward the United States that could damage U.S. foreign relations.

Opponents of unilateral restraints argue that it is unreasonable to require U.S. companies to obey U.S. health standards in countries in which they are in competition with companies not bound by the same rules. They will say these restrictions will cripple

U.S. companies and cost the U.S. economy billions of dollars in lost earnings, without any significant public health benefit because foreign companies will continue marketing aggressively even if U.S. companies do not. These arguments have strong political appeal, and are the single greatest challenge to any proposed unilateral restraint.

How valid are the opponents' claims?

Fairness. The claim that it is unfair to impose restrictions on U.S. companies in markets where their competitors are not similarly restrained presents this question: Are we more concerned by the unfairness to children and other targets of harmful marketing practices of allowing U.S. companies to continue those practices, or are we more concerned about the unfairness to U.S. companies of requiring them to abide by marketing standards that do not apply to their competitors? From a public health perspective, the answer is easy — the unfairness of the practices being prohibited is far greater.

Jobs. The claim that unilateral restrictions will cost U.S. jobs by reducing the market for U.S.-made cigarettes and by causing U.S. companies to move offshore is more difficult to evaluate. U.S. tobacco product sales overseas are growing rapidly, and the most plausible scenario is that the proposed restrictions, if they have a direct effect, would only slow the rate of growth for U.S. brands. This would not directly result in a loss of jobs, but would limit future growth. Moreover, the companies would not be likely to move offshore unless faced with extremely severe restrictions. They are strongly motivated to keep significant production in the U.S. because the political power it brings is crucial to their success in the U.S., and because the "made in the U.S.A." image brings legitimacy and an important marketing advantage in many countries. In any event, the proposals under consideration do not penalize U.S. companies

on the basis of where they grow or manufacture their products, but on the basis of how they label and market them. This provides some incentive for companies to change the domicile of the corporation, but not to move production offshore.

It is far from certain that these proposals would cause significant job loss in the U.S. To the extent that some job loss is possible, current proposals already provide extremely generous transitional funding to affected communities. S. 1415, for example, would provide approximately \$28 billion to tobacco producing communities. In the final analysis, the problem is more one of politics than policy, because it is certain that the companies will threaten to move production offshore, and many politicians will be unwilling to call their bluff on this issue.

Overall effectiveness. Would unilateral measures fail to achieve public health benefits, as opponents claim? The answer largely depends on how one defines success and failure. Certainly, as opponents will point out, competing German, Japanese and other tobacco companies will exploit U.S. restraints for competitive advantage. At the same time, the U.S. example may lead other countries to adopt stronger tobacco control measures. Seeing strong U.S.-style health warning labels, for example, may lead some countries to require that all cigarettes carry equally strong warnings. Another ironic possibility is that U.S. tobacco companies may find some success marketing themselves as "responsible" tobacco companies in other countries. Indeed, they may even lead the charge to have similar marketing restrictions placed on their competitors, just as U.S. companies led successful efforts to pass a treaty extending restrictions in the Foreign Corrupt Practices Act to other nations.

The moral and public health rationale for imposing unilateral restraints is compelling, even if the direct impact of the

restraints is marginal. The greatest challenge is in fashioning strategic measures that will have a positive impact, and in overcoming difficult, perhaps overwhelming political opposition.

Thus far in the legislative process, specific proposals have been advanced to (a) impose minimum standards for tobacco marketing and labeling, and (b) reduce international smuggling of U.S. tobacco products, and (c) retain existing FDA jurisdiction over tobacco product exports. Each of these proposals will be evaluated below.

International Marketing and Labeling Standards for U.S. Companies

S. 1415, S. 1638 and H.R. 3474 include provisions to amend the Food, Drug and Cosmetic Act to require any "U.S. concern" — broadly defined to include any agent or employee of a U.S. based tobacco company — to abide by the same rules regarding sales to minors, marketing and health warning labels in their international operations as they do in the U.S. Health warning labels would be in the primary language(s) of the country in which the products are sold. Authority to issue regulations implementing the law is delegated to the Secretary of Health and Human Services. The Secretary is given discretion, for example, to waive the health warning label requirements in any foreign country in which he or she finds that tobacco products are sold in a manner that is substantially similar to U.S. federal requirements, and that the foreign labeling requirement is adequately enforced.

These provisions would be enforced through existing civil and criminal penalties in the FDCA. The FDCA gives FDA authority to seize products that are in violation of the Act, to cite companies for violating the Act, and to prosecute or seek injunctions if warranted. The bills enhance enforcement by

providing an incentive for private citizens to bring violations to the attention of the FDA by awarding half of the criminal fine imposed for a violation (up to \$125,000) to a private citizen who brings information leading to a conviction. This measure asserts jurisdiction to the maximum extent possible under U.S. law and allows the Secretary of HHS to issue regulations and grant waivers to ensure that there is no conflict between U.S. regulations and those required by other nations.

Measures To Reduce International Smuggling of U.S. Tobacco Products

Concern about the potential for significant tobacco smuggling into the United States has been high throughout the tobacco policy debate in Congress. What has been largely overlooked is that the U.S., through its cigarette exports, is fueling an international black market that creates law enforcement, revenue and public health problems worldwide. Researchers estimate that about one-third of all cigarette exports disappear into the black market.¹⁹ International brands such as Marlboro, Camel and Winston are the most commonly smuggled. Ultimately, international agreements are needed to sharply reduce smuggling rates. In the meantime, however, there are significant steps the U.S. can take unilaterally.

S. 1415 includes a detailed proposal to address tobacco smuggling issues domestically and internationally by providing broad authority to the Bureau of Alcohol, Tobacco and Firearms (BATF) to:

- License all exporters and require appropriate record-keeping;
- Require state-of-the-art indicia on cigarette packs to allow contraband to be traced to its source

- Require exported cigarettes to indicate on the label the country of final destination.
- Require exporters to post bonds on cigarette shipments that can only be released after the cigarettes are shown to have reached their final destination.
- Require tobacco products sold on U.S. military bases and Indian reservations to be specially marked.
- Eliminate duty-free tobacco product sales and use of foreign trade zones for cigarette exports.
- Significantly expand BATF's budget to undertake these new responsibilities.

This proposal draws from experience controlling contraband in alcohol and other products, and from international experience controlling cigarette smuggling. It provides relatively broad authority to BATF to issue regulations to take advantage of new information and new technologies. While some provisions, such as those pertaining to duty-free sales and foreign trade zones, may need to be softened, the overall proposal appears to make good sense as a matter of law enforcement and public health policy.

Retaining FDA Authority Over Tobacco Product Exports

Under existing law, FDA maintains limited authority over drug and device exports under sections 801 and 802 of the Food, Drug and Cosmetic Act (FDCA). For example, the agency has the authority to prevent the export of drugs and devices that do not meet FDA performance standards unless the Secretary of Health and Human Services determines "that exportation of the device is not contrary to

public health and safety and has the approval of the country to which it is intended for export.”²⁰ The agency also requires exported drugs and devices to be labeled for export only and to be in accordance with laws of the country of destination and the specifications of the foreign purchaser.²¹

The tobacco industry is, no doubt, concerned that FDA may use its existing authority to impose on exports some or all of the product performance standards that will be required of domestic cigarettes under new legislation. Because FDA’s authority over exports is largely based on the judgment of the Secretary regarding what standards would be consistent with public health objectives if applied to exports, it is not clear how exports would be treated.

S. 1415, Section 102(j)-(l), amends the Food, Drug and Cosmetic Act to retain and clarify existing FDA authority over exports. S. 1414 and S. 1648, in contrast, each include language to remove FDA export authority. By eliminating current FDA authority over tobacco product exports, while retaining the oversight for all other drugs and devices, these bills violate the fundamental principle supported by health groups that FDA authority should not be compromised as part of any new legislation, and that tobacco products should be regulated like other drugs and devices.

Authority over U.S. cigarette exports is no small matter. Approximately one-third of all cigarettes made in America are exported, and the proportion is increasing steadily. Retaining FDA’s limited and discretionary authority over exports should be a nonnegotiable item as this issue moves through Congress.

OTHER IMPORTANT ISSUES

Additional measures that should be addressed in any comprehensive bill include:

Protecting legal rights of foreign parties. Several bills extend limited liability protection to U.S. tobacco companies in exchange for their agreement to stop harmful marketing practices and to undertake certain other obligations in the United States. Any bill that includes liability protections should also include a “savings clause” to ensure that the legal rights of foreign parties — who are not the beneficiaries of any of the voluntary undertakings by the tobacco companies — are not compromised as part of a domestic legislative trade-off. Language should be included to the effect that “nothing in this Act shall be construed to diminish the substantive or procedural rights of any party to use the U.S. legal system to pursue rights, remedies or other relief relating to harm caused by U.S. tobacco companies outside the United States.”

Tax incentives. A variety of measures could be crafted using the U.S. tax code to influence tobacco company behavior overseas. For example, the Koop-Kessler report suggested that a surtax be imposed on profits generated in markets in which tobacco companies do not observe a minimum standard of conduct. This approach uses an existing mechanism (the tax code) to provide an incentive for good conduct without prohibiting any conduct. Others have suggested making tobacco companies ineligible for the foreign tax credit with respect to any market in which they do not meet minimum standards of conduct.

Corporate compliance programs. Tobacco companies should be required to conduct company-wide programs to promote compliance with public health, anti-smuggling and lobbying laws in all the markets in which they operate.

Licensing fee. S. 1415 would impose a worldwide licensing fee on U.S. tobacco companies of two cents per pack, with the

proceeds devoted to international tobacco control efforts. While this approach has significant advantages, it includes some provisions that are of questionable legality. A better approach would be to assess the companies with a fee based on foreign income or some other measure that is not directly related to the number of packs sold overseas.

CONCLUSION

Four of the five comprehensive tobacco control bills introduced in 1998 include significant measures to address tobacco and health issues worldwide. Generally speaking, the strongest measures are included in S. 1415. Some of those measures may need to be refined to meet legal and political concerns before final passage.

A responsible U.S. policy should include the following provisions:

- Support for public sector and private sector tobacco control efforts internationally;
- End U.S. government support for tobacco interests overseas;
- Establish minimum standards for U.S. tobacco company behavior overseas or provide tax incentives for U.S. tobacco companies that observe minimum public health standards in their overseas operations;
- Retain current FDA authority over tobacco product exports;
- Stop international tobacco smuggling of U.S. exports;
- Protect the interests of foreign parties whose right to sue tobacco companies in U.S. courts could be lost as part of a

legislative trade-off that only benefits U.S. parties;

- Assess a fee from tobacco companies to support international tobacco control efforts; and
- Require tobacco companies to develop company-wide programs to ensure compliance with public health laws in the U.S. and abroad.

NOTES

¹ The author gratefully acknowledges review and helpful suggestions by David Sweanor, Robert Weissman, Simon Chapman, Alan Morrison, Karen Lewis, Mark Palmer, Sushma Palmer and Ross Hammond. All opinions reflected in this report are those of the author.

² "Health Advocates Push for International Tobacco Protections," The Associated Press, October 9, 1997.

³ World Health Organization, "Tobacco-attributable Mortality: Global Estimates and Projections," Tobacco Alert 1991, 1: 4-7 (revised October 1993).

⁴ World Bank, *World Development Report*, 1993.

⁵ Peto, R., et al., *Mortality from Smoking in Developed Countries 1950-2000, Indirect Estimates from National Vital Statistics*, New York: Oxford University Press, 1994.

⁶ *World Tobacco File, 1994*, International Trade Publications Ltd., United Kingdom, 1994.

⁷ U.S. Department of Agriculture, *Tobacco Yearbook*, U.S. Department of Agriculture, Economic Research Service, December, 1997.

⁸ Philip Morris Companies, 1996 Report to Shareholders.

⁹ RJR Nabisco, 1996 Report to Shareholders.

¹⁰ Philip Morris Companies, 1997 Report to Shareholders.

¹¹ Stancill, N., "Carolina's Flavor Moves Overseas," *The Charlotte Observer*, October 18, 1997.

¹² Frankel, G., "In Ex-Soviet Markets, U.S. Brands Took on Role of Capitalist Liberator," *The Washington Post*, November 19, 1996.

¹³ Chaloupka, F., Laixuthai, A., "U.S. Trade Policy and Cigarette Smoking in Asia," National Bureau of Economic Research, 1996.

¹⁴ Coalition on Smoking OR Health, *Trade Policy on Tobacco Exports*. Public comment on Federal Register notice (Vol., 59, No. 083, 59 FR 22714) May 27, 1994.

¹⁵ Frankel, G., "U.S. Aided Cigarette Firms in Conquests Across Asia," *The Washington Post*, November 17, 1996.

¹⁶ World Health Organization, "Tobacco Epidemic: Health Dimensions — Tobacco is a Greater Cause of Death and Disability than Any Single Disease," Fact Sheet No. 154, May, 1997.

¹⁷ Institute of Medicine, *Taking Action to Reduce Tobacco Use*, p. 22, January 1998, citing Collishaw, N., World Health Organization, personal communication, September 15, 1997.

¹⁸ Pub. L. 105-119, Section 618, also known as the "Doggett Amendment."

¹⁹ Joossens, L., Raw, M. "Smuggling and cross-border shopping of tobacco in Europe," *British Medical Journal*, vol. 310, p. 1393-7.

²⁰ Food, Drug and Cosmetic Act, Section 801(e)(2), 21 U.S.C. S. 381 (e)(2).

²¹ Food, Drug and Cosmetic Act, Section 801(e)(1), 21 U.S.C. S. 381 (e)(1).

**HEALTH
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Policy Analysis No. 4

**LIMITATIONS ON
TOBACCO INDUSTRY
TORT LIABILITY**

By

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Professor of Law
Northeastern University School of Law (on leave)

April 14, 1998

With comments by

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LIMITATIONS ON TOBACCO INDUSTRY TORT LIABILITY

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LIMITATIONS ON TOBACCO INDUSTRY TORT LIABILITY

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EXECUTIVE SUMMARY

This paper examines the potential public health impact of limiting the tobacco industry's tort liability in the context of the tobacco legislation currently being considered by Congress. Specifically, it considers the effects of the following measures, included in S. 1414, the "Universal Tobacco Settlement Act," and S. 1530, the "PROTECT Act":

- Termination of pending cases, including governmental cases and class actions, and immunity from those same claims in future cases
- Elimination of punitive damages for past conduct
- Elimination of joinder, class actions, consolidation of cases, and the trial of common issues in all pending and future cases
- Annual caps on liability, "rollover" of awards over \$1 million, and applying awards as credits against annual industry payments
- Restrictions on permissible parties to future cases (both plaintiffs and defendants)
- Prohibiting the admission of evidence about "reduced risk" products in future cases

The paper identifies three critical issues that could be affected by changes in industry liability, and evaluates the impact of the proposed liability limitations on each:

Detering Wrongful Conduct: Reducing and preventing egregious corporate conduct, such

as that pursued by the tobacco industry, is a clear goal of the tort system. Whether that system has succeeded in deterring such action in the past or not, the tobacco industry now sees the threat posed by tort liability as a major threat to its viability. Changing the system in the ways proposed could reduce this threat. But the author identifies significant current barriers to using the tort system to recover the social costs of smoking, and argues that many non-liability-related provisions in current legislation, such as advertising restrictions, would further lower industry exposure to major damage awards. In this context, liability limits would seem to have relatively little impact on the risk to the industry for future conduct based on current tort law principles. If more expansive theories of liability are adopted by the court, the risk of liability for future conduct could increase significantly.

The Risk of Bankruptcy: Some argue that major damage awards in pending and future cases could drive the industry into bankruptcy. The author explains that the aggregate outcome of such cases is extremely difficult to predict. He concludes that bankruptcy is a realistic possibility, but is improbable under current law. Enactment of liability protection would substantially reduce the risk of bankruptcy, and increase the likelihood that the industry would provide substantial payments for past damages.

This begs a broader question: what would be the impact of bankruptcy on the industry, and on public health? The author concludes that the answer is, at best, unclear. Bankruptcy would be unlikely to force the industry to stop producing tobacco products, or force stricter regulation than currently proposed in legislation. Thus, the industry could emerge from bankruptcy reorganization and resume production, unless demand for tobacco products weakened or new theories of tort liability increased the risk to the industry of future sales. Tobacco subsidiaries could be sold to new entrants who would be largely free of liability for past conduct.

Public Perception and Future Tort Litigation: One of the most important effects of litigation has been to raise public awareness – and outrage – about tobacco industry behavior. The ongoing disclosure of tobacco industry documents through litigation has been especially important in this regard. To the extent that liability limitations would discourage future cases, they could impede the flow of information about the industry, and erode public support for action against industry abuses. The author argues that while some impact on public perception would probably be lost if litigation were ended, a process for document disclosure could be enacted through legislation that would be as effective as litigation in put evidence of tobacco industry wrongdoing before the public.

In these three areas, the paper concludes that liability limitations *per se* would have a relatively minor impact on future industry behavior. But the author argues that, even if the public health community decides to oppose such limitations as an unacceptable compromise, they have a strong interest in seeing them crafted carefully. He examines the legislative provisions now before Congress and identifies a number of improvements that should be made to limit

their scope and some potential unintended consequences. Key changes include:

- **The scope of cases being terminated must be limited carefully**, to avoid disrupting cases against the industry not related to the purposes of the settlement.
- **Immunity provisions should be revised** to ensure resolution only of those claims rooted in the conduct challenged under the settled cases. Current legislation offers broader immunity than necessary to resolve current claims.
- **The law should not prohibit “simple joinder” of several plaintiffs**, such as suits by two members of the same family. In this area, the bills go beyond eliminating class actions to significantly undermine much smaller cases.
- **Damage payments should be made fairer to plaintiffs.** The liability cap should be revised upward, should include interest on awards that “rollover” to successive years.
- **Damage awards should not apply to reduce annual industry payments.** This provision further reduces the deterrent effect of tort liability.
- **Limits on permissible parties should be strictly focused on the purposes of the settlement.** As currently drafted, these restrictions would prevent many suits by private health insurers and union health funds, and could even interfere with suits by tobacco company shareholders for mismanagement.
- **Provisions barring evidence about “reduced risk” tobacco products should be eliminated**, as any legitimate purposes they serve are already covered by state and federal evidence rules.

LIMITATIONS ON TOBACCO INDUSTRY TORT LIABILITY

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INTRODUCTION

One of the most controversial aspects of the tobacco settlement, as it emerged from the negotiations, is a set of provisions limiting tort liability of the tobacco industry. These provisions go well beyond settling the pending State AG and private class actions. They also adopt a series of restrictions on other cases against the industry, both those that are now pending, and those that may be brought in the future. Two of the tobacco settlement bills, S. 1414 ("the Universal Tobacco Settlement Act", sponsored by Senator McCain), and S. 1530 ("the PROTECT Act", sponsored by Senator Hatch), adopted these provisions essentially as they emerged from the negotiations. The third bill, S. 1492 ("the Healthy and Smokefree Children Act"), contains no liability provisions.

The Limiting Liability-Tobacco Control "Tradeoff"

From the public health perspective, limitations on tort liability are not desirable in themselves, other than as an inducement to the industry to support some form of settlement. It follows that, if the benefits in the proposed settlement legislation could be obtained without the liability limitations, determining the position of the public health community on these limitations would be easy. It should support the aspects of settlement legislation that are likely to reduce smoking disease, which are significant, and urge Congress to reject all limitations on liability. In fact, the public health community should call for even stronger legislation, which includes higher

long-term industry payments, maintaining full FDA authority, and strengthening protection of minors. To a large extent, this is the approach of S. 1492, the bill introduced by Senator Kennedy.

Benefits of Continued Litigation

The failure of Congress to enact settlement legislation would mean that the state and private cases would continue. Conceivably, these cases could result in an even better outcome than settlement legislation, without requiring any revisions of the tort system. Just as the prospects for "liability-free" legislation are uncertain, however, the prospects of the state and private litigation, absent a settlement, are difficult to assess. Both sets of cases have been developed to address hurdles that have proved insurmountable to past plaintiffs. Partly as a result, both sets of cases involve untested legal theories.¹ The willingness of the tobacco industry to settle cases in Florida, Mississippi and Texas, suggests that the industry believes its litigation position is weak. On the other hand, part of the industry assessment may have been the desire to avoid damaging trial testimony, which could undermine its support in Congress even further. Thus, there is some ambiguity regarding the willingness of the companies to settle.

¹ This issue is discussed further below.

The Public Health Goal

The uncertainty about the political prospects for "liability-free" legislation and the legal prospects of the pending cases make what is already a highly complex analysis even more difficult. This paper attempts to shed some light on this complex problem by discussing the impact of the liability limitations on the goals of the public health community. For purposes of this discussion, it is assumed that the most important goal is reducing death and disease from smoking. The proposed limitations raise other important concerns as well, such as protecting the rights of individuals to recover damages and advancing social justice goals by holding individuals liable for wrongful conduct.¹ This paper is confined to discussing public health consequences.

The paper begins with a general description of the proposed limitations, and then discusses the basic relationship between tort liability and the public health. It then considers the impact of liability limitations on three tort-liability-related issues: deterrence of misconduct, the risk of tobacco industry bankruptcy, and the future public perception of the industry. This is followed by a more detailed discussion of the tort limitation provisions.

SUMMARY OF PROPOSED LEGISLATION

The major provisions of S. 1414 and S. 1530 relating to liability limitations are the following:

Termination of Pending Cases: Both bills terminate pending cases by state AG's and other governmental entities as well as pending class actions. Other private cases are allowed to continue under revised liability standards. Both bills also provide immunity for the industry in order to ensure that these

terminated claims are not pursued in the future. As discussed below, the scope of this immunity goes beyond the cases that are resolved by the settlement.

Punitive Damages: They eliminate punitive damages for all claims (pending and future) that are based on conduct that occurred prior to the effective date of implementing legislation. For example, if Congress makes settlement legislation effective on January 1, 1999, a plaintiff making a personal injury claim for conduct that occurred during the 1970's and 1980's could not seek punitive damages. On the other hand, a plaintiff who sues for fraudulent conduct occurring after January 1, 1999, could still seek punitive damages.

Joinder and Class Actions: They bar any form of joinder, including class actions, consolidations of cases, or simple joinder. This limitation applies to pending cases as well as all future cases. The primary point of this provision is to bar large class actions such as those alleging injury from addiction. However, they also bar even joinder of two plaintiffs. For example, if a spouse and a child attempt to join wrongful death claims against tobacco manufacturers, the defendants could object. Thus, this provision goes beyond the stated purposes of the settlement by erecting barriers to individual plaintiffs. The proposals would also ban the trial of common issues, a device that would be very helpful in situations in which class actions were not available.

In addition to the above effects, the class action and joinder rules would essentially eliminate all of the cases brought by union health and welfare funds, as well as those brought by the asbestos industry, where the effect of tobacco on lung cancer and other diseases is a major multiplier.

Annual Cap on Liability and Rollover Provisions: They create a cap on annual

aggregate liability judgments and settlements in the amount of 33% of the annual base payment as adjusted. (The base payment begins at \$8.5 billion then increases to a maximum of \$15 billion. These can then be revised upward or downward, depending on sales.) Thus, the total liability of all the settling manufacturers cannot exceed \$5 billion in any future year. There is also a limit of \$1 million per year for a single judgment, unless the cap is not otherwise exceeded; there is no provision for interest on any judgments that are uncollected in the year that they become final. Special provisions are included for manufacturers that are not part of the settlement.

Credit Against Annual Payment: They provide that the liability payments of any tobacco manufacturer results in a 80% credit against annual payments in the year paid. For example, if R.J. Reynolds is liable for \$1 billion in personal injury claims in 2002 and would otherwise be required to make annual payments under the settlement of \$1.5 billion that year, its annual payment obligation is reduced by \$800 million, to \$700 million.

Permissible Parties: They include a series of provisions restricting permissible parties in personal injury cases against the industry. These limit claims by third-party payors and limit the kinds of cases that may be brought against certain defendants. As discussed below, these may have the effect of interfering with suits unrelated to the purposes of the settlement. In addition, they exclude many potential defendants that could be brought into tobacco cases, including attorneys, public relations firms, and advertising agencies. These parties could have vital information that could be traded in exchange for release from liability.

Evidence about “Reduced Risk” Tobacco Products: They provide that the development of “reduced risk” tobacco products after the effective date of the implementing legislation is neither admissible nor discoverable. For example, a plaintiff in a future personal injury suit might sue under a “design defect” theory and argue that safer cigarettes are possible. In that case, the plaintiff could not obtain discovery about any developments in that area after the effective date of the legislation.

Taken together, these provisions, particularly the limitations on punitive damages and class actions and other forms of aggregation of claims, will reduce the risk of future tort liability. They essentially eliminate the prospect of massive awards in the future, e.g., \$100 million or more. They also greatly reduce the costs of any liability, by allowing the industry to offset annual payments by 80% of the amount of damage awards. Depending on how they are drafted, they may also interfere with the ability to sue the industry for a wide range of conduct, even conduct that goes well beyond the stated purposes of settlement legislation.²

These restrictions would also discourage future legal action against the industry by making it difficult for future plaintiffs to find attorneys

TORT LIABILITY AND THE PUBLIC HEALTH

Modifying tort liability can affect the public health. However, the relationship between the two is not obvious or straightforward. Three issues warrant most attention:

1. **Deterring Wrongful Conduct.** Would these proposed limitations on liability reduce deterrence of future egregious conduct by the

industry? For example, if the tort system is left unchanged, will the threat of future liability encourage the industry to be more responsible in its marketing, to develop and promote safer cigarettes, or to disclose more information to the public and government officials?

2. Risk of Bankruptcy. If the tort system is left unchanged, could future tort liability realistically lead to bankruptcy of the industry or individual companies? If so, what would be the effect on the public health? Do the liability limitations in the settlement alter these possibilities significantly?

3. Public Perception and Disclosure of Documents. Would revisions in the tort system affect the continued disclosure of industry documents and other information? Could such revisions undermine the ability of future plaintiffs to proceed against the industry, thereby foreclosing an effective mechanism for communicating the true character of the industry to the public?

Each of these issues is discussed below.

DETERRENCE OF FUTURE MISCONDUCT

Deterring harmful conduct is one of the principal goals of the tort system.³ Imposing liability on manufacturers of dangerous products can serve to "internalize" the true costs of business activity. By forcing manufacturers to pay for social costs, such as personal injuries and damage to the environment, they are forced to raise prices to cover these costs. These higher costs in turn can encourage manufacturers to make their products safer and to warn consumers of product dangers. Higher prices can also discourage consumption of products by forcing consumers to bear some of these social

costs. In theory at least, internalizing these costs means external costs such as personal injuries will be reduced, and the market will come closer to an efficient allocation of resources.

Punitive damages, that is, damages in excess of that needed to compensate injured persons, have a somewhat different rationale. The point of punitive damages is to punish an egregious wrongdoer and to discourage others from engaging in the same conduct. Only a small percentage of injured persons will successfully sue manufacturers for injuries from dangerous products. If these injured plaintiffs were awarded only compensatory damages, wrongdoers could absorb these damages "as a cost of doing business." Thus, the threat of punitive damages can serve as a powerful incentive to manufacturers to improve product safety and provide better warnings.⁴

The history of the tort system shows that the threat of liability has often changed industry behavior. For example, a wide range of industry products, from automobiles to lawnmowers to aircraft, are safer at least in part because manufacturers have been concerned about large liability judgments. This incentive influences, not only the design of products, but the availability of warnings on product labels and package inserts.

Effect of the Limitations on General Deterrence

The primary focus of the following deterrence discussion is the impact of liability limitations on the tobacco industry itself. A threshold consideration, however, is whether Congressionally imposed limitations on tort liability for one industry might have an effect that extends to other industries. For example, other industries might interpret such a Congressional policy to mean that, whenever an industry is subject to potentially massive liabilities, Congress will respond with some

kind of cap on exposure. Like the financial "bailout" of financial institutions or debt-ridden corporations, a Congressional bailout in the form of liability limitations could be viewed as signal that certain industries are too large, or too politically influential, to suffer massive losses.

It is difficult to evaluate this argument. The tobacco settlement is unlike a classic bailout, which involves a financial subsidy. Instead, it involves a cap on liabilities. In this sense, it is more akin to the special provision in the bankruptcy code addressed to future asbestos claimants.⁵ Such a provision signals a Congressional willingness to limit losses, or least act to ensure the survival of entire industry. However, from the point of view of corporate management, relying on the possibility of such protection as a rationale for failing to make product safety improvements seems extremely risky. A firm could not have a great deal of confidence that the political circumstances leading to tobacco settlement legislation would also be present in the event that it faced substantial exposure. Equally important, the settlement legislation involves substantial payments by the industry in perpetuity as well as significant new regulatory restrictions. Thus, even if Congress turns out to be willing to give an industry protection, the lesson of the tobacco settlement is that such protection comes at a price. In short, the signal sent by the settlement legislation would at best be ambiguous. For this reason, the settlement legislation, standing alone, is unlikely to affect behavior in other industries.

Deterrence and the Tobacco Industry

While general propositions about the deterrent effect of tort liability hold true for many industries, it is not clear that they apply well to tobacco. The tobacco industry has been shockingly successful in avoiding liability

throughout its history, given the extent of death and disease which is directly attributable to its products. Several explanations for this history have been offered.⁶ There appears to be general agreement among those who have studied the industry that this seeming invulnerability has been due to different factors at different periods. In the early days of tobacco litigation (sometimes called the "first wave"), plaintiff lawyers were clearly overmatched by the massive effort invested by the industry in defending against every claim. In the few cases that came to trial, courts were reluctant to conclude that the danger of cigarettes was foreseeable to the industry or that cigarettes could be viewed as defective.⁷

A later "second wave" of tobacco cases were lost for several reasons. Some courts held that traditional products liability claims, particularly failure to warn claims, were preempted.⁸ Causation was difficult for plaintiffs to establish because the relationship between smoking and disease was not clearly established.⁹ Most importantly, however, juries tended to accept the argument that smokers were aware of the risk and, thus, were responsible for their own injury.¹⁰ The view that smokers were responsible sometimes prevented recovery even though states had a "pure comparative fault" law, which allows plaintiffs to recover even if the defendant is less responsible than the plaintiff.¹¹

It is possible that the threat of tort liability may have encouraged certain members of the industry to consider developing and marketing a safer cigarette. However, even in those cases, the industry may have calculated that liability risks were increased, rather than decreased, by trying to market a "safe cigarette." There is some evidence that manufacturers were concerned that developing safer products amounted to an indirect concession smoking is dangerous. In addition, the public was not enthusiastic about

the limited attempts to market low nicotine, low tar cigarettes.

In short, during the first and second wave of tobacco litigation, the tort system appeared to have little effect on industry behavior. Despite the enormous toll of death and disease, smoking did not fit well into the established tort law paradigms developed for dangerous products. Rather than representing an occasional hidden danger, it represented a consistent deadly threat even when used as intended. In addition, juries tended to blame the smoker for engaging in such risky behavior. Ironically, perhaps, this unique situation tended to immunize the most deadly product in American history from traditional tort liability.

Some commentators have characterized the recent period of tobacco litigation as the "third wave." The third wave includes, to a large extent, the pending cases that are terminated by the settlement legislation – the large class actions based on allegations regarding addiction and the state AG cases that have alleged a breach of duty to the governmental entities themselves. These cases may have avoided the hurdles faced by plaintiffs in earlier cases. For example, the States have argued that the issue of the smokers' behavior is irrelevant since the injured parties are the states themselves, not individual smokers.¹² The addiction cases emphasize the fact that addicted smokers were not informed of the dangers of addiction, and smokers are unable to make rational decisions after they are addicted.

None of the pending class action cases has been litigated through the appellate process. Similarly, the state cases have generally not been reviewed by state supreme courts.¹³ Individual cases have something of a mixed record before juries.¹⁴ Thus, it is difficult to assess the actual risk to the industry if all these pending cases are actually litigated. To some extent, all these cases are novel, because they have been developed to avoid the

pitfalls that have plagued past cases.¹⁵ In addition to the fact that some of these theories are untested, more traditional theories, such as failure to warn, face possible preemption.¹⁶

Despite these difficulties, the industry clearly perceives that the cases are a threat to their profitability. The costs of the litigation itself, the resulting publicity, and the possibility of massive damages have clearly affected the industry's perception of the risk of tort liability. Perhaps equally important, they have resulted in a substantial reduction in stock prices due to a "risk premium" placed on these stocks by the market. These factors are probably the most powerful ones underlying the willingness of the industry to accept the limitations in the settlement. In short, the third wave of tort litigation – unlike the first or second – has had a substantial effect on industry behavior in these sense that it has influenced its willingness to accept much more extensive regulation in the context of a settlement.¹⁷

Future Conduct and Tort Liability

For purposes of analyzing the proposed liability limitations, the question is not whether the existing tort system has had a dramatic effect. The question is whether it will continue to have a significant effect on industry conduct in the future, and whether that effect would be altered by the revisions included in the legislation. The industry is still vulnerable to tort liability even if all the tort limitations included in S. 1414 and S. 1530 are enacted.¹⁸ However, the risks are clearly reduced, and the problem is to assess how this reduced risk might affect behavior. For example, is it reasonable to assume that the fear of massive tort judgments from class actions in the future would encourage the industry to engage in more responsible marketing, to develop safer cigarettes, or, in the extreme case, to stop producing tobacco products at all? To the extent that the fear of

liability would push the industry toward safer, more responsible behavior, reducing that risk could undercut those incentives. The likely effect of the tort system on industry behavior should also be compared to the behavior that would result if the settlement legislation is adopted. To the extent that these become mutually exclusive alternatives, the public health community must assess the relative desirability of these two scenarios.

Three factors suggest that the industry will be significantly less vulnerable to tort liability for conduct that takes place in the future. First, as discussed above, there have historically been considerable barriers to plaintiffs under traditional product liability standards. Some of these barriers will probably increase. For example, to the extent that awareness of the dangers of smoking undercuts plaintiffs' claims, there is clearly a greater understanding of the dangers of smoking today, including the dangers of addiction. Thus, future plaintiffs will face difficulty in establishing cigarettes are defective or in overcoming defenses that take into account plaintiffs' knowledge. It should be remembered that juries have returned only a tiny number of damage awards even when the plaintiffs in these cases began smoking before the dangers were well understood. Courts have been reluctant to conclude cigarettes are hazardous under the traditional formulation of defective products on the ground that there is general awareness of the harm from smoking.¹⁹ The recently revised restatement of tort law appears to adopt this view, though using somewhat different language.²⁰ Finally, even if all these barriers of traditional product liability standards can be overcome, plaintiffs face the risk that claims based on a failure to provide adequate warnings will be preempted.²¹

Second, the advertising practices of the industry are likely to be further constrained, particularly if settlement legislation is enacted.

The challenges to Joe Camel, the proliferation of local advertising restrictions, and the pending FDA Rule all represent efforts to constrain industry marketing. All three settlement bills contemplate substantial additional restrictions on advertising and marketing, including additional warnings. Thus, if it is assumed that the industry complies with these restrictions,²² it will be even more difficult for plaintiffs to succeed based on traditional products liability theories.²³

Finally, we are unlikely to see the kinds of egregious internal documents created in the future that have so outraged the public (and perhaps juries, though that effect is still unclear). It is fair to assume that tobacco officials will be no more or less moral than those of the past. However, the candid memorialization of attempts to mislead the public in thousands of retained documents seems unlikely to be repeated. These three considerations mean the industry is less likely to be exposed to substantial tort liability from traditional claims of fraud, failure to warn and the like, for conduct taking place in the future.

New Theories of Liability

It is still possible that plaintiffs in the future might succeed based on other tort theories that do not rely on proof of fraud, failure to warn, or hidden dangers. For example, plaintiffs in the future might sue based on a "risk-utility" theory, which holds that products are defective if their overall risks of harm outweigh their overall utility, regardless of whether there is a safer design is feasible. Some legal scholars have also argued for a related form of "enterprise liability," which would hold the industry accountable without proof that the public has been misled, that a product is "defective," or that product warnings are inadequate. There is substantial support within the academic community for

these expansive theories.²⁴ However, a sizable body of academic commentary also opposes them.²⁵

Given the cogency of the arguments for these theories and the strength of support among some segments of the legal community, there is some chance that they will become more widely adopted. It is quite possible, in fact, that the tobacco industry is willing to pay a substantial sum in part to ensure against the risk that these more expansive tort theories will be widely adopted. Uncertainty about the future of tort law makes predictions in this area particularly difficult.

Since the mid-1960's, the courts have generally come to accept the principle that liability should be imposed if a product causes injury because it is "defective" and, therefore, "unreasonably dangerous." Courts have generally agreed that there are three kinds of defects – manufacturing defects, design defects, and defects by virtue of a failure to warn. A manufacturing defect refers to an isolated case of a product that is not made as intended, e.g., a single automobile with a missing bolt. A design defect refers to an entire line of products that has been designed in a way that is particularly dangerous. A defect due to failure to warn refers to a line of products that is dangerous because the dangers are not obvious and there has been a failure to give an adequate warning of them.²⁶ Of these, a design defect theory is probably most applicable to cigarettes given the extensive federal warning requirements and the fact that failure to warn claims are preempted. Thus, future tort liability of the industry will turn to a large extent on whether cigarettes are held to be "defectively designed" even if the plaintiff cannot prove that a safer alternate design is feasible.

As the law stands today, risk-utility and enterprise liability theories have not been widely adopted by the courts. In general, courts have been unwilling to impose liability for injury from a product if the product was

manufactured as intended, there is no feasible safer design and warnings are adequate. In three cases, state supreme courts accepted the argument that a product can be defective, regardless of the feasibility of a safer design, if the overall usefulness or "utility" of the product is outweighed by its risks. Such a theory would certainly have applicability to cigarettes, given the limited nature of the "utility" of smoking compared to the enormous health risks. However, in all three of these cases, the decisions were overturned by state legislatures.²⁷

The new Restatement of Torts, finalized during May 1997, represents (in theory) a consensus statement of the law by practitioners and scholars. The new Restatement rejects new and more expansive theories of liability in favor of more traditional definitions of defective products. The Restatement endorsed a "risk/utility" assessment in determining whether a product is dangerous because of a design defect.²⁸ However, the Restatement also requires that a product cannot be found dangerously defective on this basis unless there is a feasible alternative design that would have prevented the harm.²⁹ That position appears to have been the view of the majority of the participants and the drafters of the new Restatement, who were well aware of the implications for tobacco cases.³⁰

The revised Restatement does leave some room for plaintiffs to prove that a product is dangerously defective without proof of a safer design in the case of certain extremely dangerous products. This exception appears to be an exceedingly narrow one, covering such highly dangerous products as a toy gun that shoots hard pellets. As originally drafted, the commentary explaining the exception expressly stated that cigarettes did not come within the exception. When this language came up for a vote during the last stages of the approval process, an amendment was approved deleting the reference to tobacco

products.³¹ Consequently, future plaintiffs can still argue that cigarettes come within the narrow exception. On the other hand, courts may be reluctant to conclude that the rationale for the exception extends to cigarettes.³² Overall, although there remains even within the Restatement some ambiguity about how cigarettes would fare, plaintiffs in the future will probably find it difficult to prevail on a design defect theory. To the extent that design defect claims remain a viable theory for future plaintiffs, the settlement legislation's provisions regarding discovery and admissibility of industry efforts in this area pose a serious barrier.³³

The relationship of future tort liability and the behavior of the industry toward minors is also difficult to predict. Tort claims against the industry alleging harm to minors are not limited to traditional fraud and failure to warn theories. Plaintiffs could allege various types of wrongful conduct, including marketing near places where young people congregate, and perhaps failure to restrain conventional advertising. However, if the FDA Rule is upheld, and if the additional marketing restrictions in the settlement legislation are implemented, the industry's ability to market to minors will be severely constrained. The industry may still have an incentive to hook minors.³⁴ However, if we assume that the industry complies with the restrictions on marketing imposed on it, it will probably be difficult for plaintiffs alleging harm to minors to prevail, based on traditional tort theories. That situation could also change if the courts become more sympathetic to more expansive concepts of liability.

The importance of the \$5 billion annual cap on liability to the industry shows it is anxious to limit its exposure. It seems likely, however, that motivation underlying the \$5 billion cap is the fear of cases based on conduct that has already occurred, rather than conduct

that will occur in the future. There are a large number of cases, both pending and yet-to-be-filed, that are, or will be, based on past egregious conduct. Preventing these plaintiffs from combining in class actions and from seeking punitive damages certainly affects their ability to recover. However, limiting recovery for plaintiffs who have been injured by conduct in the past does not in itself affect future conduct, one way or the other. Only the threat of liability for future conduct creates an incentive for the industry to behave more responsibly.

Summary and Conclusions

In summary, the industry may well be at its historically most vulnerable point in the risk of tort liability. It is obviously willing to pay a substantial amount to place some upper limit on liability for past conduct. However, it is difficult to predict how industry conduct in the future would be affected by the proposed revisions in tort liability. Some risk of liability – and therefore some deterrent effect – would remain, even if the limitations in settlement legislation are adopted. Plaintiffs can continue to sue the industry and can continue to seek punitive damages for conduct after the date of enactment. A single plaintiff might be able to recover a large judgment based on egregious conduct in the future. However, the 80% credit against liability goes a long way toward making even capped liability costless. Thus, one significant improvement would be to drop this 80% credit provision.

On the other hand, it is fair to say that the industry will probably not be as vulnerable to tort liability for conduct in the future as it is now for past conduct, even if none of the limitations in settlement are adopted. This conclusion does not mean that the industry officials have suddenly become responsible or that there are no longer incentives for the industry to engage in

egregious conduct. However, the greater understanding among the public, the greater constraints on industry's marketing practices, and the likely absence of a documented history of deception will make it difficult for future plaintiffs to recover large awards, at least based on existing tort theories. This situation could change if courts are willing to adopt more expansive theories of liability. Although it is by no means certain, it appears that courts remain reluctant to adopt theories of liability that would force the industry to bear all the social costs that result from smoking. To the extent that future plaintiffs face substantial difficulties in recovering from the industry under the current tort system, limiting liability will not have significant effect on future industry behavior.

TORT LIABILITY AND THE RISK OF BANKRUPTCY

Firms in some industries, for example, silicon implants and asbestos, have been pushed into bankruptcy by large number of tort claims. The number of claims pending against the tobacco industry is still far below the number facing the asbestos industry.³⁵ However, the total damage claims in the state AG suits as well as the class actions exceed the aggregate value of industry assets.³⁶ Thus, it is conceivable that, if the tort system is left unchanged, massive tort liability could lead to bankruptcy of the tobacco industry. If this prospect is realistic, perhaps the current tort system could lead to the disappearance or at least drastic shrinkage of the industry. In that case, the effects on reducing tobacco consumption might far exceed whatever benefits could be derived from settlement legislation that included limits on tort liability.³⁷ By placing some cap on anticipated liabilities, the settlement legislation would

certainly reduce whatever risk of bankruptcy now exists.

There is usually substantial uncertainty surrounding any reorganization, and the possible reorganization of the tobacco industry would be far more complex – and lead to far more uncertainty – than in most cases. For purposes of analyzing the possibility of bankruptcy and its effects, there are three key questions: 1) how likely is bankruptcy under the current tort system? 2) how are the prospects of bankruptcy affected by the proposed revisions in the tort system included in the settlement bills? and 3) what would be the effect of bankruptcy?

How Likely is Bankruptcy if There is No Settlement Legislation?

It is difficult to predict the likelihood of bankruptcy of one or more industry members under the current tort system. The face value of all pending claims exceeds the net worth of all the tobacco companies, not just the tobacco subsidiaries but the parent companies as well. For purposes of assessing the prospects of bankruptcy, however, the primary issue is not the aggregate face value of the claims, but the judgments that are awarded and the industry's perception of eventual aggregate liability. As discussed earlier, the novel nature of the cases and the poor record of past plaintiffs suggest that the actual liability could fall far well below the face value of the pending claims. At the very least, there is considerable uncertainty on all sides about the ultimate exposure.

The industry would almost certainly proceed under a Chapter 11 reorganization, rather than a Chapter 7 liquidation of assets. Under a reorganization, the industry would continue to operate and sell products, although the company would be under the overall supervision of the bankruptcy court.³⁸ The basic goal of Chapter 11 is to devise a plan that allows a company to partially satisfy

creditors, while remaining in operation. It is understood that creditors are not going to be repaid 100 cents on the dollar. However, from the creditors' perspective, partial repayment under continued operation is preferable to an even lower repayment under liquidation.

In order to devise a reorganization plan, several committees of creditors would probably be established, including a tort claimants' committee as well as committees representing other creditors. The debtor companies would attempt to negotiate with the creditor committees some repayment of debts and restructuring of the company's finances. Secured creditors have claim to whatever collateral is subject to their security interests. Unsecured creditors, such as trade creditors, banks and tort claimants,³⁹ would then make a claim against remaining assets. No group of claimants is required to agree to a particular plan. A group can insist on the right to recover what it would recover if the debtor is liquidated. However, there is usually an incentive for all creditor groups to agree, in part because the estimated recovery under liquidation could be quite small. In general, a successful reorganization means a firm survives free of most of its unpaid debts, while creditors receive more than they would in the case of a liquidation. Unsecured creditors usually receive somewhat more than they would under liquidation, though not considerably more.

There are strong incentives for the industry to avoid filing for reorganization.⁴⁰ First, the tobacco companies would, to some extent, lose control of their own operations. Companies in Chapter 11 are under the general supervision of the bankruptcy court, and perhaps trustees appointed by the court. Some management officials might lose their jobs or find their compensation reduced. Shareholders would not receive dividends. Whatever is left of confidentiality of industry documents might be lost because of this loss of

ultimate control. The industry would not necessarily be able to rid itself of tort liability for all past conduct. It can be anticipated that most outstanding claims, and probably those filed during the pendency of the bankruptcy proceeding, would be resolved by the establishment of a settlement fund, which could be funded from a variety of sources.⁴¹ The more difficult issue of what would happen to claims that have not yet been filed at the time of bankruptcy is discussed below. In summary, under a reorganization, management as well as shareholders would incur substantial costs. For these reasons, the industry will likely attempt to avoid reorganization if possible.

On the other hand, filing for protection under Chapter 11 becomes the preferred option if uncollected tort judgments and pending claims reach such a high level that any individual company calculates the burdens of reorganization are outweighed by the risk of continuing to litigate. The great advantage of entering into a Chapter 11 reorganization is that the litigation of all pending cases as well as collection of judgments and other debts are stayed, while the industry attempts to reach agreement with creditors on a reorganization plan. All discovery and trial preparation would cease, and individual companies could turn their full attention to financial restructuring. It is not necessary for a company to actually be insolvent in order to file for Chapter 11 protection. There is only a requirement that a firm makes a good faith claim that it may face ultimate liquidation without such protection. Thus, some firms, such as Dow Corning, have used Chapter 11 strategically in order to gain an advantage in dealing with plaintiffs.

It is likely that each firm's decision would be greatly influenced by its own capital structure as well as the outcome of the first series of major cases that are litigated to judgment. The assets of the domestic tobacco

manufacturing subsidiaries are clearly insufficient to pay the amounts contemplated in the settlement legislation if an immediate liquidation were ordered.⁴² If the states, or the private plaintiffs, win a series of large judgments, and any of the firms encounters substantial difficulties in funding liability judgments and ongoing litigation costs, the prospects of a firm relying on Chapter 11 become more likely. On the other hand, if the plaintiffs lose most of these cases, and firms continue to be able to raise capital, the industry is likely to continue to litigate. Predicting the possibility of bankruptcy then requires predicting the ultimate success of the pending suits, which is enormously difficult. Perhaps the fairest assessment is that there is a realistic and significant chance of bankruptcy in the absence of settlement legislation, but it is still improbable.

How Likely is Bankruptcy if There is Settlement Legislation?

Settlement legislation clearly reduces the prospects than any tobacco firm will file for bankruptcy. Although the assets of the tobacco companies are insufficient to pay the amounts contemplated in the settlement legislation, the prospect of annual payments depends upon a future stream of additional revenue generated by higher cigarette prices.⁴³ It can, in fact, be argued that the basic idea of funding payments from future tobacco sales is troubling.⁴⁴ On the other hand, the settlement is in many ways similar to a substantial sales tax on cigarettes, with the revenue committed to a public health purpose. There, too, the stream of revenue depends on future tobacco sales.

Although the likelihood is substantially lower, it is conceivable that the domestic subsidiaries could declare bankruptcy even if settlement legislation is passed. The settlement, as originally negotiated between the States and the industry, limits liability to

the domestic tobacco subsidiaries and shields the parent companies from any obligations. S. 1530 and S. 1414 retain this principle.⁴⁵ Bankruptcy would not shield the tobacco subsidiaries from liability for unpaid annual obligations. The United States would be a creditor in bankruptcy and could make a claim for these payments.⁴⁶ If the companies continued to operate after reorganization, the statutory obligations would continue and survive bankruptcy. However, if the tobacco companies are liquidated during bankruptcy or simply go out of business, their obligations are ended as well. In that event, the regulatory provisions of settlement legislation, including any liability limitations, would remain in effect, but there would be no annual payments.

It is worth reflecting about the likelihood and implications of that scenario. One potentially odd – and probably unfair – result in such a case is that the parent companies, tobacco company officials themselves, and other individuals involved in misconduct, could be shielded from all liability for past misconduct, while the public did not receive the benefits of annual payments.⁴⁷ On the other hand, the settlement already provides for that possibility in the adjustment formula for annual payments tied to the volume of domestic sales.⁴⁸ After all, the end of cigarette sales in the United States would be such a dramatic gain that there might not be concern that the industry had avoided monetary liability for past misconduct. Thus, the provisions on immunity for other persons in the industry besides the domestic tobacco companies themselves may be more problematic than the elimination of annual payments.

In short, while it is probably a fair assumption that, if the settlement legislation is enacted, the domestic companies will not declare bankruptcy, that result is not certain. These companies could decide to liquidate their assets, or to simply stop using them to

make cigarettes for the domestic market. In that event, their obligations to make annual payments would cease, at least as S. 1414 and S. 1530 are drafted. Congress could, if it wished, impose the obligations directly on the parent companies. Limiting liability to the domestic subsidiaries is not necessarily the outcome that would result under state law. The parent companies themselves could be held liable if their officials have been involved in tortious conduct, or, under some circumstances, if the subsidiaries have been deliberately undercapitalized. And, of course, Congress is not bound to make policy consistent with state tort law. It could decide to impose liability on the parents simply on the basis that the decision to control a subsidiary that sells deadly products warrants substantial payments to the United States public.

The Impact of Bankruptcy on Plaintiffs

What would be the consequences if one or more tobacco companies filed for protection under Chapter 11? The most immediate impact would fall on the tort claimants, including individual plaintiffs, the class action plaintiffs, and the states themselves. Claims brought prior to bankruptcy, and probably while the bankruptcy is proceeding, are treated as claims against the assets of the debtor and will be discharged when the debtor's reorganization plan is confirmed.⁴⁹ Historically, tort claimants, like all creditors in bankruptcy, have frequently received amounts which are far less than their claims.⁵⁰ As discussed above, a committee of tort claimants could insist at least on the amount that they would received under liquidation. In that event, the court would have to estimate the value of their share in a hypothetical liquidation. However, the assets available for distribution after satisfaction of secured creditors in a

hypothetical (or actual) liquidation would be far less than the aggregate payments contemplated by the settlement.⁵¹ In short, if one or more of the firms file for bankruptcy, claimants would probably receive substantially lower payments than those contemplated in the settlement (at least as to the payments attributable to the bankrupt firms).

Most, perhaps all, outstanding judgments and pending claims would be discharged during the bankruptcy proceeding. However, the courts have not yet decided whether it is constitutional to discharge claims during bankruptcy that, though based on prior conduct, have not yet been filed. Some of the courts in the asbestos litigation concluded that future claimants were "parties in interest" in the bankruptcy proceeding and appointed a representative for them.⁵² Ultimately, the Manville reorganization plan included a trust fund for existing and future claimants. Congress then responded to the flood of claims by authorizing the court to force post-bankruptcy claims to be brought against the fund.⁵³

This and similar approaches have not yet been approved by the Supreme Court, however. Thus, there is still no clear answer as to whether the federal courts can fix the compensation of future claimants in a way that resolves their claims during bankruptcy and permits the debtor to emerge from reorganization with a cap on total exposure from prior conduct.⁵⁴ To a large extent, the willingness of the courts to uphold such settlements will depend on whether the notice to potential plaintiffs satisfies due process requirements. Tobacco industry claims probably present a more difficult problem of notice than industries where the potentially injured persons can be more easily identified, e.g., persons who have been exposed to a known toxic chemical. In addition, the amount to be set aside for future tobacco claims are difficult to evaluate because of the

variability in individual fact situations. Thus, there is a strong possibility that the courts will not attempt to resolve the issue of future claims in the reorganization proceeding. In that event, the industry would face uncertainty about long-term liability.

The Impact of Bankruptcy on the Public Health

While it is impossible to predict with certainty how the courts would treat pending and future tort claimants, it is very likely that their ultimate recovery would be reduced below the dollar values of any judgments and far below the value of any pending claims. Moreover, the repayments would probably fall significantly below the amounts now included in the proposed settlement legislation, which are based on a viable industry operating for the foreseeable future and on funding annual payments primarily from price increases. Largely because of the fear of a reduction in ultimate recovery, some State AG's have argued for the settlement on the grounds that it would avoid bankruptcy.⁵⁵ This loss in recovery, which is itself uncertain, is clearly an important consideration for the states as well as individual claimants. However, it does not directly implicate the public health goal.

In assessing the impact on the public health, the key questions have to do with how reorganization would affect the industry's operation in the future. One issue concerns the survival of the industry. A second issue relates to the conduct of the industry if it does survive.

Bankruptcy and Industry Survival

As a threshold matter, the industry would probably survive reorganization. Manufacturing industries that have encountered large scale tort liability – for example, asbestos, Dalkon shield, and breast

implants – have greatly reduced or even eliminated the production of the harmful products. However, those cases involved products that more closely fit the traditional tort paradigms of dangerous products due to hidden defects and failures to warn.⁵⁶ In the case of asbestos, for example, individuals did not knowingly expose themselves to a dangerous product. Exposure took place without any type of warnings over several decades.⁵⁷ The industries faced a massive number of cases, with a high likelihood of liability when disease actually occurred.⁵⁸

Tobacco, on the other hand, has traditionally not fit well into traditional tort theories based on hidden defects, or failure to warn. In the event of large numbers of suits, the industry would have to decide whether the most profitable strategy in the future is to eliminate or reduce domestic sales or face the risk of liability for future production. If it is assumed that the courts will not attempt to resolve the issue of future claims in the bankruptcy proceeding, then the companies would continue to face exposure over the long run, both for new claims based on pre-bankruptcy conduct and for new claims based on post-bankruptcy conduct. As discussed earlier, there are clearly uncertainties about the future trend of products liability law. However, if the industry perceives that the risks of tort liability stem primarily from past conduct rather than future sales, it is not likely to reduce future production of cigarettes. As long as the profits from new domestic sales exceed the cost of future expected liabilities, the industry is likely to continue to sell cigarettes in the United States.

In the event that the industry is forced to liquidate some or all of its assets, the question would be whether the successor corporations would themselves be subject to substantial tort exposure. The new owners would, of course, be liable for any newly generated liability from the sales of cigarettes. However, they would generally not be liable

for prior conduct by tobacco companies. Nevertheless, they might be required to pay into the trust fund at 150% of the level specified for the original settling manufacturers if the new companies are treated as non-participating manufacturers under the settlement legislation.⁵⁹ The provision requiring non-participating manufacturers to pay higher annual payments into a liability fund was rationalized in the settlement as way of allowing the settling companies to compete with companies that are not party to the settlement.⁶⁰ One effect of that provision may be to discourage companies from buying tobacco company assets in order to enter the market.

In summary, the most likely scenario is that the industry would survive reorganization free of pre-bankruptcy tort claims, but face new claims based on both pre-bankruptcy and post-bankruptcy conduct. If it is assumed that states do not adopt new, expansive theories of liability, then tobacco firms emerging from reorganization will probably continue to sell cigarettes in the future. The stability of the industry would be even greater if the courts overseeing the bankruptcy process decided to discharge all future claims based on past conduct, by setting aside a portion of a settlement fund for this purpose. For the industry to decide to stop selling cigarettes, it would have to assume that massive liabilities would continue to recur for post-bankruptcy conduct.

If the industry sells its assets to others, these new firms would generally have no liability for pre-bankruptcy conduct by the former companies. If the states adopted new and expansive theories of tort liability, new firms might be hesitant to enter the tobacco market because of fear of liability for new cigarette sales. New firms might also be discouraged from entering the market if they have to make substantial annual payments because they are classified as non-participating

manufacturers. Under those circumstances, there might be no other firms willing to buy the tobacco industry's assets in order to sell cigarettes in the United States. As in the deterrence analysis, a crucial consideration is the likely direction of state tort law.

Bankruptcy and Industry Conduct

A somewhat different question is whether bankruptcy would result in a substantial change in industry operations, even though the industry continued to sell cigarettes. It is conceivable, for example, that a bankruptcy court might force the tobacco companies to change their method of operations. Some have argued, in fact, that a bankruptcy court would conclude that continued production of tobacco products would subject the industry to massive liability from tort claims alleging that tobacco products are inherently dangerous and that this conclusion would lead the court to greatly restrict the production of cigarettes, perhaps to bar domestic sales altogether.⁶¹ The plausibility of this scenario depends upon the willingness of the courts to endorse products liability theories that are not based on hidden defects or failure to warn, such as enterprise liability. As I discussed earlier, these theories have received some academic support but they have not been embraced by the courts.

A related argument is that a bankruptcy court would subject the industry to tighter controls on marketing, for example, requiring further disclosures, mandating additional warnings, and prohibiting marketing that may affect minors.⁶² While a bankruptcy court has the power to modify company operations, it would probably hesitate to impose consumer protection measures that differ substantially from an existing federal regulatory framework.⁶³ The primary goal of the bankruptcy court would be to increase company profits, minimize

liability and protect creditors, not to protect the public. While that perspective might lead the court to restrain tobacco marketing, it might also have the opposite effect by creating an incentive to raise profits and provide more funds to satisfy creditors. In any event, it seems highly unlikely that the restrictions placed on the tobacco industry by a bankruptcy court would be more protective of the public health than the restrictions contemplated in the settlement legislation.

Summary and Conclusions

The prospects of bankruptcy are unlikely if the tort limitations included in the settlement legislation are enacted. However, there is a realistic and significant chance if the tort system remains unchanged, and there is no legislated settlement of pending cases. In the event that the tobacco companies do file for protection under Chapter 11, there would be a significant reduction in the amount creditors, including tort claimants, would receive. Thus, it is fair to say that settlement legislation increases the prospects of long-term payments by the industry to the public. These higher payments are a major and legitimate consideration for the plaintiffs, including the states themselves. However, the level of payments does not directly implicate the public health goal of reducing death and disease caused by smoking.

If the tobacco companies do file under Chapter 11, two basic questions are whether bankruptcy will alter industry conduct or even lead to the end of domestic sales. Although it is a theoretical possibility, it is unlikely that a bankruptcy court would order the tobacco companies to stop producing tobacco products or that the court would impose stricter restrictions on tobacco company marketing than those contemplated in the settlement legislation.

It is also unlikely that bankruptcy would force the industry to liquidate or stop

selling tobacco products. Whether the firms remained in the hands of current owners and management or whether they were sold to others, most tort claims would be resolved by some type of settlement fund set aside from current assets and future earnings to satisfy pending and future claims for conduct that dates back to the 1960's. The industry could emerge from bankruptcy largely free of obligations for its past misconduct. In this sense, settlement legislation may have a more realistic chance of forcing the industry to pay for past damages than pushing the industry into bankruptcy. Whether the tobacco industry would decide to continue to operate in the United States after reorganization would depend on the strength of the domestic market, the remaining risk of liability for pre-bankruptcy conduct, and, probably most importantly, the risk of new liabilities for post-bankruptcy conduct. As discussed above, that threat in turn depends on future directions in tort law.

It is conceivable that the current tobacco subsidiaries would find it more advantageous to liquidate rather than to reorganize. In particular, this scenario might occur if the bankruptcy court would not (or could not) devise a system to deal adequately with future tort claims based on past conduct.⁶⁴ Going out of business would have the additional advantage for the parent companies that there is no longer any liability for payments under the settlement legislation, at least as the bills are now drafted. Presumably, the tobacco subsidiaries would look for prospective purchasers of their assets who were interested in entering the tobacco industry. Prospective new entrants would have an incentive to continue selling cigarettes domestically if the domestic market remained strong and doing so does not continue to generate substantial new tort liability. One factor that might discourage any new entrant is a requirement that they make annual payments equal to or greater than the annual

obligations contemplated in the settlement legislation.

PUBLIC PERCEPTION AND FUTURE TORT LITIGATION

An additional consideration relating to possible revision in the tort system is that such revisions could affect the continued disclosure of industry documents and further revelations of abusive conduct. Thus, a number of commentators have argued that, by undermining the ability of future plaintiffs to proceed against the industry, revisions to the tort system could foreclose an effective mechanism for communicating the true character of the industry to the public.

There is no doubt that the enormous publicity given to the state and private tort actions has revolutionized the public's perception of the industry. The constant drumbeat of disclosure of internal industry documents has persuaded most of the public that the industry is devious and unprincipled. The widespread resentment of the tactics of the industry over the last forty years has resulted in a political sea change. In theory, future lawsuits could continue and strengthen this trend. Thus, undermining the incentive for plaintiffs to proceed in the future could prevent the message about the nature of the industry from reaching the public. The prospects for further disclosure under the current tort system should be compared to those prospects if the limitations proposed in the settlement bills are adopted.

Document Disclosure

There are several avenues for document disclosure. Clearly, the most important avenue for disclosure in the past has been litigation. In a very real sense, the original release of the Brown & Williamson documents

revolutionized the relationship between the public and the industry and began the process that culminated in the settlement negotiations. The State AG suits have subsequently led to further disclosures.

The industry now faces a demand for even further disclosures based on Congressional action. The Chairman of the Commerce Committee recently forced release of documents that the industry had vigorously attempted to protect. All the settlement bills provide for extensive disclosure. S. 1414 (sec. 801) and S. 1530 (sec. 701) contain virtually identical disclosure provisions. The sections provide for early disclosure of documents in a series of pending cases and any other documents that refer to health research, addiction, safe cigarettes, smoking habits of minors, and the relationship between advertising and minors. Provisions are included for an expedited review of privilege claims. Finally, both bills provide for ongoing disclosure of documents relating to health, smoking of minors, and the relationship between advertising and smoking. Finally, they both include a general requirement that the companies disclose any other documents designated by the Secretary of HHS. It is conceivable that more effective disclosure provisions could be drafted. This issue is dealt with in a separate paper. If the disclosure provisions contemplated in the settlement legislation are implemented effectively, and a way is found to quickly resolve privilege claims, it seems likely that this process of disclosure will be as effective (or more effective) than future tort litigation. Future litigation could conceivably address problems that are unforeseen in the enactment of settlement legislation. On the other hand, relying on future litigation risks delays as well as the uncertainty of judicial decisions.

Continued Litigation

The public's perception of the industry will not be influenced by disclosure only. There is some value in future plaintiffs being able to focus the public's attention on specific plaintiffs and the injuries to them. To the degree that future plaintiffs can focus attention on the industry, there may be some positive effect on the willingness of state legislatures and Congress to oppose the industry. On the other hand, Congress itself remains a vehicle for bringing abuses to the public's attention.

DETAILED ANALYSIS

It is useful to evaluate the details of the liability-related provisions in the settlement legislation in detail regardless of the public health community's overall assessment of the liability provisions. Even if one were willing to accept the overall thrust of the settlement, there are substantial flaws in the way the implementing provisions are drafted in legislative proposals. In many cases, these bills go far beyond what is necessary in order to accomplish their stated goals. In some cases, the proposed legislation could substantially interfere with tobacco control efforts and even undermine public interest goals totally unrelated to tobacco control.

As settlement legislation proceeds through Congress, it is important for the public health community to be prepared to evaluate and critique any legislation at both a general policy level and a more detailed section-by-section level. The public health community should attempt to influence the ultimate structure of legislation even if it decides to oppose any bill. As a practical matter, the prospects for legislation may remain uncertain until the eleventh hour. Even if the public health community decides to oppose any settlement legislation, it should be prepared to work for marginal

improvements in a final bill in the event that legislation becomes inevitable.

This part of the paper describes each component of the liability provisions in detail. Where appropriate, it mentions the differences between the settlement itself, S. 1414, and S. 1530. S. 1492 contains no liability provisions. In most cases, the discussion suggests possible improvements in the provisions.

The discussion follows this outline:

The Scope of the Legislation

- Termination of Pending Cases
- Future Immunity from Same Claims

Limitations on Future Cases

- Punitive Damage Limitations
- Class Actions and Joinder
- Annual Cap on Liability and Rollover
- Credit Against Annual Payment
- Permissible Parties
- Evidence of "Reduced Risk" Tobacco Products

The Scope of the Legislation

There are several key questions regarding the scope of the proposed settlement bills. First, what pending cases would be terminated as a result of this settlement, and what cases would continue in the courts? Second, what cases are permanently barred in the future on the grounds that they are resolved by the settlement? Third, what future cases are covered by limitations on liability?

All these questions about scope are central to understanding the effects of various approaches. For example, an extremely broad scope might result in limiting liability for cases that are not logically related to the settlement, such as a suit by a wholesaler alleging that a manufacturer breached a contract for sale of cigarettes, or a suit by a state government that the industry has failed to pay state sales taxes. Obviously, "settlement legislation" should not

result in unanticipated bars in the future on government and private cases that are unrelated to the goals and rationale of the settlement.

Termination of Pending Cases

S. 1414 and S. 1530 terminate the existing State AG cases (as well as similar suits brought by other governmental entities) and include provisions to prevent the same claims from being brought in the future. However, the bills do not identify specific cases or even clearly describe them. S. 1414 terminates pending “civil actions” by state and local governments against settling manufacturers, distributors and retailers. S. 1530 terminates pending “health-related civil actions” by states or local governments. Thus, the language of S. 1414 is broader in this respect, though the intent may be same. Obviously, legislation should not terminate literally all pending civil actions against the industry if they are not related to the theories being pursued in the state cases, for example, a pending action to collect sales tax revenue.

As for pending private cases, the language of the settlement itself would terminate all pending class actions as well as all “addiction”/dependence claims by individuals. Although the settlement did not define these class actions, the preamble to Title VII of the settlement indicates that these are the class actions that are “related to tobacco and health.” Both S. 1414 and S. 1530 use different -- and broader -- language to terminate pending cases. Both provide that they terminate class actions “arising from the use of a tobacco product” and any other civil action “based on addiction to or dependence on a tobacco product.” S. 1530, sec. 256(b); S. 1414, sec. 701(a). Other individual claims are “reserved,” that is, will continue in the courts. However, those cases that do continue will be subject to the new rules limiting liability. Third party

payer actions pending as of 6/19/97, e.g., by Blue Cross, union health funds, and asbestos manufacturers, are not settled but are governed by provisions below applicable to past conduct, such as limits on punitive damages and joinder.

Recommendation: revise the description of terminated cases to governmental cases seeking reimbursement for government medical expenses and to class actions based on addiction or dependence.

Future Immunity from Same Claims

The proposed legislation includes a series of provisions dealing with various categories of future cases. In general, the bills identify three different categories of future cases, each of which is subject to a different approach. The first category includes claims which (in theory at least) are resolved by the settlement. The manufacturers are given total immunity for these claims, presumably on the theory that would be completely resolved by the settlement legislation. The second category involves cases that may be brought in the future, based on conduct that occurred prior to the effective date of any legislation. The third category involves cases that may be brought in the future based on conduct that occurs after the effective date of any legislation. In this section, I discuss the provisions that provide complete immunity to cases resolved by the settlement legislation.

The language of the settlement simply provides: “Present Attorney General actions (or similar actions brought by or on behalf of any governmental entity), parens patriae and class actions are legislatively settled. No future prosecution of such actions.” (Title VIII.A(1)). Although this wording is rather cryptic, it is logical because it tracks the cases that are terminated by the settlement. Presumably, the intent of settlement legislation is to

accomplish the same objective, that is, to provide immunity only for cases that are viewed as being resolved by settlement legislation. This approach is analogous to an application of "res judicata," under which claims are precluded in the future if they amount to the same claims that were made in the suits that have been settled, or if they are should have been made in those suits because they are based on the same conduct. However, both S. 1414 and S. 1530 go beyond this basic concept.

S. 1414 provides immunity for any "manufacturer, distributor or retailer" that is a signatory to the settlement from any "civil action commenced after the date of enactment...by any federal, state or local governmental entity...for all claims arising from the use of a tobacco product." Section 701(a). The literal terms of this limitation could prevent a broad range of enforcement actions, such as FDA actions to bar toxic substances in cigarettes, local actions to bar smoking in restaurants, and so on. S. 1530 creates immunity for settling manufacturers for "any civil action...by a Federal, state or local governmental entity...for all health-related claims arising from the use of a tobacco product." Sec. 256(a). Thus, S. 1530 is worded somewhat more narrowly than S. 1414 since it is limited to "health-related claims." However, it, too, creates broader immunity than necessary to make sure that the terminated cases are permanently resolved. Thus, both bills go well beyond their stated purposes.

Recommendation: revise the immunity provisions to apply only to the health care costs and class action claims that are terminated by settlement legislation and claims that would be considered precluded by settlement under established judicial doctrines of res judicata.

Limiting Liability for Future Cases

Both S. 1414 and S. 1530 place limitations on liability in two categories of future cases – those based on conduct prior to the effective date of any legislation and those based on conduct after the effective date. In general, these limitations are similar. The primary difference is that punitive damages are allowed for future cases based on conduct after the date of enactment. The following discussion addresses the specific limitations in more detail.

Scope of Limitations

The limitations on liability would apply to large categories of future cases against the tobacco industry. However, neither bill defines these cases very clearly. The limitations on liability in both S. 1414 and S. 1530 apply to "all civil actions permitted under [the bill] for relief arising from the conduct of a manufacturer ..." See S. 1414, sec. 702(a), 703(a) and S. 1530, sec. 257(a), sec. 258(a). That rather ambiguous phrase is apparently intended to describe the cases that are still allowed given the immunity limitations for cases that are resolved by the settlement. The problem with this vague phraseology is that it could sweep in all cases against a manufacturer – including those that have nothing to do with a health-related smoking claim – as long as it does not fall into the category for which immunity has been granted. For example, if manufacturers participate in a scheme to sell cigarettes directly to minors, a state could conceivably bring an enforcement action that includes a request for punitive damages. However, the literal language of S. 1414 and S. 1530 would extend the ban on punitive damages to these cases.

Recommendation: If these limitations are to be enacted, they should be narrowed to apply only to personal injury cases.

Punitive Damages

Both S. 1414 and S. 1530 eliminate punitive damages for all claims (pending and future) that are based on conduct that occurred prior to the effective date of implementing legislation. S. 1414, sec. 702(b); S. 1530, sec. 257(b). Both allow punitive damages for cases based on conduct after the date of enactment. S. 1414, sec. 703(b); S. 1530, sec. 258 (b). For example, if Congress makes settlement legislation effective on January 1, 1999, a plaintiff making a personal injury claim for conduct that occurred during the 1960's and 1970's could not seek punitive damages. On the other hand, a plaintiff who sued for fraudulent conduct occurring after January 1, 1999, could still seek punitive damages. In effect, the damage payments provided in the settlement represent the "punishment" of the industry for its conduct during the 1960's through the present. Although a court in the future could award punitive damages, the egregious conduct would have to be based on future conduct. Consequently, the primary impact of this limitation will fall on individual plaintiffs who have a plausible claim for punitive damages for past conduct, e.g., fraud regarding the addictive properties of nicotine.

Class Actions and Joinder

Both S. 1414 and S. 1530 bar any form of joinder of plaintiffs, including class actions, consolidations of cases, or simple joinder involving two related plaintiffs. This limitation applies to pending cases as well as future cases and to cases based on conduct prior to the date of enactment and well as to conduct after the date of enactment. S. 1414, secs. 702(c), 703(b); S. 1530, secs. 257(b), 258(b).

One obvious point of these provisions is to eliminate any significant risk of massive liability judgments by barring class actions. However, the bills go much further by

preventing simple joinder of two plaintiffs. For example, if a parent and a child make a wrongful death claim against the industry in the future based on the death of the other smoking parent, the settlement would allow the industry to object. Both bills provide that the remedy for a state court that allows joinder is that the case can be removed to federal court, where the federal court would presumably enforce the restriction.

Recommendation: If these provisions are to be enacted, they should not extend to simple joinder, such as suits by two members of the same family, or class actions by non-smokers.

Annual Cap on Liability and Rollover Provisions

Both S. 1414 and S. 1530 create a cap on annual aggregate liability judgments and settlements in the amount of 33% of the annual base payment as adjusted. For example, the base payment based on current tobacco sales begins at \$8.5 billion then increases to a maximum of \$15. These can then be revised upward or downward, depending on sales. Presumably, the actual amounts would be lower than these figures. If the aggregate of annual liability awards exceed these caps, they are not extinguished, but the excess rolls over to subsequent years under a somewhat complex set of provisions. A special rollover provision gives a lower priority to large awards by requiring that awards over \$1 million are deferred unless all other judgments can be paid. Moreover, these large awards are specifically deferred without interest, and are thereafter paid at the rate of \$1 million per year, subject to the annual cap.⁶⁵ If the annual cap is not reached in any year, the unallocated portion apparently remains within federal control.

These provisions reduce considerably the cost of any liability. For example, if an individual plaintiff were awarded a \$3 million judgment in 2002, she would be placed at the bottom of the priority list for receiving compensation above the \$1 million ceiling. If she had to wait for the remaining \$2 million award until the end of the succeeding year, she would have lost considerable interest payments.

Recommendation: revise the cap upward and provide for interest payments on deferred awards.

Credit Against Annual Payment

Both bills provide that the liability payments of any tobacco manufacturer results in a 80% credit against annual payments in the year paid. S. 1414, 702(h); S. 1530, sec. 256(j). Presumably, this cap remains in effect in perpetuity. For example, if R.J. Reynolds is liable for \$1 billion in personal injury claims in 2002 and would otherwise be required to make annual payments under the settlement of \$3 billion that year, its annual payment obligation is reduced by \$800 million (80% of \$1 billion), to \$2.2 billion. (For past conduct, the settlement provides that the settling manufacturers will participate in cost-sharing for liability. Consequently, we can probably assume that the annual liability of any settling manufacturer will equal its market share percentage of total industry liability for the year.) As discussed earlier, the problem with this provision is not simply that it lowers overall payments by the industry. It also undercuts whatever deterrent effect remains from tort liability.

Recommendation: eliminate this provision entirely.

Permissible Parties

The settlement bills include a series of provisions restricting permissible parties in cases against the industry. S. 1414, sec. 702(e); S. 1530, sec. 257(e).⁶⁶ The following provisions limit permissible plaintiffs:

1. Claims of individuals, or derivative claims, must be brought by persons claiming "tobacco-related injury" or their heirs. This limitation apparently means that an individual could not sue for loss of income or other damage unless it related to his own personal injury or his status as an heir. Thus, for example, a spouse could not sue for loss of consortium.

2. Third party payor claims can only be based on subrogation unless they were pending as of 6/19/97. A subrogation claim is the traditional claim made by an insurer who pays benefits to an injured individual. The insurer is viewed as "standing in the shoes" of the injured person by virtue of paying benefits to him. One implication of this perspective is that the defendant can assert the same defenses against the insurer that it could assert against the individual if the individual brought the claim, e.g., assumption of the risk. Because of the difficulty of overcoming this defense, many of the third party payor claims against the industry, including the claims by the states themselves, were not based on a theory of subrogation. Thus the settlement precludes these non-subrogation claims in the future. So, for example, a private health insurer, union health fund, or asbestos manufacturer, could not sue the tobacco industry for medical expenses in the future unless the claim is a traditional subrogation claim.

Other provisions limit permissible defendants. S. 1414, sec. 702(e)(2); S. 1530, sec. 257(e)(2). Although these sections are not clearly worded, apparently the intent is that future actions can be maintained only against the tobacco manufacturers and successor companies (including fraudulent transferees)

and agents vicariously liable for the actions of the manufacturer. This would appear to prevent suits against individual tobacco company officials, members of the board of directors, industry attorneys, trade associations, or other firms such as retailers, unless the theory of the case was that these persons were vicariously liable for the actions of the manufacturers. In most of these cases, a theory of vicarious liability would not apply.⁶⁷ Moreover, depending on the scope of these provisions, they could apply to a wide variety of cases, including those unrelated to the purposes of the settlement. It is quite conceivable that they could bar a suit by tobacco company shareholders against directors and company officials for mismanagement.

Recommendation: revise these provisions to ensure that they bar suits only to the minimum extent necessary to accomplish the purposes of the settlement.

Evidence about “Reduced Risk” Tobacco Products

Both S. 1414 and S. 1530 provide that the development of “reduced risk” tobacco products after the effective date of the implementing legislation is neither admissible nor discoverable. S. 1414, 702(g); S. 1530, sec. 257(g). To some extent, these provisions borrow from the traditional rule that evidence of repairs after an injury is inadmissible solely to prove negligence. However, the provision goes well beyond this traditional rule by preventing discovery of this information at all. For example, the current rule makes admissible evidence of subsequent remedial measures if the defendant denies that a safer design was feasible.⁶⁸ A plaintiff in a future personal injury suit against a tobacco manufacturer might contend that cigarettes are defective because a safer cigarette is feasible.

Under S. 1414 and S. 1530, the plaintiff could not even obtain discovery about any actions taken by the industry. Such a bar would obviously make this theory difficult, if not impossible, to pursue.

Recommendation: drop this provision. Any legitimate purpose of this provision is already included in state and federal rules of evidence.

NOTES

¹ For a discussion of some of these issues, as well as general arguments against liability limitations, see Richard Daynard, Changes to the Civil Justice System Under the Proposed Tobacco Settlement, Working Paper # 4, Tobacco Control Resource Center (Aug. 13, 1997) (available at www.tobacco.neu.edu/extra/papers/RAD8-12WorkingPaper4.htm).

² In particular, the scope of the bills may prevent government and private suits in a wide range of situations. This issue is discussed separately.

³ William M. Landes & Richard A. Posner, THE ECONOMIC STRUCTURE OF TORT LAW 186-87 (1987).

⁴ Traditionally, a plaintiff has been required to prove egregious conduct, e.g., reckless disregard of a known danger, in order to obtain punitive damages. States have also increasingly regulated punitive damages, for example, by increasing the plaintiff’s burden or placing monetary caps on these damages. The Supreme Court has held that the Due Process Clause places some limits on the size of punitive damages. See BMW of North American, Inc. v. Gore, 116 S. Ct. 1589 (1996), though the precise limits are not clear. In any event, it should be assumed that, without this proposed limitation, many states would allow plaintiffs to recover sizable punitive damage awards, but only if they prove egregious conduct of one or more tobacco companies.

⁵ See 11 U.S.C. sec. 524(g), which authorizes courts to force future asbestos claimants to proceed against the fund created for purposes of paying future claims.

⁶ For discussions of the history of tobacco litigation, see Robert Rabin, A Sociolegal History of Tobacco Tort Litigation, 44 Stan. L. Rev. 853 (1992); Gary Schwartz, Tobacco Liability in the Courts in SMOKING

POLICY: LAW POLITICS AND CULTURE (R. Rabin & S. Sugarman, eds.) (1993); Marcia Stein, Cigarette Products Liability in Transition, 54 Tenn. L. Rev. 631 (1987).

⁷ See Rabin, supra note 6, at 856-63.

⁸ Id. at 869. The issue of preemption is discussed further below.

⁹ Id. at 870.

¹⁰ Id. ("As crucial as the issues of preemption and causation have been, the most salient theme in the second wave litigation has been freedom of choice.").

¹¹ The most extreme example is a Mississippi case where the jury found the defendant at least partly at fault but awarded no damages. See Horton v. American Tobacco Co., No. 12325 (Miss. Cir. Ct. Nov. 2, 1990).

¹² The issues of smoker knowledge and behavior come up in several contexts. To the extent that courts consider consumer expectations in determining whether a product is dangerously defective, general awareness of the danger may lead a court to conclude that cigarettes are not defective. This probably has been the view of most courts. See, for example, the famous comment on "good tobacco" in the Second Restatement of Torts, cited infra note 19. Even if a product is held to be defective, defendants can usually assert some version of a contributory or comparative negligence defense, which includes consideration of the plaintiff's assumption of a known risk.

¹³ State appellate courts have given some support to the theories of the case. For example, the Florida Supreme Court upheld the basic theories of the state's statutory claims. Agency for Health Care Admin. v. Associated Indus. of Florida, 678 So. 2d 1239 (Fla. 1997).

¹⁴ For example, a Florida jury recently found against a plaintiff apparently on the grounds that the plaintiff knew smoking was dangerous. See Glenn Collins, Tobacco Industry Cleared in Florida Smoker's Death, New York Times, A16, May 6, 1997.

¹⁵ Both the State AG and class action cases allege a number of theories of liability. Of the forty states complaints, only eleven explicitly invoke traditional products liability as a basis for recovery. See Daniel Givelber, Cigarette Law 73 Ind. L. J. ____ n.2, (forthcoming, spring 1998).

¹⁶ Section 1334 of the Federal Cigarette Labeling and Advertising Act, 15 U.S.C. secs. 1331-1340, preempts any state "requirement or prohibition based on smoking and health" if cigarette packages are properly labeled. In Cipollone v. Liggett Group, Inc., 505 U.S. 504, 524-31 (1992), the Supreme Court interpreted this provision to mean that personal injury claims based on a failure to warn are preempted. A different majority found that claims based on an obligation to avoid manufacturing defects, claims that rely solely on testing or research practices, claims based on breach of express warranties, and claims based on fraud or conspiracies to conceal facts are not preempted.

¹⁷ On the other hand, we still have not observed a serious effort to develop a safer cigarette or, in fact, to engage in any additional disclosures voluntarily outside the context of the proposed settlement.

¹⁸ Under S. 1414 and S. 1530, plaintiffs can continue to sue the industry and seek punitive damages for conduct after the date of enactment. However, by allowing the industry to receive an 80% credit against its annual payments for tort judgments, the bills go far toward making any liability costless. This issue is discussed further below.

¹⁹ The famous (or infamous) comment to the Second Restatement of Torts section on defective products provides: "The article sold must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics. Good whiskey is not unreasonably dangerous merely because it will make some people drunk, and is especially dangerous to alcoholics; but bad whiskey, containing a dangerous amount of fuel alcohol, is unreasonably dangerous. Good tobacco is not unreasonably dangerous merely because the effects of smoking may be harmful; but tobacco containing something like marijuana may be unreasonably dangerous...." ALI, Restatement of Torts (Second) sec. 402A, comment i (1965).

²⁰ See infra notes 28-33 and accompanying text.

²¹ See supra note 16. Neither S. 1530 nor S. 1414 would amend the current preemption provisions of the Federal Cigarette Labeling and Advertising Act. Senator Kennedy's bill, S. 1492, would amend these provisions by allowing the states greater discretion to regulate cigarette advertising and by stating that state tort laws are unaffected. See S. 1492, sec. 210, adding a new

section 910(f) to the Federal Food, Drug and Cosmetic Act.

²² Manufacturers (as opposed to retailers) have traditionally complied with express restrictions on advertising and marketing. The visibility and the obviousness of these violations generally makes non-compliance very risky. On the other hand, the industry has certainly been willing to flout the intent of restrictions when they are ambiguous, e.g., by displaying logos in televised sporting events.

²³ It has been argued that the industry has actually welcomed warning requirements on the theory that these tended to bolster its assumption of the risk defense in tort cases. See Richard Kluger, *ASHES TO ASHES* 279-91 (1996) (quoting Robert Wald, who represented Lorillard, as saying: "[The legislation] got us assumption of the risk – the warning label would do that. This was the [industry's] major motivation in accepting the legislation.").

²⁴ Several scholars have presented arguments that the tobacco industry should be liable for damages from smoking regardless of the lack of negligence by the industry, the unfeasibility of a safer design, or the negligence or assumption of the risk by smokers. See, for example, Steven P. Corey & Jon D. Chanson, *Rescuing the Revolution: The Revived Case for Enterprise Liability*, 91 Mich. L. Rev. 683 (1993); Ellen Wertheimer, *The Smoke Gets In Their Eyes: Product Category Liability and Alternative Feasible Designs in the Third Restatement*, 61 Tenn. L. Rev. 1429 (1994); Givelber, *supra* note 15.

²⁵ Torts scholars are deeply divided on the appropriate test for dangerously defective products. A growing number of scholars, including those who have been very influential in drafting the current Restatement have argued against expansive products liability theories. One of the most influential articles in this line has been James Henderson & Aaron Twerski, *Closing the American Products Liability Frontier: The Rejection of Liability without Defect*, 66 N.Y.U. L. Rev. 1263 (1991). Henderson and Twerski are Reporters of the Restatement (Third) of Torts.

²⁶ See, e.g., Sheila Birnbaum and J. Russell Jackson, *Products Liability*, The National Law Journal, B5, Aug. 4, 1997

²⁷ O'Brien v. Muskin Corp., 463 A.2d 298, 307 (N.J. 1983); Halphen v. Johns-Manville Sales Corp., 484 So.

2d 110 (La. 1986); Kelly v. R.G. Indus., Inc., 497 A.2d 1143 (Md. 1985). "Each of these judicial attempts at imposing such liability have either been overturned or sharply curtailed by legislation." ALI, Restatement (Third) of Torts, Tentative Draft No. 5, at 52 (Westlaw Edition).

²⁸ See Birnbaum and Jackson, *supra* note 26.

²⁹ "[A] product is defective in design when the foreseeable risk of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller and the omission of the alternative design renders the product not reasonably safe." Restatement (Third) of Torts, Sec. 2(b).

³⁰ See Aaron Twerski, *Inside the Restatement*, 24 Pepp. L. Rev. 839, 846 (1997) ("Few within the ALI argued that risk-utility balancing should be used to declare such products as cigarettes, alcohol, or handguns defective because the overall harm of these products to society outweighs their benefits.").

³¹ Bob Van Voris, *ALI Adopts New Products Liability Law*, National Law Journal, at B1, June 2, 1997. "Just before the draft was adopted...Jay Dratler, Jr., a professor at the University of Hawaii...proposed an amendment deleting tobacco from a comment listing some unreasonably dangerous products – including alcohol and guns – which traditionally have been immune from lawsuits alleging defective design. The amendment passed. 'It was something of a Hail Mary pass – eight minutes before the end of the session and before the final draft was approved,' said Professor Dratler." *Id.*

³² Professor Twerski's explanation of the exception suggests that the exception is intended to cover products whose dangers do not offer any additional social utility and, therefore, that the danger can be eliminated without sacrificing any utility. See Twerski, *supra* note 30, at 846 ("Several courts have suggested that the designs of some products are so manifestly unreasonable, in that they have low social utility and high degree of danger, that liability should attach even absent proof of a reasonable alternative design. ...For example, a toy gun that shoots hard rubber pellets with sufficient velocity to cause injury to children could be found to be defectively designed within the rule...Toy guns that do not produce injury should constitute reasonable alternatives to the dangerous toy.") Courts may be reluctant to come to the conclusion that

smokers' balancing of the "pleasures" of smoking compared to the risks is so fundamentally irrational that cigarettes fit within this category. For an argument in support of such a conclusion, see Givelber, supra note 15.

³³ See S. 1414, sec. 702(g); S. 1530, sec. 257(g). This issue is discussed separately.

³⁴ The "look-back" provisions incorporated in all the bills attempt to create disincentives to the industry to market to minors by imposing a financial penalty if smoking rates among teenagers do not drop to certain target levels. This issue is analyzed in a separate paper.

³⁵ R.J. Reynolds recently reported to its shareholders that there were 448 tobacco-related cases pending against it or its affiliates -- more than double the number of cases in 1996. Daynard, supra note _____. When Johns-Manville filed for bankruptcy in 1982, there were 16,000 lawsuits pending. Another 6,000 were filed during the next 16 months, and additional 32,000 were expected to be filed by the 2001. Epstein, Nickles, and White, BANKRUPTCY 709-800 (1993).

³⁶ See Lynn LoPucki, Some Settlement, Washington Post, A15, Jan. 20, 1998.

³⁷ For one analysis of bankruptcy issues, see Fox, Lightwood and Glantz, Briefing: Tobacco Company Bankruptcy (Sept. 22, 1997) (available at www.smokescreen.org).

³⁸ The court could appoint trustees to help oversee the companies as well. Creditor committees, as discussed below, would also have some influence on industry conduct.

³⁹ In general, all pending tort claimants, even though where judgments have been rendered, would be treated as unsecured creditors. If a tort claimant has executed a judgment by attaching property, it is treated as a secured creditor.

⁴⁰ See Final Report of the Advisory Committee on Tobacco and Public Health (the Koop-Kessler Commission) Appendix 3E at p. 59 (available at www.science-policy.com/tobacco/report.htm#Appendix3E).

⁴¹ In the Johns-Manville asbestos bankruptcy proceeding, the fund consisted of existing case assets, liability insurance proceeds, Manville stock, and Manville bonds, which the company paid out of future

earnings. See Frank Macchiarola, The Manville Personal Injury Settlement Trust: Lessons for the Future, 17 Cardozo L. Rev. 583, 599-601 (1996).

⁴² The total identifiable assets of the "tobacco segments" of four of the major tobacco companies totals \$33.1 billion, about nine percent of the total value of the settlement. LoPucki, supra note 36. This amount does not include assets held by the parent companies in other subsidiaries, which could in theory be available if the parent companies themselves are held liable. On the other hand, all these assets would not be available to satisfy unsecured creditors, since secured creditors would recover the value of their collateral.

⁴³ A report by the Federal Trade Commission concluded that tobacco company profits might go up, not down, because of the settlement.

⁴⁴ See LoPucki, supra note 36, criticizing the "partnership between the American government and the tobacco industry to sell cigarettes to the American people and split the profits."

⁴⁵ The original settlement provides that the obligation to make annual payments extends only to "entities selling in the domestic market." Section VI.B.6. See LoPucki, supra note 36. This limitation appears to have been adopted in section 5(11) of S. 1530 and section 100(10) of S. 1414.

⁴⁶ Section 402(c) of S. 1414 adds a new paragraph to 11 U.S.C. sec. 507(a), which has the effect of giving a low priority to the United States as a creditor in making a claim in bankruptcy for the annual payments.

⁴⁷ This result would depend in part on whether the "permissible defendants" provisions contemplated in the settlement legislation are adopted as currently drafted. This issue is discussed further on pp. [??].

⁴⁸ Annual payments are adjusted upward or downward, depending on annual sales. See, for example, S. 1414, sec. 402(b).

⁴⁹ See Jeffrey Davis, Cramming Down Future Claims in Bankruptcy: Fairness, Bankruptcy Policy, Due Process and the Lessons of the Piper Reorganization, 70 Am. Bank. L.J. 329 (1996).

⁵⁰ This is, of course, not always the case; in the case of A.H. Robins, for example, all of the victims were fully compensated and the stockholders came out of

bankruptcy with shares worth four times what they were when the bankruptcy was filed.

⁵¹ See supra note 42.

⁵² See, e.g., *In re Amatech Corp.*, 755 F.2d 1034 (3d. Cir. 1985).

⁵³ The Bankruptcy Reform Act of 1994 enacted this provision, which appears at 11 U.S.C. sec. 524(g). This provision is limited to asbestos claims, and its constitutionality has not been resolved by the Supreme Court.

⁵⁴ See, e.g., *Kane v. Johns-Manville Corp.*, 843 F.2d 636 (2d Cir. 1988); Epstein, Nickles, and White, supra note 35, at 801.

⁵⁵ See Fox, et al., supra note 37.

⁵⁶ For example, a key breakthrough for plaintiffs in asbestos litigation was a decision by the Fifth Circuit Court of Appeals that asbestos manufacturers breached their duty to warn on the basis of medical evidence. *Borel v. Fiberboard Paper Products Corp.*, 493 F.2d 1076 (5th Cir. 1973), cert. denied, 419 U.S. 869 (1974).

⁵⁷ See the discussion of the history of asbestos exposure in *Anchem Products, Inc. v. Windsor*, U.S. Supreme Court Docket No. 96-270 (decided, June 25, 1997) (Slip op., at 2).

⁵⁸ Several asbestos manufacturers decided early on to settle cases brought by asbestos victims. The result was a flood of new cases. In the next decade, 25,000 cases were filed. See Rabin, supra note 6, at 864.

⁵⁹ “Non-participating manufacturers” are not eligible for liability protections and they are required to make annual payments at a level higher than the participating manufacturers. See S. 1530, sec. 259; S. 1414, secs. 613(c), 704.

⁶⁰ There was also a claim that the provisions for non-participating manufacturers are necessary to “avoid constitutional questions that would be raised by establishing a separate regime for non-participating manufacturers.” See the original settlement, Part III.C. The meaning and basis of that statement are unclear.

⁶¹ See Rabin, supra note 6 at 864.

⁶² See id.

⁶³ There is some question whether the federal bankruptcy court would have the power to order disclosures that could be considered to be in conflict with existing federal statutory requirements.

⁶⁴ For example, the Manville Trust, which was created to satisfy future asbestos claims against Johns-Manville, has proven to be inadequate, in large part because the number of claimants was underestimated. As a result, there is downward pressure on the company’s stock and the fate of the company is uncertain. See Epstein, Nickles, and White, supra note 54, at 802-03.

⁶⁵ The issue of interest payments is not addressed for other claims.

⁶⁶ The scope of this section is discussed above. To the extent that the scope extends beyond personal injury cases, limitations on parties could affect a broad range of cases unrelated to the settlement.

⁶⁷ However, non-manufacturers may be liable for their own fraud or other misconduct. In addition, they may cooperate with plaintiffs in providing evidence against manufacturers, a benefit that may be more valuable than their actual payment of damages.

⁶⁸ Fed.R.Evid. 407 (“When, after an event, measures are taken, which, if taken previously, would have made the event less likely to occur, evidence of the subsequent measures is not admissible to prove negligence or culpable conduct in connection with the event. This rule does not require the exclusion of evidence of subsequent measures when offered for another purpose, such as proving ownership, control, or feasibility of precautionary measures, if controverted, or impeachment.”).

LIMITATIONS ON TOBACCO INDUSTRY TORT LIABILITY

COMMENT BY RICHARD DAYNARD, J.D., PH.D.

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Professor Correia's paper provides a solid overview of many of the most significant issues at stake with regard to potential legislative changes in the tort liability of the tobacco industry. This comment takes issue with a number of specific points he raises, and addresses a more general premise discussed in (though not endorsed by) the paper: the need to "trade off" changes in the civil justice system to achieve public health goals.

The Power of State Settlements

Professor Correia claims on page 3 that without Federal legislation, "the relief obtained by successful states [through litigation] would vary from state to state, depending on state law, and the strength of the evidence." This analysis disregards the strong likelihood of a state-by-state settlement of these cases. The combination of the "most favored nation" (MFN) clauses found in each state settlement, along with the practice of including all past concessions in each new settlement, means that the states would gradually (over the next couple of years) develop relatively uniform and increasingly strong consent decrees.

While tobacco companies might threaten to go to trial rather than settle "at the going rate" in a state with a particularly weak-seeming case, they would be unlikely to carry out the threat for several reasons. First, the charges being made in these cases are escalating. In addition to the early emphasis on reimbursement for Medicaid expenses, cases now seek anti-trust, consumer protection, equitable, punitive damages and RICO claims. Second, the downside for the industry is greater in most cases than the

upside: if the industry wins, it will not discourage later cases, because there's too much at stake for each state. If it loses, the jury may set a new standard, e.g. for punitive damages. Third, the evidence introduced in the case will tend to discredit the industry in other forums, if the case is allowed to proceed.

The Potential for, and Impact of, Tobacco Industry Bankruptcy

With regard to tobacco industry bankruptcy, the paper argues that "the novel nature of the cases and the poor record of past plaintiffs suggest that the actual liability could fall well below the face value of the pending claims." (p. 21) In fact, the high value of the five post-June 20 settlements, plus the myriad of other plaintiffs who have appeared on the scene, suggests that the aggregate potential liability clearly exceeds the market value of the industry.

In the section on "The Impact of Bankruptcy on the Public Health," (pp. 28-32) it is unclear whether the analysis is intended of a bankruptcy under a legislated settlement, or without one. While the paper seems primarily to address the former condition, the latter is more interesting, because (1) a settlement would essentially guarantee that the existing tobacco companies will remain solvent, and (2) the bankruptcy alternative has been used to scare people into supporting legislation by raising fears of prohibition ("they'll go bankrupt, and then there won't be any legal suppliers of nicotine, and then we'll have prohibition all over again") or endless litigation ("it will get tangled up in court and no one will see their money for years").

Professor Correia argues that "it seems highly unlikely that the restrictions placed on the tobacco industry by a bankruptcy court would be more protective of public health than the restrictions contemplated" in settlement legislation, and points to a number of ways that the industry could benefit from bankruptcy (pp. 32-33). In my judgment, bankruptcy is likely to benefit the public health, perhaps more so than the proposed settlement. For example, a bankruptcy court might demand plain packaging, tombstone advertising, and other restrictions in an effort to minimize future liability. It could also demand a large liability insurance policy (or self-insurance), pushing up tobacco product prices.

Document Disclosure

The paper asserts that "the disclosure provisions contemplated in the settlement legislation...implemented effectively...will be as effective (or more effective) than future tort litigation." (p. 35) I disagree. The proposed single federal forum, deciding privilege issues once and for all, is likely to result in fewer incriminating documents seeing the light of day than the current decentralized system. A clear advantage of the current system is its asymmetry: once any court releases the documents, they are part of the public record, regardless of the views of other courts.

The Big Picture: Creative Disorder and Tobacco Control

Professor Correia argues his points closely, and takes care not to draw broad conclusions. But the arguments raised in his paper, exploring the need to provide the tobacco industry with protection from tort liability to advance public health, fit into a broader assessment of the industry and its opponents shared by many supporters of a

legislated tobacco settlement. They argue that conceding changes in the civil justice system is necessary to put in place a system to get the tobacco industry "under control". Though recognizing some merit in liability litigation, they reject the chaos and uncertainty of this strategy, claiming that "you can't control something with disorder!"

And they may be right. But perhaps you can't "control" the tobacco industry at all.

The irony in this analysis is that, historically, it's been the industry that's been "into" control. Controlling kids. Controlling the media. Controlling Congress and the state legislatures. Controlling the pace of litigation. Controlling the language of the public debate. Controlling the way that judges and jurors frame the issues before them. Controlling.

Tobacco control advocates have tried control too. Controlling sales to kids. Controlling advertising on television. Controlling the warnings on cigarette packages. We set the rules, and the industry found a thousand ways around them.

To be fair, control has sometimes worked for us. Controlling indoor smoking has worked very well here. But it hasn't worked nearly so well in Paris. What's the difference? Perhaps that these rules have tremendous popular support here. The enforcement authorities, like the Maytag repairman, don't have much to do. Nonsmokers here are happy to assert their rights, confident that informal as well as formal norms will support them. Not so in Paris.

Control suits the industry well. Make the kids associate smoking with rebellion, and perhaps they won't think about addiction, or wrinkles. Remind the media of their advertising revenue, and critical stories will get less play. Lock up the key legislative leaders and committees, and

pro-health legislation, regardless of its potential support, never makes it to the agenda. Fragment, complicate and delay the lawsuits, and the plaintiffs never get their day in court. Push "personal choice" to the fore in public and legal discourse, and neither addiction nor the industry's own choices will get much attention.

The industry needs control, because the truth is out there everywhere, always threatening to derail its best-laid plans. Narrow the debate, define the terms, persuade the influential elites to stay within these bounds, and then stigmatize, isolate, and disenfranchise the "zealots" (i.e. anyone who won't discuss the issues in the "reasonable" terms the industry has set out). It's a tough act to pull off, since once people stop thinking in the industry's terms, they're lost to the industry forever. But the industry got away with it for a long time. And, with the June 20 "global resolution", it thought it had gotten away with it again.

The industry explained, correctly, that it needed "predictability", meaning immunity from financial accountability for the harm it has done, and protection from the wrath of a jury of its peers; and the "global resolution" would provide that kind of predictability. The industry also explained, correctly, that it needed to resume its earlier respectability, through a true public "amnesty" (meaning *forgetting*), and the "global resolution" promised that too. With predictability and respectability assured, truth loses its threatening aspect. Control is reestablished.

But "tobacco control" has nothing to fear from disorder. Purloined documents, California bar smoking bans, Winthrop, Massachusetts cigarette sales bans, whistleblowers, unruly activists, huge punitive damage awards, industry executives who take the Fifth, investigative journalists, imaginative novelists and scriptwriters,

scientific researchers, enterprising plaintiffs' attorneys, angry jurors... none of these are our enemies.

No one planned Dr. Koop, Dr. Kessler, or Merrell Williams. No one planned the recent explosion of state and local legislative activity, extending nonsmoking rules to undreamed-of places, raising taxes to unhoped-for levels, banning billboards, divesting, condemning, imploring. No one planned the efflorescence of lawsuits - from individual actions, to class actions, to Medicaid reimbursement actions, to union pension fund reimbursement actions, to asbestos companies' and asbestos victims' trust cost contribution actions; from common law claims to consumer protection claims, to anti-trust claims, to RICO claims; from actions seeking damages to actions seeking medical monitoring funds, to actions seeking disgorgement of profits; from civil claims to criminal indictments.

And no one knows where we're going next. We're going in the right directions, even if we can't draw the map yet. And no one needs to know what the future holds. Besides the tobacco industry. So they can control it.

LIMITATIONS ON TOBACCO INDUSTRY TORT LIABILITY

COMMENT BY PETER D. JACOBSON, J.D.

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The article by Professor Correia on the limitations of tort liability in the tobacco control context is an important contribution to the discussion on how best to deal with the tobacco industry. So far, consideration of the settlement negotiations has been framed largely by those who view litigation as superior to the negotiated settlement in achieving better public health outcomes. Professor Correia's analysis adds a welcome skepticism to the argument that social problems can be resolved through litigation.

To be sure, litigation has been central in forcing the industry to negotiate, for requiring the release of damaging internal industry documents, and for placing tobacco control squarely on the national policy agenda. Without the pressure and negative publicity generated by the litigation, it is unlikely that the tobacco industry would have willingly participated in settlement negotiations.

Nevertheless, the settlement has come under withering criticism for abjuring harsher terms and for absolving the industry of past harms. To a certain extent, the criticism is justified. If ever there were an industry that deserved to be pilloried, the tobacco industry would top the list. But that's not the issue. Everyone in the tobacco control movement agrees that the use of tobacco should be limited, that youth smoking should be discouraged, and that the industry should be accountable for the harms it has caused.

The question is whether the terms of the settlement advance us toward meeting those goals or whether alternative solutions would achieve better health outcomes. It is in this context where the tobacco control movement has been fragmented. If one

believes that litigation is likely to achieve better outcomes, then opposing the settlement is appropriate. If, on the other hand, one is skeptical of a litigation solution, the more appropriate response is to strengthen the terms of the settlement agreement while acknowledging that settlement is better than the status quo.

Professor Correia's analysis adds an important dimension to the debate. Correia shows, convincingly in my view, that predicting the shape, course, and outcomes of litigation is risky, and thus provides a note of caution. In general, Correia realistically assesses the limits of relying on liability to change industry behavior. In particular, Professor Correia's discussion of the implications of driving the industry into bankruptcy is an issue that so far has received insufficient attention. If Professor Correia's analysis is correct, the litigation solution will ultimately not result in the public health gains expected by its proponents.¹

Professor Correia also offers sensible recommendations for amending the settlement. If Congress were to enact legislation incorporating each of these alternatives, I suspect that most tobacco control advocates would willingly support the legislation. But the political process is unlikely to yield such a favorable outcome, requiring considerably more compromise than many tobacco control advocates would find comfortable. Just as troublesome, the judgment of whether to accept legislative compromise must be made with little opportunity for extended deliberation. As Professor Correia notes, the prospects for enactment and the actual shape of the

legislation may not be known until adjournment is near.

Along with his specific discussion of the legal aspects of the proposed settlement, Professor Correia's analysis raises two issues regarding the use of litigation. First is the narrow issue of whether relying on litigation is preferable to accepting the terms of the settlement negotiations, presumably with some modifications to solidify FDA regulatory authority and perhaps to eliminate industry immunity from liability. Second is the broader issue of reliance on litigation to formulate public health policy.

As to the former, it is unlikely that either litigation or a Congressionally mandated settlement will vanquish the tobacco industry. If the goal of the tobacco control movement is to demand capitulation, much as Congressional Republicans tried to obtain from the Democrats when the former attempted to shut down the government in 1995, we will most likely be disappointed. Proponents of litigation implicitly expect similar outcomes to the asbestos and dalkon shield cases, where large damage awards resulted in removing these dangerous products from the marketplace. Unlike these examples, where litigation actually did result in crippling the industries, it seems unrealistic to assume that tobacco products will not be available in the United States, for the reasons noted by Professor Correia. A more likely result, similar to the asbestos litigation, is that any claims settlement fund will not be adequate to fund all those who have suffered from consuming tobacco.

Therefore, the settlement should be accepted or rejected on public health grounds, specifically whether the terms of the settlement add significantly to our ability to prevent non-smokers from using tobacco and to encourage current smokers to cease using tobacco. In part for the reasons suggested by Professor Correia, I am skeptical that tobacco litigation by itself will lead to improved public

health outcomes. Not only are the current legal theories untested, even if the proponents of a litigation solution are correct that the breakthrough is inevitable, the payoff will be far in the future. For one thing, the appeals process means that the payout from any large awards will be subjected to lengthy delays. For another, Professor Correia's description of the bankruptcy process suggests the difficulties that lie ahead.

There is little question that the proposed settlement is not perfect. It allows the industry considerably more freedom to operate than most of the tobacco control community would prefer, and with less stringent penalties for failing to reduce youth smoking than desirable. But is there a better alternative? If once again we allow the best to be the enemy of the good, we will have allowed the tobacco industry even more room to purvey their noxious and odious products. In fact, the reaction has already begun to emerge, both from within and from outside of the tobacco industry. For example, Jacob Sullum is publishing a book from the libertarian perspective that is likely to attack the very notion of the public health basis for regulating tobacco products.²

This raises an important issue that I think has been somewhat obscured by the debate over whether to accept the settlement. Several years ago, Professor Robert Rabin challenged tobacco control and public health advocates to do a better job of articulating the public health justification for controlling the use of tobacco products.³ I am not convinced that tobacco control advocates have adequately responded to Professor Rabin's challenge. Indeed, the arguments likely to be offered by Sullum's book will only exacerbate that challenge. My concern is that in an era of constrained government, Sullum's message may resonate well beyond the confines of the proposed settlement while advocates argue over tactical considerations that diminish long-term strategic objectives. In this sense, the

advocates' attention on the settlement is both a distraction and an impediment to the more important strategic battles ahead on how to maintain recent gains without succumbing to legislative and regulatory apathy or to the counter-reaction likely to emerge.

None of this is to suggest that the choice of accepting or rejecting the legislation that emerges from Congress is easy. Nor is it to suggest that the rupture among tobacco control advocates will be repaired overnight. It is to suggest, however, that any legislation enacted will not end the debates over how to reduce the use of tobacco products. More likely, it will just stimulate other debates about the allocation of tobacco control resources, about how to implement and enforce the legislation, and about how to respond to the inevitable tobacco industry rejoinder. We all know that the tobacco industry is a resourceful and creative adversary. No single settlement, or even a string of litigation victories is likely to alter that reality.

Admittedly, I have not been a participant in the debates now roiling the tobacco control movement. But from my perspective, the debates at least tacitly assume that the settlement is the end rather than a means to an end. Regardless of which alternative is selected, I do not anticipate the demise of the tobacco industry any time soon.

NOTES

¹ In reality, it is difficult to predict the consequences of either accepting the settlement or relying on litigation. It should also be noted that Professors Hanson and Logue reach a very different conclusion regarding the consequences of bankrupting the tobacco industry. See, Jon D. Hanson and Kyle D. Logue, "The Costs of Cigarettes: The Economic Case for Ex Post Incentive-Based Regulation," *Yale Law Journal*, forthcoming 1998. Hanson and Logue also explicitly prefer the status quo to the current terms of the settlement.

² Jacob Sullum, *For Your Own Good: The Anti-Smoking Crusade and the Tyranny of Public Health*, The Free Press, 1998.

³ Robert L. Rabin, "Some Thoughts on Smoking Regulation," *Stanford Law Review*, Vol. 43, pp. 475-496, 1991.

TOBACCO BANKRUPTCIES AND PUBLIC HEALTH

COMMENT BY MARK C. ELLENBERG, J.D.¹

EXECUTIVE SUMMARY

INTRODUCTION

Consideration of a legislative solution for tobacco-related health issues necessarily calls for comparison to remedies available through the judicial system. A potential consequence of pursuing judicial remedies is the bankruptcy of one or more tobacco companies, due to large damage awards. Two central questions must be answered. First, would tobacco company bankruptcies have an adverse impact on public health? Second, would a legislative solution including liability caps preclude bankruptcy filings by tobacco companies? These questions are addressed below.

THE PUBLIC HEALTH IMPACT OF TOBACCO BANKRUPTCIES

The legislative and bankruptcy models for addressing tobacco-related tort liability would potentially impact the public health in materially different ways. Each model has strengths and weaknesses.

The legislative model would:

- address the entire industry at once;
- provide a superior vehicle for the formulation of public health policy; and
- provide individual claimants some compensation, but deprive them of valuable legal rights.

The bankruptcy model would:

- address each company separately, in diverse fora;
- provide a limited vehicle for the formulation of policy; and
- provide an excellent vehicle for the capturing of economic value and the compensation of individual claimants.

THE IMPACT OF LIABILITY CAPS ON BANKRUPTCY FILINGS

Caps on tobacco industry liability, as proposed in the "Universal Tobacco Settlement Act" and other bills, would not preclude the voluntary filing of bankruptcy petitions by tobacco companies. There is no means test for bankruptcy. A company can commence a case whether or not it is solvent. Any legislation should address the possibility of a voluntary filing by a solvent company.

Liability caps also would not protect tobacco companies from economic adversity unrelated to tort claims. A company may find itself in a genuine financial crisis due to business reversals. Such bankruptcies are not preventable.

While bankruptcy filings would still be possible, they are not likely for reasons wholly separate from the caps. First, bankruptcy could cause management to lose control of the company. Second, claims of future smokers likely could not be addressed. Third, punitive damage awards may not be discharged.

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TOBACCO BANKRUPTCIES AND PUBLIC HEALTH

COMMENT BY MARK C. ELLENBERG, J.D.¹

INTRODUCTION

The debate over whether to adopt a legislative remedy to the public health consequences associated with tobacco products quite naturally demands comparison to the remedies available through the judicial system. A potential consequence of pursuing legal remedies is the bankruptcy of one or more tobacco companies, due to large damage awards. The United States Bankruptcy Code provides both a complex and flexible system for addressing financial liabilities. The course of an actual bankruptcy case involving a tobacco company could take any of several directions. Indeed, multiple cases involving separate companies could result in quite different outcomes. Nonetheless, certain fundamental principles, applicable in all bankruptcy cases, suggest that the bankruptcy model would diverge from the legislative model in a number of important ways. These fundamentals and their likely consequences, which have not been clearly articulated in the current debate, are discussed below.

An understanding of the bankruptcy fundamentals permits two critical questions to be answered. First, what impact would a tobacco bankruptcy have on public health policy? Second, would a legislative solution including liability caps preclude tobacco companies from filing bankruptcy cases? These questions are also discussed below.

BANKRUPTCY FUNDAMENTALS

Goals of the Bankruptcy System

The Federal bankruptcy system, as codified in the United States Bankruptcy Code, has three principal goals. The first is to provide a debtor a fresh start, free of crushing debts. The fresh start is accomplished by giving the debtor a "discharge," or freedom from any future liability on all prepetition debts. In order to obtain the discharge, the debtor must contribute his available assets to pay creditors. The second goal is to provide equitable treatment to creditors by ensuring that each will receive a ratable share of the available assets. To achieve this goal, all creditors are gathered in a single court, which will evaluate each claim against the debtor. The third goal is to maximize the value of the assets available to pay creditors. This is achieved through the careful management and orderly disposition of the assets.

Types of Bankruptcy Cases

A tobacco company bankruptcy case could take the form of either a liquidation under chapter 7 of the Code, or a reorganization under chapter 11. These alternatives are discussed below:

Chapter 7 Liquidation

In a liquidation, the debtor's assets would immediately be taken over by a trustee.

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While a chapter 7 trustee has limited authority to operate a business, the essential course of a liquidation is the discontinuance of business operations, the sale of all assets, and the ratable distribution of the proceeds to creditors. A corporate debtor does not receive a discharge from its debts, to the extent that such debts remain unpaid. However, the corporation can, and presumably would, dissolve.

Chapter 11 Reorganization

Debtor in Possession: In a chapter 11 reorganization, the debtor remains in possession of its assets. That is, existing management remains in place and continues to operate the business. Under certain circumstances, the Court could decide to replace management with a trustee, who would take over full authority to operate the business.

Plan Confirmation: The chapter 11 debtor in possession acts as a fiduciary to the corporation's creditors and shareholders, although the creditors' interests come first. The ultimate goal is to develop, and have confirmed by the bankruptcy court, a plan of reorganization which provides for payment of debts to the greatest extent possible. Because the plan preserves the value of the debtor as a going concern, the payments to creditors should exceed those in a liquidation, where the debtor ceases to operate. Indeed, one of the more important legal standards for confirmation of a reorganization plan is that each creditor receive better treatment than he would in a liquidation.

Unless affected creditors agree otherwise, a chapter 11 plan must also strictly adhere to the priority of claims against the debtor. This legal standard, known as the absolute priority rule, provides that until a creditor is paid in full, no one with a junior claim or interest can be paid anything. In the tobacco company context, an unsecured

creditor, such as a person injured by cigarettes, would have to be paid in full before any value could be given to the company's stockholders. A common reorganization technique for insolvent companies is to take ownership interests away from the old stockholders and give them to creditors. The creditors are then paid through future profits of the business or the sale of the stock distributed to them.

A final plan confirmation standard of particular relevance to the tobacco debate is the requirement that a plan be feasible. Where a plan proposes to pay creditors over time, the plan proponent must prove to the bankruptcy court that the debtor is more likely than not to make the payments. Similarly, if payment is in the form of stock or similar securities, the plan proponent must prove that the valuation of the securities is realistic.

Operating Restrictions and Impact on Affiliates: While a debtor is in chapter 11, it operates under the supervision of the bankruptcy court. Generally, a debtor can operate in the ordinary course of business without specific court approvals. Non ordinary course actions, such as major capital expenditures or asset dispositions, must be approved by the court. The court may also review and modify compensation and bonus systems.

A company which owns subsidiaries may file a petition just for itself. The subsidiaries can continue to operate outside of bankruptcy, while their stock would be an asset of the bankruptcy estate. To the extent actions of the subsidiary, such as a major asset disposition, could affect the value of the estate, the court could intervene.

By the same token, the commencement of a bankruptcy case of a subsidiary would not necessarily result in the bankruptcy of its parent. The parent, and other affiliates, could continue to operate as usual. In most instances, a parent is not liable for the debts of a subsidiary. Accordingly, the parent's assets would not be assets of the bankruptcy estate.

However, a parent could be pursued on state law veil-piercing, successor liability, or fraudulent conveyance theories. This is especially pertinent where a spinoff is effected to insulate parts of a corporate family from certain new liabilities. Where affiliated companies operate as alter egos or a consolidated economic unit, the bankruptcy court could also order the substantive consolidation of the two companies, thus combining the parent's assets with the debtors'.

Chapter 11 Committees: In every chapter 11 case, an official committee must be appointed to represent unsecured creditors in plan negotiations. This committee can retain counsel, accountants, and investment advisors, all to be paid for by the debtor. There is discretion to appoint other committees, and in every mass tort bankruptcy a separate claimants' committee has been established. Where the stock of a debtor is widely held, an equity securities holders' committee is also usually established. The committees engage in negotiations with a debtor until a plan is agreed to or one is imposed through litigation in the bankruptcy court.

Litigation and Disposition of Claims

When a bankruptcy is commenced, the Code automatically stays all pending or future litigation against the debtor for the purpose of collecting prepetition debts. Tort cases pending in state court can no longer proceed and, for all practical purposes, are terminated. The injured party's only recourse is to pursue a claim in the bankruptcy case. Legislation passed in the wake of the Johns-Manville bankruptcy does ensure that personal injury claims are heard by a jury in the federal district court where the bankruptcy case is pending.

There is an exception to the automatic stay for actions commenced by a government

to enforce its police or regulatory power. The case law interpreting this provision is somewhat opaque and, accordingly, it is not clear to what extent suits commenced by state governments against tobacco companies would be permitted to proceed. The decision whether a state could continue to press its claims would rest with the bankruptcy court. In addition, any money judgment resulting from a state action that is allowed to proceed would have to be brought to the bankruptcy court for payment.

THE POTENTIAL IMPACT OF BANKRUPTCY ON PUBLIC HEALTH

One of the clearest differences between a legislated "settlement" and tort-related tobacco company bankruptcies is that the former would be industry-wide and the latter would be piecemeal. An industry cannot file a bankruptcy petition. Even were all the tobacco manufacturers to file simultaneously, the cases would be distinct. Almost certainly, there would also be separate judges, separate debtor's counsel, separate committees with separate members and counsel, and separate venues. Each debtor would have a unique set of trade creditors, as well. From the perspective of public health policy, coherence of approach would be difficult, if not impossible, to achieve.

In the same vein, the legislative and bankruptcy models have divergent purposes. The primary focus of legislation is policy. The primary focus of bankruptcy is compensation of creditors. Each will be better than the other at what it does best. Each will be worse than the other at what it does not do best.

The bankruptcy model would compensate litigants as well as possible. Almost certainly, a tobacco bankruptcy would be in the form of a chapter 11 reorganization.

Chapter 7 would result in control of the company be handed to a trustee. The trustee would control not only the assets, but all of the company's documents and all of the company's legal privileges. It is hard to envision these being surrendered. Of course, Chapter 7 would also mean a termination of business and the consequent loss of value to shareholders.

Under chapter 11, the business would continue as a source of payment to creditors. Healthy companies which have entered chapter 11 to address special liabilities have not seen their businesses suffer. Johns-Manville, A.H. Robins, Dow-Corning, and Texaco are all examples. Indeed, A.H. Robins, which was purchased out of bankruptcy by American Home Products for over \$3 billion, clearly enhanced its value while a chapter 11 debtor. The tobacco claims would have first right to the going concern values of the tobacco company debtors.

The level of compensation of mass tort claims in bankruptcy has been good. In Johns-Manville, claimants who had proved their claims received the right to be paid from a trust fund. The fund had an increasing call on the common stock of the company to the extent it ran short of funds. In A.H. Robins, a \$2.5 billion trust fund was established solely for claimants. The size of the fund was determined by a trial which estimated the outstanding claims. As the Robins claims process approaches its conclusion, it appears that the fund has been able to pay all claims in full, and has enough left over to make an additional distribution in lieu of punitive damages. The value of the company in excess of \$2.5 billion went to the shareholders.

The A.H. Robins case also demonstrates that bankruptcy can do even better than the tort system at making some form of compensation available to tort victims. When A.H. Robins filed a bankruptcy petition, approximately 6,000 cases were pending in the courts. A.H. Robins

was on notice of another three to four thousand claims. By virtue of an extensive print and television notice program and a simple claim form which did not require assistance from a lawyer, the bankruptcy case produced over 300,000 claims against the company. To be sure, these claims winnowed down substantially. But to be equally sure, tens of thousands of victims who would never have entered the traditional tort system found a remedy in the chapter 11 case.

The ability of bankruptcy courts to establish forward-looking policy is much less certain. It has been suggested that the need to determine the feasibility of a reorganization plan would permit judges to control future conduct with respect to the manufacture and sale of cigarettes. At best, these are uncharted seas, where a judge would proceed with extreme caution. Moreover, if the parties could not agree on controls, the "policy debate" would be converted to a battle of expert witnesses. The Claimants' Committee would produce a witness to discuss the risks of future conduct by the debtor. The debtor would put on its own expert witness to express a contrary point of view. The judge would be left to sort it out.

If the parties could agree to place controls on future conduct in a consensual plan, the court would likely approve. But the likelihood of such agreement is remote. The trade creditors committee will be concerned solely with financial recovery, not public health policy. The claimants committee may raise policy issues, but may well be prepared to trade policy away for dollars. From the debtor's perspective, accepting controls on its own, without assurance that its competitors would be equally constrained, could prove problematic. Thus, the structure and dynamics of the bankruptcy model do not augur well for a policy debate.

The Effect of Industry Liability Caps on Bankruptcy

A number of bills before Congress, including the "Universal Tobacco Settlement Act" reported out of the Senate Commerce Committee on November 8, 1997, have proposed annual caps on tobacco industry liability as part of a comprehensive tobacco policy approach. One premise of these proposals is that liability caps would prevent bankruptcy filings by tobacco companies. Another premise is that, in the absence of caps, bankruptcy filings will occur. Neither premise is necessarily correct.

There is no means test for the voluntary commencement of a bankruptcy case by debtor. A corporation could commence a case simply by filing a petition accompanied by a board resolution and a filing fee. The solvency, *vel non*, of the debtor is immaterial. Johns-Manville, A.H. Robins, Dow-Corning, and Texaco were all solvent when they commenced their chapter 11 cases. A challenge to the Johns-Manville filing specifically on this ground was rejected.

A bankruptcy case can be dismissed if the court finds it was not filed in good faith. However, good faith means only that the debtor has an objectively reasonable intent of filing a reorganization plan that feasibly addresses its liabilities. A petition filed by a tobacco company the day after cap legislation became effective would likely be in good faith under this standard. That the company would be able to keep the benefits of the legislation and discharge the obligations would not provide a basis for dismissal.

Of course, legislation could, and probably should, address the prospect of subsequent bankruptcy filings. One possibility would be to make the statutory protections afforded the companies terminable upon a bankruptcy filing. Another would be to make a tobacco company ineligible to file for protection under the Code – or similar

state laws – unless it was unable to pay its debts as they came due or was demonstrably insolvent.

Apart from voluntary strategic bankruptcy filings, the legislative liability caps would not immunize the tobacco companies from economic adversity. No one knows for certain how legislative controls on the manufacture and marketing of tobacco would affect future business performance. The normal downturns, misfortunes and poor management decisions which drive other companies to the refuge of chapter 11 could also befall a tobacco company as well. Even gambling casinos go bankrupt, and their viability is assisted by the laws of probability. The possibility of an economic bankruptcy should be noted, but it is doubtful that legislation should preclude bankruptcy in a real financial crisis.

A final way in which bankruptcy could result is from an involuntary filing. An involuntary filing must be commenced by three creditors. In contrast to voluntary cases, an involuntary case will be dismissed if the debtor is not insolvent. Thus, an involuntary bankruptcy filing against a tobacco company is not likely to occur unless the company is in a true financial crisis.

LIKELIHOOD OF A TOBACCO BANKRUPTCY

Even though a tobacco company can commence a bankruptcy case without regard to solvency, bankruptcy is unlikely to present an appealing option to most boards of directors. First, bankruptcy would threaten management's control. At a minimum, operations of the company would be subject to the scrutiny of the bankruptcy court and creditors' committees. This scrutiny could extend to discovery of documents and policies, as well as business matters.

The appointment of a trustee is another control risk. While a court would be reluctant to displace mismanagement of a multimillion dollar business, proof of misdeeds by management could be sufficient to force a change. As noted above, a trustee would not only run the business, but take control of documents and corporate privileges as well.

A final control risk is the potential for the company being put in play. Once a company enters the bankruptcy process, the creditors can force a sale to a serious buyer at a fair price. The prospect for monetizing the value of the debtor's business in order to pay its creditors is compelling. A.H. Robins, for example, had no intention of being acquired when it entered chapter 11. An alliance between the claimants' committee and American Home Products forced the issue, and the company was ultimately unable to resist.

In addition to control issues, Chapter 11 may not prove an effective solution to tort liability for the tobacco companies. At the outset, claims by future smokers would pose a serious problem. In the cases of asbestos, dalkon shields, and breast implants, the products at issue were no longer being made. Future claims in those cases meant claims of persons who were exposed to the product, but not yet manifested injury. Those types of future claims are addressable by a bankruptcy because they have a prepetition nexus.

No bankruptcy court has ever asserted the right to affect claims arising completely after the filing of a bankruptcy petition. Yet persons who start smoking after a petition is filed have a more than colorable argument that they are in just that position. To be sure, the underlying tort claims of these persons may be weaker than those who began smoking years ago, but they are still claims which could be brought. The attractiveness of Chapter 11 as a remedy to a tobacco company is directly

dependent on how serious it considers the risk of the future smokers' claims.

Another significant problem would be punitive damages. Punitive damages will be subordinated to the regular claims of creditors in a chapter 11 case. The rationale is that innocent creditors should not be punished for wrongful conduct by the company. Punitive damages must, however, be paid before any value is given to shareholders. Because of the absolute priority rule, this poses a serious threat to shareholder recovery.

Even worse, punitive damages may not be subject to discharge. A discharge would be denied to the extent the punitive damages resulted from fraud or from willful and malicious injury. To the extent punitive damages were not dischargeable, the debtor would remain liable for them in full, even after bankruptcy.