

PRIVILEGED AND CONFIDENTIAL
ATTORNEYS' WORK PRODUCT

January 26, 1994

MEMORANDUM

Re: Strategy for Responding to Inquiries in Connection with the Release of a Cigarette Ingredient List, a Report by the Department of Health and Human Services on Cigarette Ingredients or a Congressional Hearing on Ingredient Matters

Since April 2, 1986, the six major U.S. cigarette manufacturers have submitted annual ingredient lists to the Department of Health and Human Services (HHS). These lists, which are regarded as trade secrets, were submitted to HHS pursuant to Section 7 of the Federal Cigarette Labeling and Advertising Act. The Act requires HHS to review the lists submitted to it and to prepare a report to the Congress on any health effects associated with the use of the ingredients.

Before the first list was submitted, a strategy was developed for handling media inquiries about the list and the use of ingredients in cigarettes and called for the channeling of inquiries to Covington & Burling, which has been functioning as counsel for the six major American cigarette manufacturers in connection with the annual preparation and submission of the ingredient lists to HHS. It was felt that this procedure would help prevent confusing and inconsistent statements and maximize the ability of the industry to present to the public its position on ingredients in a coherent manner.

LG 2003350

Section 7 of the Federal Cigarette Labeling and Advertising Act authorizes the release of ingredient information to a "duly authorized subcommittee or committee of Congress." Since the inception of the cigarette ingredient reporting requirement in 1986, ingredient lists have been released by HHS at the request of subcommittees or committees of Congress on a number of occasions. Lists were disclosed to Congressman Waxman's Subcommittee on Health and the Environment in 1986, and to Senator Kennedy's Committee on Labor and Human Resources in 1990. In 1993, lists were submitted to Congressman Waxman's Subcommittee, to Congressman Wyden's Subcommittee on Regulation, Business Opportunity and Technology and to Congressman Durbin's Subcommittee on Agriculture, Rural Development, Food and Drug Administration and Related Agencies.

The tobacco companies and HHS have stressed to Congress the confidential nature of cigarette ingredient information, and the ingredient lists submitted to Congress have not been leaked or otherwise released to the public. In connection with the release of ingredient lists to Congressional subcommittees in 1993, minority members of the subcommittees and HHS have urged the subcommittees to protect the confidentiality of the ingredient lists. It remains possible, however, that one or more of the ingredient lists submitted to Congress may be disclosed to the public at some point.

Correspondence in 1993 between HHS and the Waxman and Wyden Subcommittees disclosed that HHS has recently identified those cigarette ingredients that are approved or recognized as safe for use in food, listed those ingredients that are regulated by the federal government as hazardous substances and contracted with the National Cancer Institute (NCI) to prepare critical evaluations of specific ingredients.

Although it is not known whether HHS is actively preparing a report on ingredients, the heightened Congressional interest in ingredients and recent HHS activities in this area may prompt renewed focus on the development of a report. It is possible that a report by HHS would criticize the number of the ingredients on the list, assert an absence of data about the effects of exposure to ingredients as a result of their use in cigarettes, and/or contend that certain specific ingredients are harmful. Such a report also could contain a copy of the ingredients list without violating the confidentiality requirements for ingredient information imposed by the Federal Cigarette Labeling and Advertising Act, which exempts the reports to Congress from the confidentiality requirements.

We have repeatedly requested both orally and in writing that the Office on Smoking and Health, which is responsible for preparing the HHS report, afford an opportunity for our experts to meet with HHS before the report is finalized. The Office on Smoking and Health has informed us at every

LG 2003352

instance that their work is not yet at the point where such a meeting would be in order.

In light of the recent release of cigarette ingredient lists by HHS to Congressional Subcommittees and the possibility that such information may be leaked to the press, we have revised the previous strategy to address more fully the possibility of public disclosure of the lists and an appropriate response plan in the event of a leak.

The revised strategy retains the same basic response plan with respect to publication of an HHS report on ingredients. HHS remains obligated to provide a report to Congress, and, as noted, there may be increasing pressure from the new Administration or Congress for HHS to complete the report.

Release of the ingredient list could spark media interest and public concern. Publication of a report almost certainly would generate media attention. In fact, the release of a full report -- particularly if accompanied by claims of adverse health effects for individual ingredients -- might well prompt more publicity than if the ingredient list were merely leaked to the press. Moreover, the official nature of a report is likely to enhance the attention given to any adverse comments contained in the report, and it could affect the regulation of ingredients both in the United States and elsewhere.

LG 2003353

Under the revised strategy, Covington & Burling would continue with the assignment to respond initially on behalf of the industry to release of the ingredient list or the HHS report. This is a feasible approach to the extent that the industry response will make general points and not address detailed scientific issues.

If release of the list or the HHS report attracts significant media attention, however, it is likely that some issues would have to be addressed by scientific experts, either those who are employees of individual companies or retained experts.

As noted, the Waxman and Wyden Subcommittees have recently expressed strong interest in cigarette ingredient matters. In addition, Representative Synar has introduced legislation that would establish strict labeling and safety requirements for cigarette ingredients. In view of these developments, it is possible that one or more Congressional hearings will be held this year on cigarette ingredient matters. Congressional hearings on ingredient issues may generate significant press interest and media inquiries.

Depending upon the nature and timing of a Congressional hearing on cigarette ingredients, and the number of scientific and technical issues raised in connection with the hearing, it may be necessary to present expert scientific testimony, as well as testimony on legal and policy issues.

LG 2003354

General Objectives and Tactics

Our hope, of course, is that the release of the list or publication of an HHS report will not receive significant media attention, in which event the industry should do nothing that would stimulate media interest in ingredient issues. However, a widely disseminated ingredient list or a highly critical report could generate such strong and widespread adverse media coverage that it may be necessary vigorously to respond.

The strategy described below would (1) explain the industry's long history of cooperation with HHS on this issue, (2) emphasize that the evaluation of ingredients is a scientific process that should go forward without disruptive publicity, (3) decline to discuss individual ingredients based on trade secret considerations but address criticisms directed to major classes of compounds, such as natural extracts, and (4) emphasize important general points about ingredient usage. If a critical report were released, the industry also would (5) protest its exclusion from the process that produced the report (if that should prove to be the case) and (6) address specific criticisms where it is possible to do so without violating confidentiality requirements. If the list were released, the industry would object to the disclosure of confidential information and stress the need for a balanced scientific assessment of ingredients.

LG 2003355

The specific tactics for achieving these objectives necessarily will depend on the scope and intensity of media reaction to a release of the list or publication of a report by HHS. Several different scenarios could unfold, and each is described below.

**SCENARIO I: The Ingredient List is Released and
Attracts Little Public Attention**

If the ingredient list is leaked and attracts little public attention -- which appears highly unlikely -- the draft statement under Tab A would be employed by Covington & Burling to respond to media inquiries.

**SCENARIO II: The Ingredient List is Released and
Attracts Significant Media Attention
and Criticism**

Release of the ingredient list might attract significant media attention and might elicit criticism from anti-smoking groups and others. In this case, a more detailed statement would be employed, along the lines of the draft in Tab B.

**SCENARIO III: A Noncritical HHS Report is Released
and Does Not Include an Ingredient List**

This type of report would probably attract limited media attention. Inquiries would be handled by a brief statement acknowledging the release of the report, and expressing the industry's past cooperation with HHS and its desire to continue to cooperate in the future. This statement

could be used as a talking paper during telephone discussions with reporters or released in response to inquiries.

A draft of the statement that would be used by Covington & Burling is enclosed at Tab C. Tabs D and E contain drafts of brief statements that could be used by individual companies and the Tobacco Institute to refer inquiries to Covington & Burling.

SCENARIO IV: The Report Questions the Use of Ingredients and May Contain the Ingredients List

Under this scenario, the report might raise a variety of questions, such as the large number of ingredients that are used or the relatively limited amount of publicly-available information on the pyrolysis of ingredients. Such a report probably would generate at least a brief flurry of media interest. The inclusion of the list itself in an otherwise mild report could enhance the level of press interest.

News stories that result from the release of such a report might highlight the length and complexity of the ingredient list, discuss the concerns described in the report with regard to the safety of cigarette ingredients, and discuss a number of specific ingredients. Statements by anti-smoking advocates might be quoted, and these could be fairly specific in nature. Anti-smoking advocates could argue that the report indicates that the companies are putting unknown or dangerous materials into cigarettes.

LG 2003357

In these circumstances, we would respond to press inquiries by expressing disappointment about the conclusions reached in the HHS report. If the industry has been excluded from the process that led to the report, we would point that out. We also would (1) note the functions performed by ingredients and the quantities of ingredients present in cigarettes, (2) explain that many cigarette ingredients are used in foods and other articles for human consumption, and (3) refute specific criticisms in the report. A draft statement making these points is attached at Tab F. The statement might be released in response to press inquiries or used as a talking paper during telephone discussions.

SCENARIO V: The Report Is Highly Critical and Generates Sustained and Intense Media Coverage of Ingredient Issues

This scenario is different from Scenario IV only in degree. Under this scenario, an initial flurry of news stories accompanying the release of the report probably would be followed by an extended period of in-depth media interest in ingredients issues. This interest could take a variety of forms, including stories in newspapers and magazines or features on nightly newscasts or weekly news programs such as 60 Minutes.

Considerable attention might be devoted to issues such as the effects of pyrolyzing ingredients, the adequacy of industry testing programs, the asserted need for additional test data, the lack of information as to the ingredients used in

individual brands, the desirability of tighter controls on ingredient usage, and ingredient regulations in other countries that are stricter than the requirements in the United States. Attention also could focus on particular ingredients, with questions being raised about the implications of the available data and the possible contribution of specific ingredients to the alleged hazards of cigarette smoke. Anti-smoking advocates with scientific credentials might be asked to review the available information on specific ingredients and to comment on possible health issues raised by their use. In addition, companies might be pressed to disclose whether specific ingredients are used in their brands.

In this situation, reliance on a general statement probably would be inadequate to address media concerns. The industry would have to be prepared to address a wide range of questions and to rebut several allegations. We have attempted to anticipate issues that might arise if intense media interest results from the release of a report on ingredients and to prepare model responses. A draft set of questions and answers is included at Tab G.

Because of the concerns of product liability counsel, we have not included questions and answers on individual ingredients. We have, however, included possible responses relating to certain specific classes of compounds. In addition, if the issue is raised we would be prepared to deny that the six

LG 2003359

companies use coumarin, cloves, eugenol or other substances that may appear on a composite list that reflects the submissions to HHS of importers and small manufacturers.

The strategy for interacting with the media at this stage would necessarily remain flexible. As noted above, we would hope to maintain a low profile, but it may be necessary to take steps to rebut assertions that are unfair or inaccurate. The statement at Tab G contains several statements designed for this purpose. In addition to responding to calls from reporters, it might be appropriate to meet with a small group of media representatives or release a background paper responding to various issues that have been raised.

If scientific issues are raised that Covington & Burling is not able to address, the industry should rely on scientists who could respond to specific questions or make themselves available for interviews with appropriate reporters. The companies have a number of experts on the use of ingredients, and we have been working with a group of independent scientific consultants, several of whom could serve as spokespersons. The independent scientific consultants have prepared a safety assessment of cigarette ingredients, included at Tab I, that could be employed in responding to media inquiries.

LG 2003360

SCENARIO VI: Congressional Hearings Are Held

Representative Synar has introduced a bill in the current Congress that would impose stringent regulatory requirements for cigarette ingredients. Hearings may be held on the Synar bill, as well as on cigarette ingredient matters in general. Hearings also would be likely in response to an HHS report on ingredients. Such hearings may address any HHS recommendations with respect to ingredients, the safety of particular ingredients, and the adequacy of existing test data. Attention also would be focused on the need for new legislation that might require additional testing, grant jurisdiction over ingredients to FDA or otherwise create an ingredient approval procedure, require the disclosure of ingredients on the labels of individual brands or require brand-specific reporting of ingredients to HHS.

Bills introduced by Senator Kennedy and Representative Waxman in prior Congresses have contained a number of proposed regulatory requirements with respect to ingredients. Hearings have been held on those bills, and ingredient issues have been addressed in the hearings. The tobacco industry testimony in the hearings has addressed legal and policy aspects of ingredient regulation and has not focused on specific scientific or safety issues regarding ingredients.

If hearings are held on the Synar bill or similar legislation, or in response to a release of the HHS report, it

may be necessary to address scientific and safety issues concerning ingredients. While a strategy to deal with these concerns is beyond the scope of this effort, Tab H is a preliminary draft statement that was prepared for use by one of our consulting scientists in connection with possible further hearings. This statement will require expansion and further work once the ingredient report is released or the focus of a particular hearing is made clear. It should, however, provide guidance as to the kind of expert testimony that would be desirable. The testimony of a consulting scientist would include introduction into the hearing record of the safety assessment of cigarette ingredients, which was prepared by five independent consulting toxicologists and is included in Tab I.

Stanley L. Temko
Clausen Ely, Jr.

TAB A

STATEMENT FOR COVINGTON & BURLING
IN RESPONSE TO RELEASE OF INGREDIENT
LIST WHICH RECEIVES LITTLE PUBLICITY

A list of ingredients added to tobacco in the manufacture of cigarettes was recently disclosed by _____ . The list had been provided to the Department of Health & Human Services (HHS) by the six major American cigarette companies in compliance with section 7 of the Federal Cigarette Labeling and Advertising Act.

The release of the list is unfortunate because the identities of the ingredients added to tobacco in cigarette manufacture are important trade secrets whose confidential status is recognized by the Act itself. The Act directs HHS to conduct a scientific review of the ingredients on the list. The industry has offered to participate in this review as it proceeds. Despite the unfortunate disclosure of the list, we hope that the issue of cigarette ingredients will continue to be approached from a scientific perspective as envisioned by the Act.

LG 2003363

DRAFT STATEMENT IN RESPONSE TO RELEASE
OF INGREDIENT LIST WHICH RECEIVES
WIDE PUBLICITY

A list of ingredients added to tobacco in the manufacture of cigarettes was recently disclosed by _____. The list had been provided to the Department of Health & Human Services (HHS) by the six major American cigarette companies in compliance with section 7 of the Federal Cigarette Labeling and Advertising Act. The list was the latest in a series of lists that have been provided annually since 1986.

The release of the list is unfortunate because the identities of the ingredients added to tobacco in cigarette manufacture are important trade secrets whose confidential status is recognized by the Act itself. We are disappointed that the list has been disclosed despite the confidentiality protection provided by law. During the eight years the Act has been in effect, the confidential status of cigarette ingredient information had never before been breached.

The Act directs HHS to conduct a scientific review of the ingredients on the list. The industry has offered to participate in this review as it proceeds. Despite the unfortunate disclosure of the list, we hope that the issue of cigarette ingredients will continue to be approached from a scientific perspective as envisioned by the Act.

Because of trade secret concerns, the ingredients used by particular companies or in specific brands cannot be

discussed. However, certain general comments will help place the contents of the list in perspective.

The list contains several hundred substances, most of which have been in use for decades. However, about 30 substances account for approximately 99% of total ingredient usage. A number of these compounds are processing aids that remain in the final cigarette in minute quantities, if at all. Others are casing materials, flavors or moisturizers that have long been used in cigarettes.

The remaining ingredients are used in smaller quantities, in many cases less than 10 pounds per year for all the companies. Most of these compounds are components of formulated mixtures purchased by the cigarette manufacturers from flavor suppliers. Only a small quantity of flavor ingredients would be present in an individual brand, and all of these ingredients generally constitute less than a tenth of a percent by weight of an individual cigarette.

Virtually all of the ingredients on the list are approved as food additives or generally recognized as safe by the Food and Drug Administration, and they have been extensively tested and reviewed by the tobacco companies.

LG 2003365

STATEMENT FOR COVINGTON & BURLING IN
RESPONSE TO INQUIRIES FOLLOWING RELEASE
OF A NON-CRITICAL INGREDIENT REPORT

On _____, 1994, the Department of Health and Human Services released a report on ingredients used in the manufacture of cigarettes. The report concluded that the use of ingredients does not raise any significant health concerns. On behalf of the six major U.S. cigarette manufacturers, Covington & Burling has submitted to the Department of Health and Human Services eight annual lists of ingredients used in the manufacture of cigarettes. These submissions were made in accordance with the requirements of the Federal Cigarette Labeling and Advertising Act. Under the Act, companies that manufacture, package or import cigarettes into the United States must submit annually to HHS a list of ingredients added to tobacco in the manufacture of cigarettes.

The Act recognizes that the identity of specific ingredients is an important trade secret that is entitled to protection from disclosure. The Act provides that manufacturers required to provide a list may designate a third party to compile and submit a combined list of ingredients. Covington & Burling, in accordance with this provision, has prepared and submitted each joint list on behalf of the American Tobacco Company, Gallaher Limited, Brown & Williamson Tobacco Corporation, Liggett Group, Inc., Lorillard, Inc., Philip Morris, Inc., and R.J. Reynolds Tobacco Company.

The companies cooperated with HHS in connection with its review of ingredients. Although we believe that the report should put to rest any concerns about the use of ingredients, the manufacturers remain prepared to work with HHS in any future review of the use of ingredients.

STATEMENT FOR TOBACCO COMPANIES TO BE USED
IN RESPONDING TO INQUIRIES CONCERNING THE RELEASE
OF A REPORT CONCERNING INGREDIENTS BY HHS

On _____, _____, the Department of Health and Human Services released a report concerning the use of ingredients in cigarettes. The report was based in part upon a list of ingredients provided by our company and the other major American cigarette manufacturers to HHS pursuant to the requirements of Section 7 of the Federal Cigarette Labeling and Advertising Act. [We are pleased with the conclusion reached by HHS that ingredients do not present a significant health issue, for we have long believed that this would be the result of an unbiased evaluation of the use of ingredients.]

The companies designated the Washington, D.C. law firm of Covington & Burling to compile the combined lists that were submitted to HHS. Any questions concerning the HHS report or the submission of ingredient lists to HHS should be directed to Stanley L. Temko (202-662-5514) or Clausen Ely (202-662-5152) of Covington & Burling.

TAB E

STATEMENT FOR THE TOBACCO INSTITUTE TO BE
USED IN RESPONDING TO INQUIRIES CONCERNING
THE RELEASE OF AN INGREDIENT REPORT BY HHS

On _____, 1994, the Department of Health and Human Services released a report concerning the use of ingredients that are added to tobacco in the manufacture of cigarettes. The Tobacco Institute has not been involved in the preparation of the report or the submission of ingredient lists by manufacturers to HHS pursuant to the Federal Cigarette Labelling and Advertising Act. The major American cigarette manufacturers have utilized the Washington, D.C. law firm of Covington & Burling to represent them in making submissions to HHS on the ingredient issue. Any questions concerning the ingredients report should be directed to Stanley L. Temko (202-662-5514) or Clausen Ely (202-662-5152) of Covington & Burling.

LG 2003369

DRAFT RESPONSE OF INDUSTRY UPON RELEASE
OF A CRITICAL REPORT CONCERNING INGREDIENTS

On _____, 1994, the Department of Health and Human Services released a report concerning the use of ingredients added to tobacco in the manufacture of cigarettes. This report was prepared pursuant to Section 7 of the Federal Cigarette Labeling and Advertising Act.

The report unjustifiably criticizes the use of ingredients in the manufacture of cigarettes. In preparing the report, HHS failed adequately to consider available scientific data from all perspectives.

HHS declined the repeated offers of the cigarette manufacturers to work with HHS to produce an objective and complete report on the use of ingredients. Since 1979, the industry has offered to cooperate with HHS in preparing a balanced and scientific evaluation of the use of ingredients. These offers were rejected, and HHS prepared its own report without the benefit of the knowledge and experience of the people who know most about the use of ingredients in cigarettes. This resulted in an unfair report.

The Act recognizes that ingredient information is an important trade secret. It therefore would be inappropriate for us to comment on the use of particular ingredients by individual companies. However, certain general comments can be made concerning the conclusions of the HHS report.

First, HHS criticizes the use of ingredients simply because of the number of ingredients used. Yet, only about ten percent of the many thousands of ingredients used in food products are used in cigarettes. The issue is not the number of ingredients used. Rather, the issue should be whether ingredients are harmful.

Moreover, the emphasis on the number of ingredients used obscures the fact that about 30 ingredients account for approximately 99 percent of total ingredient usage. Three of these ingredients are processing aids that are found in the final cigarette in minute quantities, if at all. Others are casing materials, flavoring materials or moisturizers that have been used in cigarettes for decades. Casing materials, such as sugar, are used to smooth and balance the taste of cigarettes. Flavoring materials provide the distinctive brand aroma.

Most ingredients are used in extremely small quantities, in many cases less than 10 pounds per year for the entire American industry. This is in contrast with the over 850 million pounds of tobacco used in cigarettes sold in the United States each year. Most cigarette ingredients are components of formulated flavor mixtures. All of these aroma ingredients generally constitute less than a tenth of a percent by weight of the individual cigarette.

Most ingredients used in cigarette manufacture in the United States are commonly used in foods and have been approved

LG 2003371

by the Food and Drug Administration or are included in lists of substances "generally recognized as safe" maintained by FDA and the Flavor Extract Manufacturers Association.

Furthermore, governmental bodies in other countries, such as Great Britain and West Germany, have also evaluated ingredients used in cigarettes in their countries. For example, a British list, commonly referred to as the Hunter-Froggatt List, was developed by a medical and scientific committee appointed by the British government, the Independent Scientific Committee on Smoking and Health. Virtually all of the ingredients used by the six leading U.S. cigarette manufacturers can be found on the accepted lists of one or more of the following governmentally affiliated or recognized organizations: the U.S. Food and Drug Administration, FEMA-GRAS, the Independent Scientific Committee on Smoking and Health (Hunter-Froggatt Committee), and the relevant government departments and agencies of Canada, Belgium, Switzerland, France and the Council of Europe.

Despite this evidence, the report criticizes the use of ingredients because of what it characterizes as a lack of evidence concerning adverse health effects. This statement is not accurate. Ample scientific data are available to demonstrate that the use of these ingredients in cigarettes has no adverse effects for consumers. A recent report by five independent toxicologists, based on review of the confidential

LG 2003372

ingredients list and extensive scientific studies on ingredients, concluded that ingredients added to tobacco in the manufacture of cigarettes by United States producers are not hazardous under the conditions of use.

The tobacco industry remains committed to engaging in serious scientific discussions with responsible authorities interested in approaching the ingredients issue from a scientific perspective. We regret that HHS has not seen fit to adopt such an approach in this instance.

QUESTIONS AND ANSWERS CONCERNING INGREDIENTS

1. Why are ingredients used?

ANSWER: Some ingredients aid in processing tobacco in the initial stages of cigarette manufacture. These ingredients help in the processing of tobacco but remain in the final cigarette in minute quantities, if at all. Other ingredients are used as casing materials or humectants. Casing materials, such as sugar, help to smooth and balance the taste of cigarettes, while humectants keep the tobacco in cigarettes moist. Finally, many of the ingredients are used to give individual brands of cigarettes their distinctive flavor and aroma.

2. How long have ingredients been used in cigarettes?

ANSWER: Ingredients have been used for over 150 years. When Europeans first learned about smoking tobacco from the Indians, the tobacco they smoked was flavored with citrus peels and other spices and herbs. In the United States, the use of flavorings has been a common practice since colonial times. Most of the principal processing aids, casing materials, and humectants, for example, have not changed for decades.

3. Why are so many ingredients used?

ANSWER: To put the number of ingredients in perspective, it is worthwhile to note that there are some 380 different brands and packings of cigarettes sold in the United States. The ingredients on the HHS list are an aggregate of all the ingredients used. Obviously not all ingredients are used in every cigarette.

Furthermore, about 30 of those ingredients comprise approximately 99% of the total amount, by weight, of ingredients used in the industry. The other ingredients are used in smaller amounts, and most of the ingredients on the list submitted to HHS are used in extremely small quantities as part of flavor formulations. These formulations often include a number of ingredients, but typical industry-wide usage of many of these flavor components is under 10 pounds a year. This is in contrast with the over 850 million pounds of tobacco employed in cigarettes sold in the United States each year. The flavor formulations used by the companies change occasionally as new products are introduced or existing products are reformulated in response to consumer preferences.

4. Why are so many ingredients used in American cigarettes, when many fewer ingredients are used in cigarettes made in many other countries?

ANSWER: The very premise for this question is not true if you are talking about U.S. style cigarettes. This is

because American style cigarettes are a blend of different types of tobacco, some of which call for more ingredients than others. Consequently, where American style blended cigarettes are the norm, there may be only slight differences in the numbers of ingredients used by manufacturers in different countries.

However, there are certain countries, such as the U.K. and its former colonies, where smokers prefer cigarettes which do not contain a blend of different types of tobacco but contain only Virginia style flue-cured tobacco. The latter do not require as many ingredients to smooth their taste as do some of the tobaccos found in blended cigarettes. Nevertheless, ingredients are used in Virginia style cigarettes as well.

5. Are ingredients used in large amounts?

ANSWER: About 30 ingredients such as casing materials (which smooth and balance the flavor of cigarettes), moisturizers, and major flavors (such as menthol), account for 99% of the weight of ingredients actually found in cigarettes. All of the remaining ingredients that are present in cigarettes occur at levels below 500 ppm (0.05%), and over one-third occur at levels below 1 ppm (0.0001%). Certain ingredients that serve as processing aids are used in volume during the early stages of

LG 2003376

manufacturing but their presence is virtually eliminated in the manufacturing process. Such processing aids remain in the finished cigarette in trace quantities, if at all.

A larger number of the ingredients are used as aroma flavors to give different cigarette brands their distinctive aromas, but these substances are in the final cigarette in minuscule amounts. Most of the ingredients comprise these proprietary flavor mixtures, and usage of many of these ingredients by the entire industry is under 10 pounds per year.

6. Haven't the cigarette manufacturers started using more and more ingredients to compensate for the reduction of tar and nicotine in cigarettes?

ANSWER: Neither the number nor quantity of casing materials (which smooth and balance the taste of cigarettes) nor moisturizing agents have changed as a result of the growing range of tobacco products, including the introduction of lower "tar" and nicotine brands. While the number of flavors which constitute the special aromas of individual brands may have increased, it is important to note that flavors are used in minuscule amounts, the total amount of all flavors used constituting less than one tenth of one percent by weight of a finished cigarette.

LG 2003377

7. Why hasn't the identity of ingredients been provided to the public before?

ANSWER: While the identity of the ingredients has not been provided to the public, the U.S. Government has had access to the list of all the ingredients used by the six major U.S. cigarette manufacturers.

It is common for all companies to guard specific product formulas, and Congress recognized this when it passed the Federal Cigarette Labeling and Advertising Act. The Act requires U.S. cigarette manufacturers to submit an annual list of their ingredients but guarantees protection against disclosure of this information. The flavors added to foods, for example, are treated as trade secrets and need not be disclosed on the labels of these products.

Not only have U.S. manufacturers submitted ingredient lists each year since 1986 in full compliance with the law, but since 1979 the industry has voluntarily provided HHS with information about ingredients. Under an agreement reached in 1982, the manufacturers had provided HHS with a list of commonly-used ingredients added to tobacco in the manufacture of cigarettes. The industry agreed then to consult with HHS as it addressed any questions about specific ingredients. Consequently, the U.S. government has had access to information about ingredients for over 10 years.

LG 2003378

Because they contribute to the taste and appeal of individual brands, the identities of specific ingredients in cigarettes are also closely guarded trade secrets. Disclosure of the ingredients used in cigarette manufacture could reveal product formulas that required years of research to develop. The Federal Cigarette Labeling and Advertising Act recognizes the highly confidential nature of ingredients information by directing HHS to establish procedures to protect the confidentiality of the ingredients list.

8. What role did the industry have in the preparation of HHS' ingredient report?

ANSWER: We regret that the industry had no role in the preparation of the report. This strikes us as particularly unfair since as early as 1979 the industry has cooperated with HHS with respect to the ingredient issue. Well before the legislation that required that annual lists be submitted, the industry voluntarily provided information to HHS. The industry has informed HHS of its willingness to participate in a scientific review of ingredient usage.

Despite these repeated offers, the industry was offered no role in the HHS review of the ingredient lists. The industry was not consulted about the types of data that might be reviewed, and industry scientists who are perhaps the most knowledgeable persons about the use of ingredients

LG 2003379

in cigarettes were not called upon by HHS to provide information. Thus, HHS ignored a potential source of highly valuable information, and this resulted in numerous erroneous conclusions.

9. Don't consumers have the right to know what is in the products they buy?

ANSWER: The formulas of any number of consumer products are not treated as public information. These formulas often have great competitive value and require substantial time and expense to develop. The law therefore allows them to be treated as trade secrets. For example, the flavorings used in hundreds of foods and in fragrances are treated as trade secrets.

10. Why aren't the ingredients used in cigarettes listed on the package?

ANSWER: The identities of specific ingredients used in a particular brand of cigarettes are important trade secrets. The taste of a specific brand may take years of time and millions of dollars to develop, and the law recognizes that such valuable information is entitled to confidential treatment. For example, the flavors used in hundreds of foods are treated as trade secrets.

11. The list of additives which has been supplied to HHS consists of those substances which are currently added to

cigarettes. Have any substances been phased out of use in cigarettes since the submission of annual lists began?

ANSWER: Yes. Like almost all consumer products, from frozen foods to breads or soft drinks, cigarettes undergo constant change as new brands are introduced and old brands are modified or phased out. Modifications in cigarette formulations may be required to compensate for changes in tobacco caused by variations in weather patterns, environmental conditions, agricultural practices, as well as in response to changes in consumer taste. However, most of the modifications in the composition of cigarettes affect flavors which are already in use and which are employed in extremely small quantities, less than one tenth of one percent by weight of a final cigarette. For many of these ingredients, the amount used annually is less than ten pounds for the entire industry. The major ingredients change less often, and many of them have been used for years.

12. Are there any substances currently added to cigarettes sold only in other markets, particularly Third World markets, which are not used in cigarettes sold in the United States?

ANSWER 1: The Federal Cigarette Labeling and Advertising Act only requires that information be submitted concerning ingredients used in cigarettes sold in the United States, and we have not compiled information on cigarettes sold in other countries. However, a number of

other countries regulate the use of ingredients in cigarettes, and the companies comply with these regulations wherever they exist.

ANSWER 2: The Act only requires that information be submitted concerning ingredients used in cigarettes sold in the United States. However, we can assert that the cigarettes manufactured for export and sold overseas are identical to the comparable brands manufactured for sale in the U.S. There is no double standard. All the ingredients used in the manufacture of cigarettes are acceptable in the countries in which they are used. Indeed, many countries regulate the use of ingredients in cigarettes and we comply with these regulations.

13. Are ingredients added to filters, and if so, what ingredients are added and what tests have been done to evaluate their safety?

ANSWER: The Federal Cigarette Labeling and Advertising Act requires only that information be submitted concerning ingredients added to the tobacco used in cigarettes sold in the United States. However, we believe that the addition of ingredients to filters is not harmful to smokers.

14. Are the ingredients used in cigarettes harmful?

ANSWER: Recently, five eminent toxicologists determined that the ingredients added to tobacco in the manufacture of

cigarettes are not hazardous as used. Their conclusion was based on an independent analysis of the confidential ingredients added to tobacco in the manufacture of cigarettes, and confirms that there is no legitimate basis for the conclusion that the addition to cigarettes of the ingredients on the list is harmful to smokers. Virtually all substances are toxic at very high levels, but there is no evidence that the small quantities of ingredients used in cigarettes are harmful.

15. What evidence is there that the ingredients are not harmful?

ANSWER: Over 90% of ingredients used in cigarettes manufactured in the United States are commonly used in foods, have been reviewed by the Food and Drug Administration (FDA) and are included on the FDA lists of approved food additives or substances "generally recognized as safe" (GRAS), or on the Flavor Extract Manufacturers Association's GRAS list.

Furthermore, governmental bodies in other countries, such as Great Britain and West Germany, have also evaluated ingredients used in cigarettes in those countries. The inclusion of ingredients on these lists reflects a careful review of available data by scientists. For example, the British ingredients list was developed by a medical and scientific committee appointed by the British

LG 2003383

government, the Independent Scientific Committee on Smoking and Health.

Virtually all of the ingredients used by the six leading U.S. cigarette manufacturers can be found on the accepted lists of one or more of the following governmentally affiliated or recognized organizations: the U.S. Food and Drug Administration, FEMA-GRAS, the U.K. Food and Drug Administration, the U.K. Independent Scientific Committee on Smoking and Health (Hunter-Froggatt Committee), and the relevant government departments and agencies of Canada, Belgium, Switzerland, France and the Council of Europe.

We regret that the report criticizes the use of ingredients because of what it characterizes as a lack of evidence concerning adverse health effects. This statement is not accurate. Considerable scientific data are available with respect to cigarette ingredients. Five eminent independent toxicologists have recently reviewed the confidential cigarette ingredient lists, examined extensive published and unpublished scientific studies on ingredients, and concluded that the ingredients added to tobacco in the manufacture of cigarettes by United States manufacturers are not hazardous under the conditions of use.

LG 2003384

The tobacco industry remains committed to engaging in serious scientific discussions with responsible authorities interested in approaching the ingredients issue from a scientific perspective. We regret that HHS has not seen fit to adopt such an approach in this instance.

16. Are there any substances which have historically been used as ingredients in cigarettes that are now regarded as hazardous?

ANSWER: Cigarette manufacturers continuously review the questions that have arisen concerning ingredients. The companies believe that there is no harm to smokers from the addition to cigarettes of former or current ingredients. This opinion was recently confirmed by a panel of five independent toxicologists who reviewed the safety of ingredients added to tobacco. They unanimously concluded, based on review of the confidential lists of ingredients and extensive published and unpublished studies on ingredients, that the ingredients added to tobacco in the manufacture of cigarettes are not harmful to smokers.

17. Why is there any reason to think that an ingredient is not harmful just because it has been used for a longer period of time?

ANSWER: Cigarette manufacturers continuously review questions that have arisen concerning ingredients. The companies believe that the addition to cigarettes of

ingredients formerly or currently used are not harmful to smokers. Indeed, over 90% of the ingredients used in the production of cigarettes are either foods or are approved for use in foods or in the manufacture of food products.

18. What effect do ingredients have on non-smokers exposed to cigarette smoke?

ANSWER: Cigarette manufacturers continuously review questions that have arisen concerning ingredients. The companies believe that the addition to cigarettes of the ingredients on the list is not harmful to smokers. The companies likewise believe that the addition of ingredients to cigarettes is not harmful to non-smokers who may be exposed to cigarette smoke.

19. Have each of the ingredients been tested to ensure that they are not harmful?

ANSWER: Since over 90% of the ingredients are approved for use in foods, testing to determine their toxicity has been conducted. Furthermore, the scientific literature on all ingredients has also been reviewed. This is always the first step in determining acceptability. In addition, patterns of usage of ingredients in consumer products have been studied. The literature and data from all the tests as well as the scientific literature demonstrate that the ingredients used are not harmful. The tobacco companies

LG 2003386

have conducted their own additional tests, which indicate that the ingredients are not harmful. Furthermore, a panel of five eminent toxicologists recently determined that the ingredients added to tobacco are not hazardous as used. Their conclusion was based on an independent analysis of extensive published and unpublished studies on ingredients.

20. What kinds of tests have been done on ingredients?

ANSWER: The need for testing, and the types of tests to be conducted, depend on a range of factors. There are a variety of accepted testing methodologies which can be used to evaluate ingredients. Depending on the circumstances, the research conducted includes smoke chemistry, acute, subchronic and chronic toxicity studies, metabolism studies, and genotoxicity.

21. The GRAS list and other compilations list many of these ingredients as fit for human consumption, but fail to address the issue of potential dangers posed by the burning of these substances. What research has the industry done concerning the effects of pyrolysis on these substances?

ANSWER: In order to answer this question, it is first necessary to understand what happens when a cigarette burns. Different types of ingredients react differently when subjected to heat. Most of the ingredients that are used by the industry go into the flavoring materials used

in cigarettes. These flavoring materials are sufficiently volatile that, before they get hot enough to burn, they are boiled away and transferred intact into cigarette smoke. Indeed, flavoring agents are often selected because of their low boiling point, which assures that their aroma properties are imparted to cigarette smoke without undergoing any change. Thus, if there is exposure and absorption, metabolism would be similar to ingestion. These ingredients are also used in minuscule amounts. Total industry usage of many of these flavoring ingredients is less than 10 pounds a year.

For many other ingredients, overall usage levels indicate that pyrolysis data is of low priority. Indeed, only about 30 ingredients account for approximately 99% of the total amount by weight of all ingredients used. And a number of these major ingredients are processing aids that remain in the final cigarette in trace quantities, if at all. Other ingredients which are pyrolyzed go into the casing materials -- which smooth and balance the taste of the cigarette -- and the humectants -- which help cigarettes retain the right moisture level.

Among those ingredients that do pyrolyze, their chemical similarities to tobacco leaf components, and their relatively low levels, suggest that they do not significantly alter the composition of tobacco smoke. With

respect to all the ingredients used in cigarettes, whether or not they are pyrolyzed, the companies continuously review the scientific literature. If the literature suggests the need to test certain of these ingredients, the companies undertake appropriate testing procedures.

22. Why haven't pyrolysis tests been run for all ingredients being used?

ANSWER: First, it is important to understand that the vast majority of ingredients in cigarettes are not pyrolyzed. They have relatively low boiling points, below the temperature of a burning cigarette, and they are transferred intact from the cigarette to the tobacco smoke. In fact, flavors are often selected for their low boiling points, which assure that their flavoring properties are imparted to cigarette smoke. Hence, for these ingredients, pyrolysis tests are not relevant.

Pyrolysis product testing on other types of ingredients is not called for in view of the manner in which they are used. Processing aids, for example, appear in the final cigarette in trace quantities, if at all. In addition, a large number of ingredients used as components of flavor mixtures are likewise found in cigarettes in minuscule quantities. Among those ingredients that do pyrolyze, their chemical similarities to tobacco leaf components, and their relatively low levels, suggest that

LG 2003389

they do not significantly alter the composition of tobacco smoke. Moreover, ingredient pyrolysis products have not been shown to be toxic in inhalation studies.

23. Are there any studies that examine the effects of the ingredients when they have been inhaled?

ANSWER: Yes. Inhalation studies on ingredients have been conducted where appropriate. These studies have shown that the addition to cigarettes of the ingredients tested is not harmful to smokers.

24. Have inhalation tests been conducted on all ingredients?

ANSWER: No. Scientific convention establishes criteria for the need for various types of testing and the determination of the appropriate test based upon the available body of scientific information. To start with, the vast majority of ingredients are not pyrolyzed. They have relatively low boiling points, below the temperature of a burning cigarette, and are transferred intact from the cigarette to the tobacco smoke.

Of the remaining ingredients that are subject to pyrolysis, testing of the pyrolysis product has been undertaken in both acute and chronic bioassays. The pyrolysis product is the aggregate of all the non-tobacco materials which are burned.

With respect to the testing of individual ingredients, it has been established scientifically that laboratory pyrolysis tests of individual ingredients in isolation from each other is not appropriate since this type of testing does not accurately reflect the exposure conditions of ingredients in a burning cigarette.

25. What value is any test other than a pyrolysis or inhalation test?

ANSWER: There are a number of other tests that are accepted in the scientific and regulatory community, including chemistry and metabolism studies, and chronic toxicity studies, such as ingestion studies. Indeed, scientists routinely evaluate all available information before deciding what further testing is appropriate. For cigarette ingredients, inhalation or pyrolysis product tests may provide the most directly relevant data, but other tests can be valuable.

26. Are you aware of any adverse health data generated either by the companies or available in the published literature?

ANSWER: The companies are aware of routine testing by government agencies, such as the National Toxicology Program, and in the general scientific community which evaluate the use of ingredients in products including food and cosmetics, as well as cigarettes. While some of these

LG 2003391

studies may suggest adverse effects, based on a review of all the available data and information, the companies believe that the addition of the ingredients to cigarettes is not harmful to smokers.

27. Is more testing of ingredients planned?

ANSWER: The testing of ingredients has been conducted by individual companies on their own initiative. Companies will continue to conduct tests where they believe such tests are warranted, as well as monitor independent research findings.

28. You have noted that various bodies such as FEMA or FDA have approved the ingredients for use in foods. Why does that matter, since those organizations have not burned the ingredients?

ANSWER: The inclusion of the ingredients on lists of substances approved for food use by FEMA or FDA indicates that data have been reviewed by scientists who have concluded that the ingredient is suitable for human consumption. In addition, the companies routinely evaluate scientific data on ingredients. The vast majority of cigarette ingredients are not pyrolyzed, and any exposure to such ingredients would be comparable to ingestion. It should be noted that many foods and food ingredients are subject to high temperatures during food processing and common forms of cooking, such as frying, baking and

broiling, circumstances that are analogous to those undergone by ingredients in a burning cigarette.

29. Isn't it true that the committees which compiled the list of approved tobacco additives in Great Britain and in Germany did not have much information available to them about specific ingredients, but rather conducted a cursory examination?

ANSWER: On the contrary, the reviews are independent and thorough. I would remind you that the Independent Scientific Committee on Smoking and Health in the United Kingdom was established under the Department of Health and Human Services. It is also broadly recognized that the German government has been scrupulous in its review of the ingredients issue. These committees included independent scientists and government representatives. In developing a list of approved substances, they examined the evidence they believed necessary to make an adequate evaluation, and concluded that the ingredients were suitable for use in cigarette manufacture. In some cases, the committees had available to them a large body of evidence, including test results. In other instances, a smaller amount of evidence may have been available, particularly for substances typically used only in small quantities. Nevertheless, the review was independent and thorough.

30. What are the large-volume ingredients, why are they used, and what is known about their health effects?

LG 2003393

ANSWER: Ingredients generally have been used in cigarettes for decades and are extensively used in foods. Most of these ingredients serve as casing materials, humectants, or processing aids. Processing aids, such as carbon dioxide, will remain in the final cigarettes only in trace quantities, if at all. Casing materials, such as sugar, smooth and balance the taste of a cigarette, and humectants, such as propylene glycol, serve to retain the moisture in cigarettes. A variety of tests have been done to evaluate the health effects of the major ingredients. These include tests by the companies, as well as other work reflected in the published literature. Based on the available information, the companies believe that the addition to cigarettes of the ingredients on the list is not harmful to smokers.

31. How many known carcinogens are on the list of ingredients which was submitted to HHS?

ANSWER: None of the ingredients on the list is considered a potential human carcinogen by HHS, the International Agency for Research on Cancer (IARC), or other recognized organizations which evaluate the carcinogenic potential of substances.

32. Are natural extracts harmful?

LG 2003394

ANSWER: Natural extracts are used in a multitude of foods, drugs, and other products. Criticism of their use in cigarettes is contrary to FDA's approval of such extracts for use in many other products. And a review of the scientific literature does not justify any cause for concern. All substances, natural and synthetic, are toxic at very high levels, but there is no evidence that small quantities of ingredients used in cigarettes are harmful.

33. Have the cigarette manufacturers ever used cloves, eugenol, or coumarin in their cigarettes?

ANSWER: Because specific ingredients are important trade secrets, the industry will not comment on whether these substances are being or have been used. [Note -- this response will be used for all questions about specific ingredients.]

34. The HHS report indicates that ingredients such as cloves, eugenol and coumarin are used. Is the industry really using these compounds?

ANSWER: While we cannot comment on the specific ingredients used by United States manufacturers, it is important to note that HHS received submissions not only from Covington & Burling on behalf of the six major United States manufacturers, but from other manufacturers and importers of cigarettes as well.

35. A government scientist referred in an article a few years ago in Mother Jones magazine to an unidentifiable "Compound X" which he had discovered in a cigarette. Does this compound really exist, and if so, what does the industry know about it?

ANSWER: The companies have no information about the specific compound which is referred to but not identified in the Mother Jones article.

36. Why is the industry using Covington & Burling as its spokesperson?

ANSWER: The Federal Cigarette Labeling and Advertising Act allows companies jointly to designate an agent to prepare a combined list of ingredients. This is designed to protect the trade secret status of each company's ingredient information. Covington & Burling assisted the industry in earlier discussions with HHS concerning ingredients, and the companies have asked Covington & Burling to continue that representation.

37. Isn't it true that you really do not know what effect these ingredients are having on the health of smokers?

ANSWER: The companies have reviewed the scientific literature on ingredients and, where appropriate, they have conducted their own tests to obtain additional scientific evidence. The companies believe that the addition to cigarettes of the ingredients on the list is not harmful to smokers.

38. Don't ingredients simply add to the danger presented by cigarettes?

ANSWER: The industry does not believe that it has been established that cigarette smoking causes disease in smokers, or that the addition to cigarettes of the ingredients is harmful to smokers. Most cigarette ingredients are food or approved for use in food by FDA. The companies have reviewed the extensive scientific literature on ingredients, conduct their own tests where appropriate and concluded that the addition of the ingredients on the list to cigarettes is not harmful.

39. Shouldn't the United States have a list of approved ingredients, as in Great Britain or West Germany?

ANSWER: The Federal Cigarette Labeling and Advertising Act provides HHS with ample authority to review the ingredients in use. Current regulation of ingredients is flexible, in that it permits product innovation and still allows HHS to monitor the use of ingredients. We do not believe that any change in this approach is necessary.

40. In light of the nonchalant way in which the cigarette industry has used untested additives in billions of cigarettes every year, isn't it time that ingredients were brought under the aegis of the FDA?

ANSWER: The industry believes very strongly that it has acted in a responsible and scientifically rigorous manner. Moreover, as the recently released report by HHS shows, HHS

has the necessary authority to review the use of ingredients. We see no reason to create an additional review mechanism.

41. Several ingredients used by tobacco companies are not approved for use in foods. How can companies justify exposing people to unapproved ingredients?

ANSWER: Virtually all of the ingredients used by the six leading U.S. cigarette manufacturers can be found on the accepted lists of one or more of the following governmentally affiliated or recognized organizations: the U.S. Food and Drug Administration, FEMA-GRAS, the U.K. Independent Scientific Committee on Smoking and Health (Hunter-Froggatt Committee), and the relevant government departments and agencies of Canada, Belgium, Switzerland, France, and the Council of Europe.

Of the few ingredients that the HHS report claims are not approved for use in foods, most [or all] are in fact approved by one or more of the above organizations. Furthermore, a report by a group of five independent scientists recently concluded that the ingredients added to tobacco by the leading U.S. manufacturers are not hazardous. The tobacco industry firmly believes that the ingredients added to tobacco do not present any health hazards.

42. Several ingredients added to tobacco are regulated as hazardous substances by EPA or other governmental agencies. Aren't these ingredients harmful in cigarettes?

ANSWER: No. Several of the ingredients listed in the report as being hazardous substances are processing aids that appear in final cigarette products in minute quantities, if at all. Moreover, a report by a panel of five independent toxicologists recently concluded that all ingredients used in tobacco by U.S. cigarette manufacturers including those named in the HHS report, are not harmful.

43. Is nicotine extracted and reintroduced, or otherwise added to tobacco during the manufacturing process?

ANSWER: No. U.S. manufacturers do not follow any process in which nicotine is extracted and reintroduced to tobacco except through the production of reconstituted tobacco sheet. This process results in no increase in nicotine in the finished sheet. Nicotine is also introduced indirectly to tobacco in minute amounts as a component of some flavoring agents. The only significant source of nicotine in finished cigarettes is the cured tobacco.

44. Shouldn't the federal government require disclosure of the identity of ingredients on cigarette packages?

ANSWER: No. Such disclosure is unnecessary for public protection and it would compromise the trade secret status of ingredient information.

Under Section 7 of the Federal Cigarette Labeling and Advertising Act (the "Act"), each company that manufactures, packages or imports cigarettes must provide annually to the Secretary of Health and Human Services ("HHS") a list of ingredients added to tobacco in the manufacture of cigarettes. Ingredient lists have been provided to HHS by the major American cigarette manufacturers since the Act became effective in 1986. The Act recognizes that ingredient information is highly sensitive trade secret data, and it bars disclosure of this information.

The Act also requires HHS to review the scientific and health information relating to ingredients, to evaluate the safety of ingredients and to report to Congress on that evaluation. Congress, in turn, may take appropriate action based upon HHS' findings.

The vast majority of cigarette ingredients are components of confidential flavor formulations. Individual flavors of this kind are not required to be identified on the labels of food or other consumer products. Other cigarette ingredients are processing aids which remain in the final cigarette in minute quantities, if at all. Processing aids also are not required to be identified on food labels.

Disclosure of ingredients on cigarette packages would not enhance public safety, would not provide meaningful information to cigarette purchasers and would jeopardize the closely guarded trade secret status of cigarette ingredient information.

DRAFT CONGRESSIONAL TESTIMONY
BY CONSULTING SCIENTIST

My name is _____ and I am appearing today on behalf of the six major American cigarette manufacturers to discuss scientific information relating to ingredients that are added to tobacco in the manufacture of cigarettes. Based on my consultation with the industry and detailed review of the relevant scientific information, it is my opinion that the cigarette ingredients used by these manufacturers do not pose a risk of adverse health effects.

[Describe credentials and experience]

During the past three years, I have provided advice and consultation to the six major American cigarette manufacturers with respect to the scientific review of cigarette ingredients. As part of this process, I have been provided full access, under a confidentiality agreement, to ingredient lists submitted to HHS on behalf of the companies, ingredient use information, scientific reviews and reports, and test information on cigarette ingredients. I have also reviewed ingredient data and test results possessed by individual cigarette manufacturers, and have engaged in detailed and ongoing discussions with company scientists regarding ingredient issues. My testimony today is based on this extensive review and consultation.

I have served on a panel with four other independent toxicologists, who have also reviewed the ingredient data and test results. We have prepared a joint report that I am submitting together with my testimony.

Although I am not free to discuss specific ingredients or test results, I would like to explain briefly the basis for my conclusion that there is no cause for concern with respect to possible adverse health effects from cigarette ingredients.

First, I have been very favorably impressed with the strong commitment of the major American cigarette manufacturers carefully to assess the possible health effects of ingredients, with the expertise and forthrightness of the company scientists responsible for ingredients and with the quantity and quality of the test information on ingredients developed by the companies. It is against this background that my views are framed.

Second, it is important to bear in mind that only a few cigarette ingredients comprise the great bulk of the total quantity of ingredients employed by the industry and that the vast majority of ingredients are used in very small amounts, resulting in levels of generally less than 5 parts per million (ppm) in the finished cigarette.

It is a fundamental principle of toxicology, which is frequently confirmed in my research, that toxicity is a function of dose and that many compounds are toxic at very high dose levels but not at the lower levels to which humans are

ordinarily exposed. This is true of naturally occurring and added substances in food and equally true of the ingredients employed in cigarettes. Accordingly, the vast majority of cigarette ingredients would not be expected to raise a health concern, based simply on the minuscule amounts present in the finished product.

Third, virtually all of the ingredients used by American cigarette manufacturers are foods, normal components of foods, ingredients approved for addition to foods by the federal Food and Drug Administration (FDA) and/or expert bodies as Generally Recognized as Safe (GRAS) for human consumption, and/or normal constituents of tobacco leaf or smoke. The few ingredients that do not fall within one or more of these categories have been carefully evaluated by scientists employed by the tobacco industry and determined not to present any measurable risk under the conditions of use in cigarettes. My review of the companies' studies confirms this judgment.

Fourth, based on my review of the ingredient lists submitted to HHS and my knowledge of the relevant scientific literature and government publications, none of the ingredients used by the companies for which I am appearing has been determined to be a carcinogen. Where questions have been raised regarding the carcinogenic potential of a substance, a careful determination has been made that the substance is not in fact, a carcinogen. In addition, I do not believe that any of the

LG 2003404

ingredients are mutagenic or teratogenic. None of the compounds is recognized as a known teratogen. Mutagenicity tests have been conducted on a large number of cigarette ingredients. A very small percentage have tested positive in mutagenicity screening tests. Where this is the case, more extensive research has established that there is no cause to believe that the ingredient is harmful.

Finally, as I noted at the outset, the tobacco industry has an extensive program for review and testing of ingredients. Depending upon the type of substance, level of use and other factors, ingredients have been subjected to a variety of toxicity tests, including acute, subchronic and chronic studies. Each company has its own review mechanism for ingredients, and each has carefully selected the ingredients it uses. These decisions are made by each company individually, of course, since the identity of ingredients is an important trade secret.

Based on my consultation with the companies and review of their data, it is clear to me that the companies have carefully reviewed each ingredient and properly concluded that none of them raises health concerns. This conclusion is based upon the available scientific evidence for specific ingredients, including information from the public literature and information developed by the companies. The companies have considerable

scientific resources, and have utilized those resources in a responsible manner.

As noted, my conclusions are shared by four independent toxicologists who authored with me a joint report regarding the safety of tobacco ingredients. This report is based on each scientist's independent review of the confidential ingredients list and extensive published and unpublished scientific data. All of us agree that none of the ingredients added to cigarettes by U.S. manufacturers is harmful as used.

I would be happy to try to answer any questions that you may have, consistent with my area of expertise and subject to the important confidentiality concerns that I have mentioned.

LG 2003406

A SAFETY ASSESSMENT OF
INGREDIENTS ADDED TO TOBACCO IN THE
MANUFACTURE OF CIGARETTES

by

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A SAFETY ASSESSMENT OF
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MANUFACTURE OF CIGARETTES

I. INTRODUCTION

Flavoring ingredients have traditionally been added to tobacco, and tobacco used in cigarettes commercially manufactured in the United States has always contained such ingredients. Non-tobacco ingredients consist of 3 general types:

Processing aids are used to adjust products to meet consumer demands, such as lower yields of "tar" or nicotine, and to facilitate the manufacturing process. Most processing aids are recovered during manufacturing, although minute residues of a few parts per million (ppm) range may remain in the tobacco. An example of a processing aid commonly used in cigarette manufacturing is carbon dioxide.

Casing Materials and Humectants are added to replace sugars lost during curing of the tobacco, to retain moisture, as a carrier for flavor, and to make the smoke smoother and milder. All casings and humectants used by United States cigarette manufacturers are foods, food products, or ingredients approved for use in food by the Food and Drug Administration (FDA). An example of a widely used casing material is sugar, and an example of a humectant used in cigarette tobaccos is propylene glycol.

Flavorings are added to tobacco to impart distinctive flavors, and to fortify natural flavors lost during curing and processing of tobacco. They consist of natural herbs and

spices, or their essential oils, as well as synthetic flavors. Most flavorings occur at very low levels (i.e. < 1 ppm), usually as part of specific proprietary formulations. An example of flavorings commonly added to cigarette tobacco is vanillin.

II. THE EVALUATION OF INGREDIENTS ADDED TO CIGARETTE TOBACCO

The authors of this report, whose qualifications are summarized in the appendix, each independently reviewed the scientific data on ingredients added to cigarette tobacco, and this report represents their consensus on the safety of the ingredients.

The material examined was extensive, and included the confidential list of the ingredients added to tobacco in the manufacture of cigarettes. The authors were also provided with summary data of all relevant published and unpublished toxicity tests and reports, as well as the original publications of data when requested. Pyrolysis and transfer rate data, maximum use levels, and annual poundage data for the ingredients were also evaluated. Each scientist independently visited the individual tobacco companies to examine the testing and research programs used for the ingredients. Reports and raw data from the studies were made available and were examined as necessary, and each scientist formed an independent opinion regarding the adequacy of the testing and safety of each ingredient.

III. TOXICITY DATA ON INGREDIENTS ADDED TO CIGARETTE TOBACCO

Approximately 94% of all ingredients added to cigarette tobacco in the United States are approved as food additives by the FDA, or have been given the status "Generally Recognized As Safe" (GRAS) by the FDA or other expert committees. Some ingredients are highly volatile and are, thus, lost during the manufacturing process rather than being present in the finished cigarette. Moreover, many of the ingredients are identical or essentially similar in composition to natural leaf tobacco components. The pyrolysis products of such ingredients are not expected to depart significantly from the amounts or types of components generated from a range of additive-free tobaccos or tobacco blends. Furthermore, the ingredients do not contribute measurably to tar yields.

The 28 non-tobacco ingredients that are present at the highest levels in cigarettes occur at levels ranging from 0.05% to 11.58% by weight, the latter being sugars. These ingredients, along with the processing aids, also account for more than 99% of the total weight of the ingredients added to cigarette tobacco. All of the remaining non-tobacco ingredients that are present in cigarettes occur at levels below 500 ppm (0.05%), and over one-third occur at levels below 1 ppm (0.0001%).

The authors reviewed extensive data on the ingredients added to cigarette tobacco from large numbers of published and

unpublished studies. Included among these data were findings from in vitro and in vivo tests on metabolism, genotoxicity and reproduction, as well as acute, subchronic, and chronic toxicity tests. These studies are of the same type as those used to assess the biological effects of food additives, drugs and environmental chemicals. The objectives of these studies are to determine the exposure levels at which adverse effects may occur and the nature of the adverse effects.

Metabolism studies specifically examine the manner in which a substance is absorbed in the body, broken down, and eliminated. These processes can all be influenced by the doses administered, and they also may vary among species. Such information is, therefore, often essential for determining the relevance of high dose effects in animals to the relatively low levels of human exposure.

Genotoxicity studies assess the capacity of a chemical to alter the genetic material in cells. Tests are conducted to detect the potential for inducing either gene mutations, chromosome damage, or DNA damage. Substances which experts recognize as clearly positive in such tests may be harmful, particularly with regard to potential risks of cancer or birth defects.

Acute, subchronic and chronic toxicity studies involve the administration of test substances to animals by routes similar or analogous to those known for humans, at various

doses, and for time periods ranging from very brief to lifetime exposures. Animal studies with the ingredients added to cigarette tobacco have included skin painting, inhalation, and oral routes of exposure. The objectives of such studies are to identify the type(s) of toxicity and the organs affected at high test doses, to determine levels of exposure that will pose no unacceptable risks to humans and, in the case of skin painting, to determine tumor promotion effects. These studies require thorough clinical and pathologic evaluations of many test animals during and following the exposures, plus a final interpretation of the relevance of the findings to human risk.

Reproductive studies are specialized types of subchronic and chronic toxicity experiments which specifically examine the effects of a test substance on fertility, gestation, and fetal and neonatal development.

In reviewing the data related to the safety of ingredients added to cigarette tobacco, emphasis was given to the major ingredients (those comprising 99% of the ingredients added), since exposure to these would be expected to be highest. Most ingredients are present at very low levels as components of proprietary flavor formulations, and exposure, if any, would be toxicologically insignificant. Exposure to many of these flavor ingredients is, in fact, greater through the diet than it is through cigarette smoking.

Although all types of toxicological data have some utility for evaluating the safety of ingredients added to cigarette tobacco, particularly relevant are inhalation studies involving actual smoking experiments in animals which compare the biological effects of inhaling tobacco smoke with and without added ingredients. In such experiments, animals inhale smoke from burning cigarettes for extended periods, and toxicological effects are assessed by thorough clinical and pathologic examinations. Although all body systems are examined, emphasis is given to the upper and lower respiratory tracts and the cardiovascular system. Ingredients added to cigarette tobacco have not been observed to induce adverse effects in these experiments. In fact, in many cases added ingredients have reduced the levels of irritation from tobacco smoke.

The authors also reviewed the available data on pyrolysis of the ingredients added to cigarette tobacco. Based upon such data from representative ingredients, it has been determined that most volatile ingredients do not pyrolyze in burning cigarettes, i.e., they do not decompose or chemically change as a result of heat. They are transferred intact in smoke. Thus, if there is exposure and absorption, metabolism would be similar to ingestion. Among those that do pyrolyze, their chemical similarities to tobacco leaf components, and their relatively low levels, suggest that they do not

LG 2003413

significantly alter the composition of tobacco smoke. In any event, toxicity from pyrolysis products would be evident in smoking studies and, as indicated above, such studies have been negative.

Based upon analyses of all of the toxicological data reviewed by the authors of this report, it was concluded that there was no evidence that any ingredient added to cigarette tobacco produces harmful effects under the conditions of use in cigarettes.

IV. SUMMARY AND CONCLUSION

Ingredients are added to tobacco to aid in processing, retain moisture, add flavor, and reduce "tar" and nicotine yield. They have always been used in commercially manufactured cigarettes in the United States. Most are present at extremely low levels, and, as most ingredients are essentially similar to natural tobacco components, the pyrolysis of these ingredients is not expected to depart significantly from the pyrolysis of additive-free tobacco.

It is important to recognize that the use of these ingredients has enabled manufacturers to develop cigarettes with lower "tar" and nicotine yields than would otherwise be available, and the primary issue in safety assessment is whether or not cigarettes are potentially hazardous as a result of the added ingredients. A careful analysis of the scientific data clearly indicates that this is not the case.

LG 2003414

The 28 non-tobacco ingredients that are present at the highest levels in cigarettes occur at levels ranging from 0.05% to 11.58% by weight. These ingredients, along with processing aids, comprise 99% of the total poundage of ingredients added to tobacco in the manufacture of cigarettes, and have been extensively tested for safety. All remaining ingredients occur at lower levels, with many below 0.0001% (1 ppm). Approximately 94% of all ingredients are approved as food additives, or are generally recognized as safe (GRAS) by expert committees, and exposure to these ingredients is generally higher in food than through smoking.

The authors of this report independently examined extensive published and unpublished toxicologic, metabolic, and pyrolysis data on the ingredients added to cigarette tobacco, and found none to be potentially toxic at levels of use.

It is concluded that the ingredients added to tobacco in the manufacture of cigarettes by United States manufacturers are not hazardous under the conditions of use.