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Introduction

On behalf of the nearly 11,000 employees of Philip Morris USA (PM USA) I am very pleased to submit these remarks, and to express our strong support for H.R. 1108, legislation that would give the Food and Drug Administration (FDA) authority to regulate tobacco products. Almost five years after we announced our full support for FDA regulation, PM USA remains committed to passage of comprehensive regulation of tobacco products. H.R. 1108 can serve to create a uniform set of federal standards for the manufacture and marketing of tobacco products. In addition, regulations promulgated pursuant to this legislation should provide clear guidelines and oversight of products that could potentially reduce the harm caused by tobacco use.

H.R. 1108 is the result of many difficult choices and compromises by all those who have been involved in this process over the last several years. The bill clearly provides the framework for comprehensive FDA regulatory authority over tobacco products. We commend you for moving forward with this bipartisan legislation that provides important policy solutions to many of the complex issues involving tobacco products.

We applaud Congressman Waxman and Congressman Davis for the leadership they have shown on this issue. Likewise, we appreciate the leadership shown by Senator Kennedy and Senator Cornyn in introducing companion legislation in the United States Senate. We look forward to working with you and your colleagues in the Senate to enact this legislation intended to benefit adult consumers by reducing the harm caused by tobacco consumption, and to establish clear rules that will be applied to, and hopefully enforced uniformly, throughout the tobacco industry. Uniform enforcement of such rules by the FDA will be critical to reducing the harm for adult tobacco product consumers.

Harm Reduction — First and Foremost

We believe that adult consumers should be and will be a primary beneficiary of FDA regulation. H.R. 1108 will serve to accomplish this goal by providing a new framework within which manufacturers can re-focus their efforts in reducing the harm of their products. As in many other industries, the companies that do the best job of exceeding their consumers' expectations, while meeting regulatory standards, will both benefit their consumers and achieve the best business results.

Our goal, which we believe would ultimately provide both societal and shareholder value, is to design the best products we can, and then, ideally under the full regulatory oversight of the FDA, make them available to adult smokers who do not quit. It seems clear to us that we will not be able to make progress in

this area unless two critical conditions are met: first, that manufacturers such as ourselves develop successfully and make available products that reduce smokers' exposure to harmful compounds compared to conventional cigarettes, and second, that current smokers are given a reason — through communication of truthful, non-misleading information that avoids unintended consequences — to switch to these products. For people who continue to smoke, we believe that this is the best way to meaningfully reduce the overall harm caused by smoking.

We have invested in extensive research programs that focus on advancing our knowledge about tobacco and tobacco smoke to support our efforts to develop and launch new product designs. We believe these product technologies and related approaches show promise for the future, and that the FDA should be empowered as quickly as possible by enactment of this legislation to evaluate products and their potential for reducing the risk of contracting smoking-related diseases.

We respectfully urge our future regulators at the FDA to keep in mind that innovation in developing new products is crucial to the ultimate success of this legislation. In order to have any real impact, reduced exposure and other potential harm reduction products must be acceptable to adult tobacco users. We see little benefit to consumers or society if harm reduction is not pursued in the context of tobacco products that adult consumers will enjoy using. As the 1998 Canadian Experts' Committee, which addressed potential harm reduction products for smokers, concluded, "[i]f smokers would not buy these products,

product modification initiatives would fail.”

Importantly, once the FDA concludes as a matter of science that a new product has the potential to offer reduced exposure or reduced risk, H.R. 1108 grants the agency an essential role in performing its own assessment and oversight of any claims, explicit or implied, made about the product by the manufacturer regarding exposure- or risk-reduction. Crafting appropriate claims regarding these products requires great care and attention. We are mindful of the critical need for manufacturers to work closely with the FDA on consumer messages.

Once again, as with determinations regarding the scientific issues of potential exposure and risk reduction, we believe H.R. 1108 correctly gives FDA jurisdiction over communications to consumers. Future FDA regulations should ensure that consumers are not mistakenly led to believe that the use of a particular tobacco product reduces the health risks as much as quitting. At the same time, we do not believe future regulations should be utilized as a tool to suppress information that is truthful and not misleading.

We are keenly aware that some members of the public health community are opposed to the very concept of developing and offering “reduced exposure” or “reduced risk” tobacco products. They are concerned that the availability of such products might discourage smokers from quitting or encourage people to start using tobacco products. These advocates appear to believe that the only acceptable message for the government to communicate, irrespective of

potential alternatives, is a directive not to consume tobacco products at all. PM USA strongly believes if products that could ultimately reduce the harm caused by smoking are developed, it would be wrong to deny adult smokers access to information about the facts of reduced exposure or reduced risk products and the potential benefits of such products. Section 911 sets out rigorous requirements that must be met before manufacturers could communicate about these types of products. We agree fully with the need for such rigorous requirements while urging future FDA regulators to take note of the Institute of Medicine admonition in its 2001 report that “[the] regulatory process should not discourage or impede scientifically grounded claims of reduced exposure, so long as steps are taken to ensure that consumers are not misled...” We believe that approach is both good policy and required by the First Amendment.

Reducing Youth Smoking — A Critical Priority

In 1998 PM USA created a Youth Smoking Prevention department with the objective of helping to prevent kids from smoking cigarettes. We are committed to this effort because we firmly believe that kids should not smoke.

H.R. 1108 aims to help reduce youth smoking. Among other things, it would prohibit self-service transactions (except in adult-only facilities), establish a national minimum age of 18, require age verification for anyone younger than 27 years of age, and prohibit the sale of unpackaged cigarettes (so-called “loosies”). We commend the cosponsors of this legislation for taking these steps. We

believe that by working together, we can all contribute to continuing the reduction in youth smoking rates that has occurred over the past decade.

A number of other provisions in the legislation deserve further discussion and comment.

Sec. 901 — FDA Authority Over Tobacco Products

H.R. 1108 creates a new chapter within the Food, Drug, and Cosmetic Act to regulate tobacco products. Importantly, tobacco products will not be regulated as a drug or device. Moreover, the bill explicitly states that one of “the purposes of this Act” will be “to continue to permit the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers.” While the bill extends the scope of FDA’s authority to all manufacturers of tobacco products selling tobacco products in the United States, it also makes clear that FDA does not have the authority to regulate tobacco growers. FDA will *not* be on the farm.

Sec. 903 — Misbranded Tobacco Products

Pursuant to the legislation, tobacco products will be deemed misbranded if their label is false or misleading or they are not correctly labeled. Of real significance to America’s tobacco growers and their families and communities, a tobacco product will be misbranded if the label does not contain an accurate statement of the percentage of the tobacco used in the product that is domestically grown and the percentage that is foreign grown.

Sec. 904 — Submission of Health Information

The bill requires, within six months of passage, submission to the Secretary of documents and information concerning ingredients, compounds, paper, filter and other components of tobacco products as well as content, delivery and form of nicotine. PM USA fully supports this requirement with appropriate safeguards to protect our trade secrets, which this bill provides. We think the FDA should be able to give smokers confidence that the ingredients added to cigarettes do not increase the inherent health risks of smoking, including increasing the addictiveness. Further, we have no objection to disclosing the results of our own ingredients testing to the FDA so it can assess every ingredient we use. The same is true for other information that may be requested by the Secretary under this section including information related to research activities and findings, scientific information on reduced risk products and technology and marketing research.

Sec. 905 — Annual Registration

H.R. 1108 requires the registration of every entity that owns or operates any establishment in any state engaged in the manufacture, preparation, compounding, or processing of tobacco products. While these same requirements extend to foreign manufacturers of tobacco products, it will be critical for FDA to ensure the even-handed application of the legislation to these foreign manufacturers, including through appropriate inspections.

Sec. 906 — General Provisions Respecting Control of Tobacco Products

The section allows for regulations requiring good manufacturing practices (GMPs) with input from the public and interested parties and provides for a three-year delay for compliance to ensure that manufacturers have ample opportunity to comply.

Sec. 907 — Product Standards

H.R. 1108 grants the Secretary the authority to adopt performance standards for tobacco products if “appropriate for the protection of the public health.” Although broad, the delegation of authority to the FDA to issue product standards is fully supported by PM USA. It will allow FDA to reduce harm by imposing mandatory design changes on tobacco products. These standards could include provisions to regulate nicotine yields and other constituents and components of cigarettes. It also will ban the sale of candy or fruit-flavored cigarettes.

We believe future FDA regulators should be very cautious and avoid doing what no one should want: to impose changes that are so radical that tobacco products are effectively banned, or consumers are driven away from the legitimate market towards illicit, completely unregulated products. In fact, the legislation explicitly directs FDA to consider whether a standard would create a significant new demand for contraband, including counterfeit, products, in determining what would, and would not, be “appropriate to protect public health.”

We urge future FDA regulators to fully consider the warning voiced by the FDA in the 1996 tobacco rule regarding this subject:

Black market and smuggling would develop to supply smokers with these products ... [which] would be even more dangerous than those currently marketed, in that they could contain even higher levels of tar, nicotine, and toxic additives.

In addition, a product standard may not have the effect of “banning all cigarettes” or reducing nicotine yields “to zero”; this power is explicitly reserved to Congress.

Sec. 911 — Modified Risk Tobacco Products

Much of my earlier testimony is focused on the importance of harm reduction. These provisions are essential to that goal and must be implemented by FDA in a careful, thoughtful manner in order to be successful in achieving everyone’s goal of reducing the harm caused by tobacco products. In its 2001 report, the Institute of Medicine committee made two important, fundamental recommendations: (i) determinations about what is, and what is not, a reduced-risk or reduced-exposure product should be made by the government on a purely scientific basis and (ii) any claims made about such products should be strictly regulated to ensure that consumers are not misled. We believe H.R. 1108 gives FDA the necessary level of authority and discretion to achieve both.

Significantly, the bill creates a special rule for certain products where the label, labeling or advertising contains an explicit or implied statement that the product contains a reduced level of a substance, or presents a reduced exposure

to a substance if the Secretary makes such a finding based on a number of criteria. We believe the bill appropriately and reasonably empowers FDA to approve applications for products that make exposure-reduction claims for five-year periods, utilizing criteria that appear to have been substantially derived from the 2001 Institute of Medicine Report.

Sec. 920 – User Fees

H.R. 1108 requires the Secretary to require tobacco product manufacturers and importers to pay for providing, equipping and maintaining adequate service for regulating tobacco products. PM USA believes the collection of such user fees is reasonable, assuming appropriate oversight and strict collection and enforcement by the agency.

Sec. 102 — Repromulgation of FDA’s 1996 Final Rule

Within thirty days of enactment of H.R. 1108 the Secretary is required to publish a final rule on the advertising of, and access to, tobacco products, which shall become effective no later than one year after the date of enactment. The rule will be identical in its provisions to the advertising and access regulations promulgated by the FDA in 1996. Prior to making any amendments to the rule, the Secretary would be required to publish a proposed rule.

In addition, under section 906(d) of the legislation, FDA would have authority to impose additional or different restrictions on the sale, distribution, advertising and promotion of tobacco products if the Secretary determines that the regulation would protect the public health and, as the bill specifies, the

marketing and advertising restrictions are consistent with the First Amendment.

The bill explicitly provides that FDA will not be permitted to prohibit the sale of any tobacco product to adults age 18 and over. Further, it does not permit the Secretary to require that tobacco products be available only by prescription.

The timing of these requirements is important. At the same time that we will be making the transition into the new regulatory environment, we understand that FDA will also be transitioning into its new role, including putting the necessary regulatory structures and resources into place.

As such, it will be critically important for FDA and the industry to work closely together in order to provide for a smooth transitional period, such as was accomplished with the State Attorneys General with respect to the transition into the MSA and with other government agencies that have been granted new or additional authority over tobacco products. For example, it will be important to work out reasonable timelines for the substantial new requirements that are contemplated by the legislation.

PM USA will also work with FDA and other interested stakeholders to make sure that any advertising or marketing restrictions comport with the First Amendment.

Sec. 201 — Cigarette Label and Advertising Warnings

This section of H.R. 1108 specifies nine new warning labels required to appear on cigarette packages and advertisements. The warnings must comprise

at least the top thirty-percent of the front and rear panels of the package, and at least twenty-percent of the related advertisements. It will be unlawful for a manufacturer, importer, distributor or retailer to advertise any cigarette unless its advertising bears one of the required warning labels. PM USA fully supports these provisions regarding the new warning labels and their size and placement. PM USA also supports the grant of authority to FDA to modify or enlarge these warnings in the future through a rulemaking process where the potential benefits, risks and unintended consequences of such proposed changes will be thoroughly examined.

Conclusion

I will conclude by reiterating a point made earlier: a comprehensive national tobacco policy should bring more, not less, beneficial competition to the U.S. tobacco industry. We do not believe that H.R. 1108 is designed to, or would in fact, give any one tobacco company a commercial advantage over others, notwithstanding the assertions of some manufacturers. Tobacco companies know very well that the First Amendment of the Constitution guarantees that the FDA could not ban tobacco product advertising. An appropriate and constitutionally sound regulation of tobacco products and advertisements would effectively ensure the continuation of vigorous competition in the market place.

The most significant restrictions placed on the tobacco industry in recent history were those contained in the Master Settlement Agreement (“MSA”). Those changes, which restrict billboard and transit advertising among other

things, did not lock in any single company's market share. In fact, since the adoption of the MSA, there are examples of both new brands and pre-existing ones that have increased their market share.

History and the facts simply do not support the contention that constitutionally proper advertising or marketing restrictions will lessen competition, create a monopoly or lock in market share. Indeed, we believe that, with clear guidelines and oversight, there should be an opportunity for increased competition as both new and existing manufacturers work to develop and commercialize products that could potentially reduce the harm caused by tobacco use.

Thank you for allowing us to submit these views to the Committee. Thank you for your leadership and commitment to this issue. Please know that we will work tirelessly to secure enactment of H.R. 1108, which represents a truly historic opportunity to establish a comprehensive and coherent national tobacco policy.