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Dr. Lawrence Deyton
Director, Center for Tobacco Products
U.S. Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850-3229

Dear Dr. Deyton:

The blatant misbranding of roll-you-own tobacco as pipe tobacco has created a major public health problem that FDA has the statutory authority to correct. The damage done to the public health by this clear, deliberate and uncorrected abuse is already substantial and it continues to grow.¹

In 2009, Congress substantially increased the federal excise tax on cigarettes and roll-your-own tobacco (“RYO”) and equalized the tax burden on these products. The legislation increased the federal excise tax on pipe tobacco only modestly and thus created a large disparity in the tax burden between pipe tobacco and RYO. As a consequence, beginning in April 2009, when the federal excise tax increase on RYO took effect, there has been a massive financial and regulatory incentive for sellers of RYO to misbrand their product as pipe tobacco.

According to figures released yesterday by the CDC, sales of RYO fell from a per-cigarette equivalent of 10.7 billion cigarettes in 2008 to 6.0 billion in 2009. Since that time, sales of RYO fell further to the equivalent of 2.6 billion cigarettes, a decline of 75.7 percent since 2008. By contrast, the sales of “pipe tobacco,” which had been almost static for many years, rose from the equivalent of 2.8 billion cigarettes in 2008 to 6.3 billion in 2009 and have skyrocketed to 17.5 billion in 2011, an increase of 573.1 percent. Moreover, an examination of monthly figures provided by the Tobacco Tax and Trade Bureau pinpoints the beginning of this transformation in April 2009, precisely the time when the tax rate was changed. In 2008, “pipe

¹ The evidence of this abuse is documented in a GAO Report of April 2012, Tobacco Taxes, Large Disparities in Rates for Smoking Products Trigger Significant Market Shifts to Avoid higher Taxes, GAO Report No. 12-475 (hereinafter “GAO Report”).

tobacco” accounted for about 0.7% of combustible tobacco sales in the United States. In 2011, “pipe tobacco” accounted for 5.3% of U.S. combustible tobacco sales.

The reason for this massive shift in the market is the deliberate misbranding of RYO as pipe tobacco. Products that for years had been sold as RYO are now sold in bags labeled “pipe tobacco.” In some cases, the subterfuge is so crude that labels saying “pipe tobacco” were affixed on bags previously marked as “RYO tobacco.”

Maintaining high consumer prices for cigarettes through the maintenance of high cigarette taxes has been a cornerstone of tobacco control policy for many years. By enabling sellers of RYO to avoid the federal excise tax on TYO, the misbranding of RYO as pipe tobacco undercuts this policy.

A portion of the growth in misbranded so-called “pipe tobacco sales” is accounted for by the increase in RYO use as the result of the popularization of cigarette-making machines in retail outlets, which make it possible for consumers to roll their own tobacco in the store. When TTB sought to require store owners with such machines to register as tobacco product manufacturers (and therefore make them responsible for payment of federal excise tax on the product), its action was enjoined by a federal district court that ruled that it lacked statutory authority to do so.² However, Congress recently enacted legislation to give TTB clear statutory authority to accomplish this goal.³ Enactment of the legislation, however, will only address a small portion of the problem. The large majority of misbranded RYO is not sold for rolling in in-store machines. Moreover, the development and popularization of individual rolling machines for home use is already expanding the potential market for misbranded RYO.

“Roll-your-own” tobacco is defined in the Tobacco Control Act as “any tobacco product which, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making cigarettes.”⁴ As this definition makes clear, simply labeling a product “pipe tobacco” instead of “roll-your-own” tobacco is insufficient to avoid statutory requirements applicable to RYO. Tobacco that is indistinguishable from tobacco previously sold as “roll-your-own” remains RYO regardless of the label that is attached to it. Moreover, the manner in which this tobacco is marketed makes it unmistakably clear that the product is “suitable for use and likely to be purchased as tobacco for cigarettes.” Indeed, the timing of the changed labeling, the knowledge that this tobacco was being used in roll-your-own machines in stores and the dramatic rise in sales without any information that actual pipe use has suddenly grown indicates that these sellers and manufacturers knew or had reason to know the actual purpose for which these products would be used.

² RYO Machine Rental, LLC v. United States Department of the Treasury, 2010 U.S. Dist. LEXIS 13206 (D. Ohio 2010).

³ P.L. 112-141 (July, 2012).

⁴ This definition is the same as that in the Internal Revenue Code, 26 U.S.C. § 5701, 5702.

The distinctions between RYO and legitimate pipe tobacco are numerous and obvious. The strands of tobacco cut for use in cigarettes are thinner and longer than strands used for pipe tobacco. Moreover, pipe tobacco has a far higher moisture content and sugar content than cigarette tobacco. In addition, cigarette tobacco is unsuitable for smoking in a pipe because it has too low a resistance to draw and requires constant puffing in order to keep the fire lit. Furthermore, because of its different characteristics real pipe tobacco introduced into a cigarette rolling machine would quickly clog the machinery.

Pursuant to section 903(a) of the Tobacco Control Act, “a tobacco product shall be deemed to be misbranded if its labeling is false or misleading in any particular.” Labeling RYO tobacco “pipe tobacco” is both false and misleading. Moreover, the blatant falsity of the misrepresentation, coupled with the obvious economic incentive for misclassification, makes it clear that the misrepresentation is deliberate. FDA has broad authority to prevent the sale of misbranded tobacco products, including the authority to seize the product.

The misbranding of RYO as pipe tobacco constitutes not only an evasion of federal excise taxes, but also a nullification of federal regulatory policy. In 2009, when Congress enacted the Family Smoking Prevention and Tobacco Control Act, it gave FDA regulatory authority over cigarettes, roll-your-own tobacco (“RYO”), and smokeless tobacco. FDA was given authority to extend its regulatory authority to other tobacco products, but to do so it was required to promulgate a rule. No such rule has been promulgated to date and as a result pipe tobacco remains outside the scope of current FDA jurisdiction. In addition to being outside FDA’s regulatory jurisdiction, sales of pipe tobacco do not give rise to an obligation to pay FDA user fees. Furthermore, pipe tobacco sales are not subject to significant regulatory restrictions applicable to RYO under the Tobacco Control Act, such as the ban on flavorings, the pre-market application provisions of the Act on modified risk tobacco product claims, and the requirement for pre-market applications for the marketing of new products. As FDA already has jurisdiction over RYO, no additional rulemaking would be required as a prerequisite for taking enforcement action against misbranded RYO.

We strongly urge FDA to deem roll-your-own tobacco that is erroneously labeled as pipe tobacco “misbranded” within the terms of section 903(a) and to vigorously exercise its regulatory jurisdiction over such products.

Sincerely,

A handwritten signature in black ink that reads "Matthew L. Myers". The signature is written in a cursive, flowing style.

Matthew L. Myers
President
Campaign for Tobacco-Free Kids