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November 19, 2013

Sr. Ramiro Mendoza Zúñiga
Contralor General de la República de Chile

Dear Sr. Ramiro Mendoza Zúñiga,

I understand that the government of Chile has enacted Decree 50/2013 banning the use of menthol in tobacco products pursuant to Law No. 1941, which grants the Ministry of Health authority to prohibit the use of additives and substantives that increase levels of addiction, damage, or risk to consumers of tobacco products. I further understand that the Contraloría General de la República has found the prohibition on menthol to be impermissible.

As a scientist who has focused on addiction, tobacco-related health harms, and tobacco product design and regulation for more than three decades, I am writing to you to provide my perspective on the critical importance of effectively regulating tobacco product additives, including menthol. I am writing on my own behalf and not as a representative of the organizations, of which I am a member, consult for, or voluntarily serve.

To provide you with some basis for my perspective, I am an Adjunct Professor of Behavioral Biology, in the Department of Psychiatry and Behavioral Sciences at The Johns Hopkins University School of Medicine, and Vice President for Research and Health Policy, Pinney Associates. From 1980-1996, I conducted and led tobacco and other drug research at the National Institute on Drug Abuse (NIDA). While at NIDA, I served as Chief of its Human Performance Laboratory, Chief of the Biology of Dependence and Abuse Potential Assessment Section, and Chief of the Clinical Pharmacology Research Branch. I was also a frequent liaison to the U.S. Food and Drug Administration on tobacco products and tobacco addiction treatment. I contributed to numerous U.S. Surgeon General's reports as well as reports by other agencies. I presently serve on the World Health Organization (WHO) Tobacco Regulation Study Group (TobReg) which provides scientific guidance for implementation of several articles of the international tobacco treaty, the WHO Framework Convention on Tobacco Control (FCTC). I was trained in behavioral science, pharmacology, and other disciplines relevant to understanding addictive substances.

Tobacco use is the world's leading cause of preventable death and smoking kills over 10,000 people annually in Chile.[1] Smoking is highly addictive, as demonstrated by the high prevalence of smoking among adults and youth in Chile, 40 % and 27%, respectively.[2] Chile has the highest smoking prevalence rate in Latin America.[3]

Tobacco products are designed to be sophisticated drug delivery systems – engineered and manufactured to make them easier for young people to take up, as well as to maximize addiction and sustain use.[4] Menthol plays a large role in bringing about these results.

There is abundant evidence on menthol's effects on tobacco use initiation, dependence (addiction), level of use, and success in quitting. Many studies evaluate and compare these outcomes between menthol cigarette smokers, both youth and adults, and non-menthol smokers. After conducting a review of the evidence on the health effects of menthol from a variety of sources, The U.S. Food and Drug Administration's Tobacco Product Scientific Advisory Committee (TPSAC) released a comprehensive report on the use of menthol in cigarettes in 2011, *Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations*. The FDA then conducted its own review and evaluation of the evidence, culminating in the report, *Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes"* in July 2013. Key findings emerging from these reports include: [5] [6]

1) Menthol cigarettes increase the number of children who experiment with cigarettes and the number of children who become regular smokers, increasing overall youth smoking;

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[1] Global Burden of Disease [database on the internet]. Institute for Health Metrics and Evaluation (IHME). c2013 [cited 2013 November 18]

[2] Ministry of Health of Chile (MINSAL). Tabaco. 2013. Available from: http://www.redsalud.gov.cl/temas_salud/tabaco.html.

[3] Caris, Luis, Varas, Marianela, Anthony, Christopher B., & Anthony, James C.. (2003). Behavioral problems and tobacco use among adolescents in Chile. *Revista Panamericana de Salud Pública*, *14*(2), 84-90. Retrieved November 18, 2013, from http://www.scielosp.org/scielo.php?script=sci_arttext&pid=S1020-49892003000700002&lng=en&tlng=en. 10.1590/S1020-49892003000700002.

[4] Jack E. Henningfield and Mitch Zeller, "Could Science-Based Regulation Make Tobacco products Less Addictive?" *Yale Journal of Health Policy Law Ethics*, 3(1):127-38, 2002; Bates C, Jarvis M, Connolly GN, Tobacco Additives, Cigarette Engineering and Nicotine Addiction, 1999; World Health Organization, Study Group on Tobacco Product Regulation ("TobReg"), Report on the Scientific Basis of Tobacco Product Regulation, WHO Technical Report Series 967 (2012).

[5] Tobacco Products Scientific Advisory Committee, Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations, July 21, 2011 http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf.

[6] FDA, *Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes, July 2013*, http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/UCM361598.pdf.

2) Young people who initiate using menthol cigarettes are more likely to become addicted and become long-term daily smokers and, *importantly, there is strong evidence that adolescent menthol cigarette smokers are more dependent on nicotine than adolescent non-menthol cigarette smokers*; and
3) The availability of menthol cigarettes reduces smoking cessation; smokers of menthol cigarettes are less successful in quitting than non-menthol cigarette smokers.

As a result of these findings, the TPSAC report concluded, "Removal of menthol cigarettes from the marketplace would benefit public health in the United States."

Menthol and other flavored cigarettes are marketed disproportionately to younger smokers.[7] These efforts have proven successful. A substantial proportion of young people use menthol and other flavored cigarettes. In Brazil, for example, almost 60 percent of 13- to 15-year-old youth experiment with flavoured cigarettes, particularly menthol.[8] A 2008 U.S. study revealed the use of flavored cigarettes was 11.9% among smokers aged 17-26 years whereas only 6.7% smokers over the age of 25 years used these products. [9] Recently, tobacco companies have introduced innovative designs to make menthol cigarettes even more enticing to young people, such as equipping them with crushable menthol capsules. The consumer market research publication, Euromonitor, reports that in 2012, tobacco companies responded to the strong demand for menthol and capsule cigarettes in Chile by increasing their menthol flavored offerings. [10]

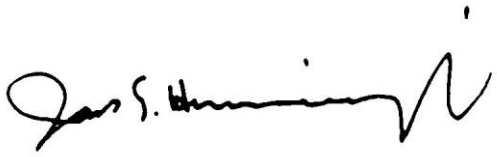
It is well established that people who avoid taking up smoking during youth and early adulthood are unlikely to ever to become smokers.[11] [12] The findings discussed above demonstrate that the availability of menthol cigarettes and the youth-targeted marketing of these products directly sabotage this result. In doing so, they undermine the goals of substantially reducing tobacco consumption and protecting both present and future generations from the devastating harms of tobacco

[7] Klausner K. Menthol cigarettes and smoking initiation: A tobacco industry perspective. Tobacco Control. 2011;20 (Suppl_2):ii12–ii19.
[8] Figueiredo V et al. Use of flavored cigarettes among Brazilian adolescents: A step toward nicotine addiction? Available at http://emtemporeal.com.br/anexos/Flavored_cigarettes_v1.pdf.
[9] Klein SM, Giovino GA, Barker DC, Tworek C, Cummings KM, O'Connor RJ, "Use of flavored cigarettes among older adolescent and adult smokers: United States, 2004-2005," *Nicotine Tob Res.* 10(7):1209-14, 2008.
[10] Euromonitor on line. Tobacco Chile. October 2013. Available at http://www.euromonitor.com/tobacco-in-chile/report.
[11] U.S. Department of Health and Human Services. Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2012.
[12] Jha, P. et al. (1999). *Curbing the epidemic: Governments and the economics of tobacco control*. Washington, DC: World Bank.

consumption and exposure to tobacco smoke articulated in the Framework Convention on Tobacco Control, to which Chile is a party.

In sum, menthol in cigarettes make an inherently harmful and deadly product even more harmful by attracting and increasing the number of young smokers, creating higher levels of addiction, and decreasing successful quit attempts. Regulation prohibiting the use of menthol in tobacco products, therefore, plays an important role in preventing these harmful results and in protecting present and future generations from tobacco harms.

Respectfully,



Jack E. Henningfield, PhD

Cc: Patricia Arriagada Villouta
Contralor General de la Repúblic, Subrogante.