

EXHIBIT 3

July 16, 2018

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. FDA-2017-N-6189 Regarding the Regulation of Nicotine Levels

Dear Sir/Madam:

I appreciate the opportunity to provide comments regarding the regulatory actions that the Food and Drug Administration is considering regarding the regulation of nicotine levels.

I am a managing director in the mass torts and securities practices at NERA Economic Consulting in New York. I am an economist by training and have over 25 years of experience in economic consulting on issues related to product liability, mass torts, consumer behavior, complex damages disputes and securities. I have consulted on numerous matters involving consumer behavior, quantified tort liabilities and conducted economic impact studies. I have testified before the U.S. Department of Labor's Hearings on an economic and statistical analysis of the methodology used to quantify the expected benefits of the proposed rule regarding silica.¹ I have also recently submitted comments regarding the CFPB's request for changing the Bureau's public reporting practices of consumer complaint information and have conducted studies on the economic impact of smoking bans.² I received my Ph.D. from Stanford University and have been designated by the American Statistical Association as an Accredited Professional Statistician. I have published on issues related to tort reforms, propensity to seek legal actions, mutual funds fees, and the impact of the credit crisis, among other issues, in the *Journal of Structured Finance*, *Journal of Investment Compliance*, *Journal of Alternative Investments*, *Business Economics*, *International Trade Journal*, and others.

¹ See, "Re: Docket No. OSHA-2010-0034 Occupational Exposure to Respirable Crystalline Silica – Comments of Dr. Faten Sabry, Ph.D. of NERA Economic Consulting for the US Chamber of Commerce," January 27, 2014, available at: <https://www.regulations.gov/document?D=OSHA-2010-0034-2263>.

² See, "Re: Docket Number CFPB-2018-0006 Regarding the Consumer Financial Protection Bureau's ("CFPB") Reporting Practices of Consumer Complaint Information," April 19, 2018, available at: <https://www.regulations.gov/document?D=CFPB-2018-0006-0017>. See also, Faten Sabry and Robert Patton, "Village of Tinley Park - Study of Impact of Smoking Bans Final," *NERA Economic Consulting*, March 12, 2007.

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I have been asked by the Cigar Rights of America, the Cigar Association of America, and the International Premium Cigar and Pipe Retailers Association to provide an empirical analysis of consumers' behavior regarding the dual use of premium cigars and cigarettes. I relied on Corey et al. (2017) for the definition of premium cigars and also relied on the same PATH database, Wave 1, to examine the consumption patterns of premium cigars.³ I will be providing additional analysis in response to the comment docket regarding the regulation of premium cigars on July 25, 2018.

Using the same PATH database and definitions used in the Corey study, I further analyzed the consumption patterns of current premium cigar smokers.⁴ First, I compared the frequency and intensity of premium cigar use among current premium cigar smokers depending on whether they are also current cigarette smokers. Exhibit 1 shows the frequency and intensity for premium cigar smokers who are also current cigarette smokers and those who are not. According to the PATH data, respondents who reported smoking less than one cigar per day were assigned as smoking 0.5 cigars per day. Among current premium cigar smokers, those who are also current cigarette smokers smoke premium cigars 1.1 days per month as compared to 1.9 days per month for those who are not current cigarette smokers. Premium cigars consumed per day, among these two groups, were 0.6 cigars per day among current cigarette smokers and 0.7 cigars per day for those who are not current cigarette smokers.

³ Corey, C.G., E. Holder-Hayes, A.B. Nguyen, et al. "U.S. Adult Cigar Smoking Patterns, Purchasing Behaviors, and Reasons for Use According to Cigar Type: Findings From the Population Assessment of Tobacco and Health (PATH) Study, 2013-2014", *Nicotine & Tobacco Research*, September 15, 2017, available at: <https://academic.oup.com/ntr/article/4159211/U-S-adult-cigar-smoking-patterns-purchasing>.

⁴ I was able to replicate Corey et al. (2017) with respect to the overall premium cigar prevalence rate and dual use of cigarettes and premium cigars finding.

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Exhibit 1. *Frequency and Intensity of Premium Cigar Use Among Current Premium Cigar Smokers*

	Current Cigarette Smokers?	
	Yes (1)	No (2)
Days smoked premium cigars in past 30 days ¹		
Median	1.1	1.9
Interquartile range	(0.0-4.3)	(0.2-5.0)
Number of premium cigars per day ²		
Median	0.6	0.7
Interquartile range	(0.0-0.9)	(0.1-0.9)
Number of observations	125	252

Notes and Sources:

- Data are from Population Assessment of Tobacco and Health (PATH) Study Restricted-Use Files.
- The median is the weighted middle value in a sequence of observations. The interquartile range represents the weighted 25th and 75th percentiles.

¹ Number of days smoked in the past 30 days is available for someday smokers. Everyday smokers are assumed to smoke on all 30 days.

² Respondents reporting smoking less than one cigar per day were assigned as smoking 0.5 cigars per day.

Second, I calculated additional summary statistics on cigars and cigarettes consumption. Exhibit 2 presents frequency and intensity of cigarette smoking among current cigar smokers. The exhibit shows that the typical current premium cigar smoker did not smoke cigarettes on any day in the past 30 days.⁵ The median number of cigarette smoking days and the median number of cigarettes per day are both zero. By contrast, the typical current non-premium cigar smoker smoked cigarettes on 29.0 of the past 30-day period, and typically smoked 5.2 cigarettes a day. The typical current cigarillo smoker smoked cigarettes on 19.9 days of the past 30-day period and smoked 4.2 cigarettes a day. The typical current filtered cigar smoker smoked cigarettes on 29.2 days of the past 30-day period and smoked 9.2 cigarettes a day.

⁵ The typical current premium cigar smoker is represented by the median observation. The median observation is the middle point value separating the higher half of the observations from the lower half.

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Exhibit 2. *Frequency and Intensity of Cigarette Use Among Current Cigar Smokers*

	Premium Cigars (1)	Non-Premium Cigars (2)	Cigarillos (3)	Filtered Cigars (4)
Days smoked cigarettes in past 30 days ¹				
Median	0.0	29.0	19.9	29.2
Interquartile range	(0.0-28.1)	(0.0-29.5)	(0.0-29.5)	(1.4-29.6)
Number of cigarettes per day				
Median	0.0	5.2	4.2	9.2
Interquartile range	(0.0-4.5)	(0.0-18.5)	(0.0-14.7)	(0.0-18.9)
Number of observations	377	489	1,186	551

Notes and Sources:

- Data are from Population Assessment of Tobacco and Health (PATH) Study Restricted-Use Files.
- The median is the weighted middle value in a sequence of observations. The interquartile range represents the weighted 25th and 75th percentiles.

¹ Everyday smokers are assumed to smoke on all 30 days. Respondents who never smoked are assumed to not smoke any days.

Yours Sincerely,



Faten Sabry
Managing Director