

ONE HUNDRED TWELFTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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WASHINGTON, DC 20515-6115

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March 28, 2011

The Honorable Margaret Hamburg
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner Hamburg:

Evidence obtained last Congress by the Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations raises serious questions about the actions of Kretek International, a privately held company that imports and markets clove tobacco products. Specifically, documents provided to the Committee indicate that Kretek has introduced a line of new clove-flavored cigars to circumvent the recent federal ban on clove-flavored cigarettes.

On September 22, 2009, the Food and Drug Administration banned the sale of flavored cigarettes, including those flavored with clove. FDA took this action under the authority of the Family Smoking Prevention and Tobacco Control Act. When you announced the ban, you explained that “flavored cigarettes are a gateway for many children and young adults to become regular smokers.”¹ Dr. Howard Koh, the Assistant Secretary for Health, stated: “Flavored cigarettes attract and allure kids into a lifetime of addiction. FDA’s ban on these cigarettes will break that cycle.”²

The FDA ban applies only to cigarettes, which are defined as tobacco products wrapped in paper.³ The ban did not apply to cigars, which are tobacco products wrapped in tobacco leaf. The documents provided to the Committee show that Kretek deliberately sought to exploit this

¹ U.S. Food and Drug Administration, *Candy and Fruit Flavored Cigarettes Now Illegal in United States; Step is First Under New Tobacco Law* (Sept. 22, 2009) (online at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2009/ucm183211.htm).

² *Id.*

³ Family Smoking Prevention and Tobacco Control and Federal Retirement Reform, Pub. L. No. 111-31 (2009).

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loophole by creating a clove cigar with “exactly the same formula as our clove cigarette” and “launching a cigar replacement product that will continue our business.” According to one internal Kretek document, “GOAL IS SEAMLESS CONVERSION TO CLOVE CIGARS.”

I urge you to protect youth from the dangers of Kretek’s new product by extending the ban on flavored cigarettes to flavored cigars that have been designed and marketed to circumvent the FDA prohibition.

The Dangers of Clove-Flavored Tobacco Products

Established in 1981, Kretek imports clove tobacco products into the United States from Indonesia.⁴ Prior to the ban on clove-flavored cigarettes, Kretek controlled 97% of the U.S. clove-flavored cigarette market.⁵ Internal corporate documents estimate that over 1.3 million people in the United States smoked clove-flavored cigarettes.⁶ In 2007, imports of clove-flavored cigarettes into the U.S. totaled nearly 400 million.⁷

Kretek International imported clove cigarettes manufactured by PT Djarum. Djarum is the second-largest clove cigarette manufacturer in Indonesia.⁸ According to Djarum’s website: “Kretek are composed of three key ingredients: tobacco, cloves and spice and fruit sauce.”⁹ The website explains: “The final ingredient in any kretek is the sauce, a closely guarded recipe containing spice, fruit and herb extracts, and flavorings.”¹⁰

⁴ E-mail from John Geoghegan, Director of Strategic Planning and Brand Development, Kretek International, to Mark Cassar, President and Chief Executive Officer, Kretek International (June 14, 2008) (KRETEK005480). *See also* 2009 National Sales Meeting (July 13-15, 2009) (KRETEK001322).

⁵ *Id.*

⁶ 2009 National Sales Meeting (July 13-15, 2009) (KRETEK001339).

⁷ U.S. Trade Representative, *Non-Confidential Summary of the First Submission of the Republic of Indonesia before the World Trade Organization* (Oct. 22, 2010) (WT/DS406) (online at www.ustr.gov/webfm_send/2491).

⁸ E-mail from John Geoghegan, Director of Strategic Planning and Brand Development, Kretek International, to Mark Cassar, President and Chief Executive Officer, Kretek International (June 14, 2008) (KRETEK005480).

⁹ PT Djarum, *Derived from Nature* (online at www.djarum.com/index.php/en/history) (accessed on Mar. 2, 2011).

¹⁰ *Id.*

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Health officials in the United States have found significant risks to children from Kretek's cigarettes. The American Academy of Pediatrics has explained that "[b]ecause the eugenol in the clove cigarette acts as a topical anesthetic . . . it reduces the noxious element of smoking."¹¹ According to the National Institute on Drug Abuse, "Clove cigarettes are sometimes referred to as 'trainer cigarettes' and may serve as 'gateway' products that introduce young people to smoking."¹²

Surveys of tobacco use by youth confirm these concerns. According to the National Survey on Drug Use and Health, young people between the ages of 12 and 17 are two times more likely than adults age 26 or older to have smoked clove cigarettes in the last month and nearly two times as likely to have smoked clove cigarettes in the past year.¹³ According to the 2005 Monitoring the Future survey, over 7% of 12th graders smoked clove-flavored cigarettes in the prior month.¹⁴

The Kretek Documents

In October 2009, the Committee sent a letter to Kretek International requesting documents and information concerning the company's introduction of flavored cigars following the FDA ban on flavored cigarettes.¹⁵ In total, the Committee received over 7,000 pages of documents from the company.

These internal corporate documents reveal that senior executives at Kretek International developed clove cigars over the course of two years as a contingency in the event that clove

¹¹ American Academy of Pediatrics, Committee on Substance Abuse, *Hazards of Clove Cigarettes*, Pediatrics, Vol. 88, No. 2 (Aug. 1991).

¹² National Institute on Drug Abuse, U.S. Department of Health and Human Services, *Alternative Cigarettes May Deliver More Nicotine Than Conventional Cigarettes*, NIDA Notes, Vol. 18, No. 2 (Aug. 2003) (online at archives.drugabuse.gov/NIDA_notes/NNVol18N2/Alternative.html) (accessed on Mar. 2, 2011).

¹³ Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services, *Results from the 2003 National Survey on Drug Use and Health* (Sept. 2004).

¹⁴ Johnston, L.D., et al., Institute for Social Research, University of Michigan, *Monitoring the Future National Survey Results on Drug Use 1975-2005*, National Institute on Drug Abuse (2005).

¹⁵ Letter from Henry A. Waxman, Chairman, Committee on Energy and Commerce, and Bart Stupak, Chairman, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, to Mark Cassar, President and Chief Executive Officer, Kretek International (Oct. 2, 2009).

cigarettes were banned in the United States. According to the documents, the purpose of these actions was to introduce a strikingly similar product and avoid FDA regulation.

Kretek's plans apparently started as early as 2007. In an e-mail dated October 15, 2007, a senior executive wrote that one of the company's "objectives" was to "[b]e prepared for a seamless transition from Djarum Clove cigarettes to Djarum Clove cigars in the event of FDA ban on clove."¹⁶ The e-mail describes "Two strategic actions: a) Establish the brand and product before the FDA bill goes through, and b) Develop the brand for rollout with multiple facings to replace clove cigarettes."¹⁷

The effort by Kretek to develop a clove-flavored cigar to replace the company's clove-flavored cigarettes was discussed at the highest levels of the company. On August 2, 2008, Hugh Cassar, Chairman of the Board of Directors at Kretek, wrote in an e-mail:

Your management team and my management have discussed for many months the production of Clove cigars using similar packaging as our present clove cigarettes . . . I have no idea why it is taking so long with getting into production so we can start introducing them into the market just in case clove cigarettes are outlawed in the USA.¹⁸

In the same e-mail, Mr. Cassar wrote that "[t]he cigars will look and taste just about the except for the wrapper and therefore will not qualify as a cigarette," apparently omitting the word "same" by mistake.¹⁹

One month later, Mr. Cassar again raised the issue of developing clove cigars that were the same as clove cigarettes except for the wrapping material. He wrote: "Gentlemen why cannot the clove cigar be exactly the same formula as our clove cigarette except for the HTL wrapper."²⁰ The HTL wrapper refers to a wrapper made of homogenized tobacco leaf.

Communications among senior executives at Kretek are explicit that corporate officials wanted to introduce clove-flavored cigars to evade the anticipated FDA ban, as well as higher taxes being levied on cigarettes. John Geoghegan, Kretek's Director of Strategic Planning and

¹⁶ E-mail from John Geoghegan, Director of Strategic Planning and Brand Development, Kretek International, to Bunjoto Astono et al. (Oct. 15, 2007) (KRETEK00588).

¹⁷ *Id.*

¹⁸ E-mail from Hugh Cassar, Chairman, Board of Directors, Kretek International, to Robert Budi Hartono et al. (Aug. 2, 2008) (KRETEK005261).

¹⁹ *Id.*

²⁰ E-mail from Hugh Cassar, Chairman, Board of Directors, Kretek International, to Bunjoto Astono et al. (Sept. 23, 2008) (KRETEK005103).

Brand Development, sent an e-mail on May 14, 2009, to Kretek's sales force and key account managers detailing the company's motivation in introducing clove-flavored cigars as a replacement for clove-flavored cigarettes. Mr. Geoghegan stated that Kretek needed to "make sure that our customers understand why we are introducing this product line."²¹ He explained:

First, because clove cigarettes may be banned before the end of this year, and we are launching a cigar replacement product that will continue our business.

Second, because the SCHIP bill has raised the price of all cigarettes and tobacco products, and we want consumers who enjoy cloves to have an affordable product.

Third, because we are number one in cloves and we want to stay that way – continuing to provide our distributor customers with a solid source of business.²²

On July 11, 2009, Mr. Geoghegan transmitted a sales presentation to senior executives at Kretek, including the President and Chief Executive Officer of the company, attaching a presentation for the company's national sales meeting.²³ A slide in the presentation detailing "key activities moving forward" depicted the transition from clove-flavored cigarettes to clove-flavored cigars:

²¹ E-mail from John Geoghegan, Director of Strategic Planning and Brand Development, Kretek International, to Kretek Sales and Key Account Managers (May 14, 2009) (KRETEK001955).

²² *Id.* See also 2009 National Sales Meeting (July 13-15, 2009) (KRETEK001329); 2009 National Sales Meeting (July 13-15, 2009) (KRETEK001330); 2009 National Sales Meeting (July 13-15, 2009) (KRETEK001331).

²³ E-mail from John Geoghegan, Director of Strategic Planning and Brand Development, Kretek International, to Joel Myden, Director of Sales, Kretek International, Eliot Suied, Director, Government Affairs, Kretek International, and Mark Cassar, President and Chief Executive Officer, Kretek International (July 11, 2009) (KRETEK001319).



Subsequent slides in the presentation explain the transition from clove cigarettes to new flavored cigars. Key points that describe the cigarette and cigar “action plan” include:

- Clove cigarettes may not be in interstate commerce after September 22, 2009.
- GOAL IS SEAMLESS CONVERSION TO CLOVE CIGARS AS CIGARETTES ARE DEPLETED.²⁵
- A replacement product for Djarum Clove Cigarettes.
- The rich smooth taste clove smokers expect.²⁶

²⁴ 2009 National Sales Meeting (July 13-15, 2009) (KRETEK001327); 2009 National Sales Meeting (July 13-15, 2009) (KRETEK001328).

²⁵ 2009 National Sales Meeting (July 13-15, 2009) (KRETEK001332).

²⁶ 2009 National Sales Meeting (July 13-15, 2009) (KRETEK001334). *See also* 2009 National Sales Meeting (July 13-15, 2009) (KRETEK001333); 2009 National Sales Meeting (July 13-15, 2009) (KRETEK001335); 2009 National Sales Meeting (July 13-15, 2009) (KRETEK001336); 2009 National Sales Meeting (July 13-15, 2009) (KRETEK001337); 2009 National Sales Meeting (July 13-15, 2009) (KRETEK001338); 2009 National Sales Meeting (July 13-15, 2009) (KRETEK001340); 2009 National Sales Meeting (July 13-15, 2009) (KRETEK001341); 2009 National Sales Meeting (July 13-15, 2009) (KRETEK001342); 2009 National Sales Meeting (July 13-15, 2009) (KRETEK001343); 2009 National Sales Meeting (July 13-15, 2009) (KRETEK001344); 2009 National Sales Meeting (July 13-15, 2009)

The documents also show that company officials wanted to obscure the evidence that their new cigar was created to circumvent the FDA ban. Over two years ago, Mr. Geoghegan wrote in an e-mail: “We will need to demonstrate to distributors and trade that there is a market driven reason for filtered clove cigars, rather than just a reaction to FDA.”²⁷ He reiterated this point in a May 27, 2009, e-mail, writing: “The strategy is to totally ignore FDA as a reason why, and to barely touch on SCHIP/taxes as an overarching condition of the industry.”²⁸

Mr. Geoghegan expressed a similar concern in transmitting the sales presentation on July 11, 2009. In his e-mail, he wrote: “Please note. There is a lot to be said that is NOT written down. Everything we write, everything we research, everything we present is subject to future review by the FDA.”²⁹

Conclusion

The documents provided to the Committee raise serious concerns about the actions of Kretek International. They detail a plan to subvert the FDA ban on flavored cigarettes by introducing a nearly identical product as a flavored cigar. The documents are remarkably explicit, describing the “GOAL” as a “SEAMLESS CONVERSION.”

I recognize that there are historical differences between cigarettes and cigars. Congress recognized these differences by requiring FDA to ban flavored cigarettes, while giving FDA discretion to decide whether to ban flavored cigars. In this case, however, Kretek is exploiting

(KRETEK001345); 2009 National Sales Meeting (July 13-15, 2009) (KRETEK001346); 2009 National Sales Meeting (July 13-15, 2009) (KRETEK001347).

²⁷ E-mail from John Geoghegan, Director of Strategic Planning and Brand Development, Kretek International, to Bunjoto Astono, International Sales Manager, Djarum (Oct. 3, 2007) (KRETEK006250).

²⁸ E-mail from John Geoghegan, Director of Strategic Planning and Brand Development, Kretek International, to Bunjoto Astono, International Sales Manager, Djarum, and Eliot Suied, Director, Government Affairs, Kretek International (May 27, 2009) (KRETEK00311). *See also* 2009 National Sales Meeting (July 13-15, 2009) (KRETEK001324); 2009 National Sales Meeting (July 13-15, 2009) (KRETEK001325); 2009 National Sales Meeting (July 13-15, 2009) (KRETEK001326).

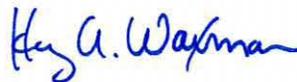
²⁹ E-mail from John Geoghegan, Director of Strategic Planning and Brand Development, Kretek International, to Joel Myden, Director of Sales, Kretek International, Eliot Suied, Director, Government Affairs, Kretek International, and Mark Cassar, President and Chief Executive Officer, Kretek International (July 11, 2009) (KRETEK001319).

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the distinction to keep its dangerous product on the market. This transparent attempt to evade the requirements of the law should not be tolerated.

I urge you to investigate Kretek's actions and extend your ban on flavored cigarettes to flavored cigars that are being marketed for the purpose of circumventing the cigarette ban. This action is necessary to prevent Kretek's product from continuing to be a gateway drug that lures children into a lifetime of addiction.

Sincerely,



Henry A. Waxman
Ranking Member

cc: The Honorable Fred Upton
Chairman

The Honorable David Camp
Chairman
Committee on Ways and Means

The Honorable Sander M. Levin
Ranking Member
Committee on Ways and Means

The Honorable Max Baucus
Chairman
Senate Committee on Finance

The Honorable Orrin G. Hatch
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Senate Committee on Finance

Mr. John J. Manfreda
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