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DEPARTMENT OF JUSTICE



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April 11, 2018

James Jack  
Capitol Strategic Advisors  
1215 K Street, Ste. 1760  
Sacramento, CA 95814

RE: Cigar Warnings

Dear Mr. Jack:

You have asked our office whether, in our view, warnings for cigars mandated under the FDA's 2016 tobacco regulations (21 C.F.R. § 1143.5) constitute clear and reasonable warnings under California's Safe Drinking Water and Toxic Enforcement Act of 1986, commonly known as "Proposition 65." (Health & Saf. Code, § 25249.5 et seq.) As you noted, the federal warnings are almost identical to warnings previously approved by the Federal Trade Commission ("FTC") in Consent Orders with leading cigar manufacturers in 2000. At the time, our office sent a letter to the FTC stating our view that compliance with the Consent Orders would result in compliance with Proposition 65, and with an additional requirement for cigar warnings under state law set forth in Health and Safety Code sections 104550-52 ("AB 1595").<sup>1</sup> We have reviewed the new federal warning requirements and determined that, with one important caveat set forth below, compliance with the federal requirements will constitute compliance with Proposition 65 and AB 1595.

The Food and Drug Administration ("FDA") adopted the warning requirements as part of regulations finalized on May 10, 2016. (81 Fed. Reg. 28,974 (May 10, 2016) (codified at 21 C.F.R. pts. 1100, 1140, and 1143).) The new warning requirements take effect in August 2018. The FDA regulations make it unlawful to sell cigars in the United States without warnings displayed prominently on the two principal display panels of the packaging and in advertisements, as well as in point-of-sale signs for cigars sold individually. (21 C.F.R. § 1143.5.) The package warnings must comprise at least 30 percent of each of the display panels. (*Id.*, subd. (a)(2)(i).) As with the warnings under the FTC Consent Orders, there are multiple warning messages that must be randomly displayed and roughly equally distributed over each 12-month period. (*Id.*, subd. (c).) With two exceptions, the rotating warning messages are the

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<sup>1</sup> A copy of the Attorney General's June 23, 2000, letter to the FTC is enclosed with this letter.

same as those in the Consent Orders. They are set forth below, with the new warning messages underlined:

- (i) WARNING: Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale.
- (ii) WARNING: Cigar smoking can cause lung cancer and heart disease.
- (iii) WARNING: Cigars are not a safe alternative to cigarettes.
- (iv) WARNING: Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers.
- (v) WARNING: Cigar use while pregnant can harm you and your baby; *or*  
  
SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight.
- (vi) WARNING: This product contains nicotine. Nicotine is an addictive chemical.

As noted, only the two underlined warnings (v and vi) are new.<sup>2</sup> In our analysis of the FTC Consent Orders in 2000, we concluded that the rotating warnings were sufficient to provide clear and reasonable warning that cigars expose persons to tobacco smoke and other chemicals known to cause cancer and reproductive toxicity, as required under Proposition 65. (Health & Saf. Code, § 25249.6.) Two of the FTC warnings were about cancer risk, and the warning about “the risk of infertility, still birth and low birth weight” referenced specific types of birth defects and reproductive harm for which Proposition 65 requires a warning. Therefore, we concluded the warning content complied with Proposition 65. We also concluded that the rotating warning program for these specific products was a reasonable method to deliver the warnings, even though some of the warning messages address harms that Proposition 65 does not cover. Cigar users tend to use the products repeatedly, so they would see all of the warnings over time.

We have reviewed the new warnings and concluded that, with one important exception, they also comply with Proposition 65. Consumers who receive warnings specific to cancer, and to the increased risk of infertility, stillbirth and low birth weight, will have received clear and reasonable warning under Proposition 65. Moreover, although adding a sixth warning, about nicotine addiction, will cause each of the warnings to be displayed slightly less than when there were only five warnings, our analysis of the FTC rotating warning requirement still applies. As noted in the 2000 letter, given the nature of cigar products, the requirement to randomly and

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<sup>2</sup> Another difference is that all of the warnings under the FTC Consent Orders began with “Surgeon General Warning.” The FDA’s decision to remove the words “Surgeon General” from all but one of the warnings does not change our analysis.

equally display the warnings within a 12-month period makes it likely that consumers will receive all of the warnings.

The exception is for the new warning language that companies can use at their discretion *instead of* the infertility/stillbirth/birth weight warning for the fifth warning message. (21 C.F.R. § 1143(a)(1)(v).) Choosing the message “WARNING: Cigar use while pregnant can harm you and your baby” instead of the alternative message will not result in compliance with Proposition 65.<sup>3</sup> This is because tobacco smoke is listed under Proposition 65 as a chemical known to cause cancer, developmental harm (i.e., harm to the developing fetus), *and* harm to the female and male reproductive systems. (Cal. Code Regs., tit. 27, § 27001.) A company that chooses the warning message about using cigars “while pregnant” fails to deliver a warning about the risk of *male or female reproductive harm*. Warning about the increased risk of infertility, on the other hand, addresses this health risk. Therefore, to comply with the Proposition 65 warning requirement, it is our view that a company must choose the warning set forth in section 1143(a)(1)(v)(B) (“SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight”), instead of the warning in subdivision (a)(1)(v)(A).<sup>4</sup>

You did not ask specifically about the effect of the new FDA warnings requirements on California’s additional requirement for cigar warnings under AB 1595, but we address it here since we also addressed it in the June 2000 letter. AB 1595 requires cigar manufacturers to use three specified warnings on cigar packaging on a rotating basis. (Health & Saf. Code, § 104550.) The warnings refer to many of the same health risks as the federal warnings, but use different language. Under AB 1595, however, if a federal provision is enacted that requires health warnings for cigars, “those federal provisions shall supersede the provisions of this article.” (Health & Saf. Code, § 104552.) In 2000 there was some question whether the FTC Consent Orders constituted “enactment” of a federal provision subject to section 104522, although we concluded that it did. The FDA’s adoption of warning provisions as part of a regulation adopted pursuant to the Administrative Procedures Act clearly is an enactment subject to section 104522. Therefore, the federal warnings supersede the warning provisions in AB 1595.

In conclusion, we have reviewed the FDA’s requirements for health warnings for cigars and concluded that compliance with the FDA warnings will result in compliance with Proposition 65 if the company chooses the warning in title 21 of the Code of Federal Regulations, section 1143(a)(1)(v)(B) (“Risk of Infertility, Stillbirth and Low Birth Weight”), instead of the optional alternative warning in section 1143(a)(1)(v)(A) (“use

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<sup>3</sup> If a company chose to rotate the “Cigar use while pregnant” warning on an equal basis with the “Risk of Infertility, Stillbirth and Low Birth Weight” warning and other warnings, we would deem this rotation to be consistent with Proposition 65 as well because the pregnancy warning also addresses Proposition 65 endpoints. The problem arises only when the company discards the “Risk of Infertility” warning and replaces it entirely or on a less than equal basis with the “Cigar use while pregnant” warning.

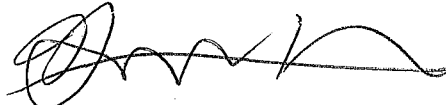
<sup>4</sup> Companies that are parties to a Proposition 65 settlement requiring compliance with the FTC warnings would also need to choose option (v)(A) to remain in compliance with the settlement.

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while pregnant can harm you and your baby.”) We also have concluded that compliance with the FDA warnings results compliance with AB 1595.

Do not hesitate to contact me if you have further questions.

Sincerely,

A handwritten signature in black ink, appearing to read 'H. Pollak', with a stylized flourish at the end.

HARRISON M. POLLAK  
Deputy Attorney General

For XAVIER BECERRA  
Attorney General

HMP:JM

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STATE OF CALIFORNIA  
OFFICE OF THE ATTORNEY GENERAL  
BILL LOCKYER  
ATTORNEY GENERAL

June 23, 2000

*Via Facsimile & U.S. Mail*

The Honorable Robert Pitofsky, Chairman  
Federal Trade Commission  
600 Pennsylvania Avenue, NW  
Washington, D.C. 20580

RE: Cigar Warnings

Dear Chairman Pitofsky:

You have requested a statement from the Attorney General regarding whether compliance with the FTC's Consent Orders requiring health warnings for cigars will constitute compliance with California laws requiring warnings for the same products, specifically the Safe Drinking Water and Toxic Enforcement Act of 1986 ("Proposition 65") and the more recently enacted amendments to California Health and Safety Code sections 104550-104552, which require specific warnings for cigars. In responding, we think it is best to set forth our understanding of the legal requirements at issue.

A. **FTC Consent Order**

The FTC, in consultation with the Surgeon General, has reached an agreement with seven major cigar companies, under which health warnings will be required pursuant to a Consent Order with each company. We understand that these seven companies manufacture about 95% of the cigars sold in the United States. Under the Consent Order, the FTC requires five "rotating" warnings. The warnings must be provided on labels. In addition, warnings will be required in cigar advertising. The text of the warnings is as follows:

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**SURGEON GENERAL WARNING: Cigar Smoking Can Cause  
Cancers Of The Mouth And Throat, Even If You Do Not Inhale.**

**SURGEON GENERAL WARNING: Cigar Smoking Can Cause  
Lung Cancer And Heart Disease.**

**SURGEON GENERAL WARNING: Tobacco Use Increases The Risk  
Of Infertility, Stillbirth And Low Birth Weight.**

**SURGEON GENERAL WARNING: Cigars Are Not A Safe  
Alternative To Cigarettes.**

**SURGEON GENERAL WARNING: Tobacco Smoke Increases The  
Risk Of Lung Cancer And Heart Disease, Even In Nonsmokers.**

The Consent Order contains specific provisions governing the format and visibility of the warnings.

The Consent Order also provides that its requirements are uniform and that any different state labeling or advertising warning requirements are "in conflict with" the FTC orders. It limits this preemptive scope, however, to apply only where the local or state law "requires that the state or local warning appear on any package or advertisement required to display the Federal warnings set forth herein." (Section X, p. 16.) While there may be issues concerning whether the FTC has authority to preempt state law through this Consent Order, since compliance with the Consent Order will result in compliance with state law, there is no need to resolve this issue at this time. Moreover, we note that the preemptive scope of the order is limited to warning requirements that appear "on any package or advertisement" that carries the federal warning. (Consent Order, § X.) Under Proposition 65, operators of premises on which smoking is permitted may be required to provide persons entering the premises with posted warnings that they are being exposed to tobacco smoke.<sup>1</sup> Neither these warnings, nor any other warning appearing other than on packages or advertising, would be preempted by this language.

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<sup>1</sup>Many of these premises post signs stating "WARNING: This Facility Permits Smoking, and Tobacco Smoke Contains Chemicals Known to the State of California to Cause Cancer and Birth Defects or Other Reproductive Harm."

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B. Applicable State Laws

I. Proposition 65

The Safe Drinking Water and Toxic Enforcement Act of 1986 is an initiative statute passed as "Proposition 65" by a vote of the people in November of 1986. The warning requirement of Proposition 65 is contained in Health and Safety Code section 25249.6, which provides:

No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual, except as provided in Section 25249.10.

Proposition 65 establishes a procedure by which the state develops a list of chemicals "known to the State to cause cancer or reproductive toxicity." (Health & Saf. Code, § 25249.8.) Pursuant to this process, various chemicals have been "listed" by the State and therefore are subject to the law. (22 Cal.Code Regs., § 12000.) These "listed" chemicals include tobacco smoke (listed both as a carcinogen and a reproductive toxin) and a number of chemical constituents of tobacco smoke. Exposures are exempt from this requirement where the business proves that the level of exposure to chemical poses "no significant risk" of cancer, or is less than one one-thousandth of the "no observable effect level," for reproductive toxins.<sup>3</sup>

Under the statute warnings "need not be provided separately to each exposed individual and may be provided by general methods such as labels on consumer products, . . . provided that the warning accomplished is clear and reasonable." (Health & Saf. Code, § 25249.11(f).)

Implementing regulations provide more specific standards for the appearance and content of warnings. With regard to content, certain warnings are "deemed to be clear and reasonable warning" (22 Cal.Code Regs., § 12601(b)), but the language in the Consent Order does not fall within these established "safe harbors." Any language may be found acceptable, however, if it "clearly communicate[s] that the chemical in question is known to the state to cause cancer, or birth defects or other reproductive harm." (22 Cal.Code Regs., § 12601(a).)

With respect to the form and appearance of the warning, the regulations provide a safe harbor for consumer products so long as the warning is "prominently placed upon a product's

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<sup>3</sup>A separate section of the statute prohibits discharges of the same chemicals into "any source of drinking water," hence the title "Safe Drinking Water and Toxic Enforcement Act." (Health & Saf. Code, § 25249.5.)

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label or other labeling . . . with such conspicuousness, as compared with other words, statements, designs, or devices in the label . . . as to render it likely to be read and understood by an ordinary individual under customary conditions of purchase or use." (22 Cal. Code Regs., §§ 12601(b)(1)(A), 12601(b)(3).) Where warning methods do not fall within the safe harbor, they nonetheless comply with the regulations where "the method employed to transmit the warning [is] reasonably calculated, considering the alternative methods available under the circumstances, to make the warning message available to the individual prior to exposure." (22 Cal. Code Regs., § 12601(a).)

In 1988, the Attorney General brought a Proposition 65 enforcement action against a number of manufacturers and retailers of cigars, entitled *People of the State of California, ex rel. John K. Van de Kamp v. Safeway Stores, Inc., et al.* (San Francisco Superior Court No. 897576). Three very similar but separate Consent Judgments were entered in that case with different groups of defendants, one of which was composed of cigar manufacturers. Those judgments specifically provide that the respective defendants/parties will provide warnings stating "WARNING: This product contains/products chemicals known to the State of California to cause cancer, birth defects and other reproductive harm."

## 2. AB 1595

In 1999, the California Legislature enacted, and the Governor approved, a new statute requiring label warnings for cigars. Commonly referred to by its legislative bill number, AB 1595, the law requires that specific language be placed on cigar packages.<sup>3</sup> Under the provisions of this law, manufacturers or importers of cigars must place three rotating warning labels on retail packages of their products. Each warning discusses a different set of effects, but each also specifically incorporates the Proposition 65 safe harbor warning, i.e., "This product contains chemicals known to the State of California to cause cancer and birth defects and other reproductive harm." While the language of the warnings is not identical to that required by the FTC Consent Order, it addresses many of the same health effects.

### C. Comparison of Proposition 65 and FTC Consent Order Warning Language and Methods

In analyzing the FTC warnings, two of the five specifically mention the risk of cancer in smokers, which is one of the types of harm covered by the Proposition 65 warning language. Another refers to increased risk of "infertility, stillbirth, and low birth weight." While typical Proposition 65 language refers to "birth defects or other reproductive harm," in this instance the

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<sup>3</sup> Ch. 693, Statutes of 1999, adding sections 104550 -104552 to the Health and Safety Code.



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FTC language is a more specific reference to the particular types of birth defects or reproductive harm that may be caused by smoking.

Due to the rotating warning program, however, those three warnings will not appear on all packages of cigars. Nonetheless, we have concluded that, in this instance, the rotating warnings are acceptable. First, the product in question is frequently and repeatedly consumed by the same person, meaning that an individual consumer will see numerous packages of the product over a relatively short period of time, thereby seeing all of the warnings over a reasonable period of time. (This contrasts with some long-term use products, e.g. mini-blinds, because once such a product is purchased the consumer would be unlikely to read another label for the same product for some time.) The FTC's "rotation plan" requirement increases the likelihood of all warning messages being seen, because it results in packages with all of the rotating warnings being present in a store at the same time. As a result, even somebody perusing packages at a counter would be likely to encounter all of the warnings at the same time. Second, the rotation is to accommodate other warnings about serious health effects not covered by Proposition 65, which we have an interest in accommodating, in contrast to other commercial information. (Of course, additional warnings could be provided on packages, but this can result in smaller type face, making the entire warning less likely to be seen and read.)

The FTC warnings, however, are not consistent with the warnings currently being given under the Consent Judgment in *People v. Safeway Stores, et al.* Accordingly in order to assure that the parties to that judgment are not subject to arguably conflicting requirements, we intend to seek a modification of that judgment that will allow the parties to provide the warnings in the form and content required by the Consent Order.

In addition, we have reviewed the technical requirements for the size and location of the warnings under the FTC Consent Order, and have concluded that they meet the "conspicuousness" requirements of Proposition 65.

#### D. Compliance With AB 1595

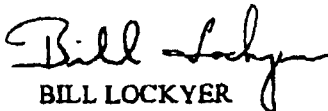
AB 1595 mandates certain warning language *verbatim*, without allowing for similar messages. Nonetheless, AB 1595 was drafted with some anticipation that the federal government might adopt a warning requirement for cigars, and accordingly provides that "... to the extent this article conflicts with any federal provision enacted subsequent to the effective date of this article that requires cigar manufacturers and importers to provide warning labels on cigars, those federal provisions shall supersede the provisions of this article." While the term "federal provision enacted" arguably is susceptible to different interpretations, we think that the term embraces the proposed Consent Order, once it is formally adopted by the Commission. Thus, by its own terms, AB 1595 will be superseded by the Consent Order once adopted. Although full implementation of the Consent Order will occur sometime after AB 1595 becomes effective on

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September 1, 2000 (see Consent Order § XII), the Consent Order will be final before that date and, as such, it will supercede the requirements of AB 1595 before they become effective.

In sum, we conclude that compliance with the FTC Consent Order will result in compliance with Proposition 65 and AB 1595. Since 1988, California has been the only state in the nation to require warnings for cigars, and we are pleased to see that the FTC has taken action to assure that consumers throughout the nation are given this important health information.

Sincerely,

  
BILL LOCKYER  
Attorney General