

Administrative Law – Final Examination

Summer 2009

Professor Davies

N.B. Short answer questions omitted herein; only the essay portion of the exam is included.

EXAMINATION COVER SHEET

Student Examination Number: _____

**Final Examination
Monday, June 29, 2009
Summer 2009**

⌚ Time Allowed: 4 hours

Authorized Materials: This exam is open book. You may consult any hard copy written materials, but you may not receive assistance from other people.

Special Instructions: This exam consists of five parts:

- **Fact Pattern**
- **Essay Question No. 1**
- **Essay Question No. 2**
- **Short Answer Questions**
- **Bonus Questions**

The exam is being graded on a 200 point scale. The bonus questions at the end are worth up to a total of 7 additional points. The point value of each section in percentage terms is as follows:

Essay Question No. 1 – 60%

Essay Question No. 2 – 20%

Short Answer Questions – 20%

The Fact Pattern provided at the beginning of the exam is common to all questions. You may answer the question sections in any order you choose, but a grasp of the Fact Pattern is necessary for each section (excepting the bonus questions).

With respect to the short answer questions, record the question numbers and your answers to each *in your word-processed answer* or, if you are using one, *your Bluebook*. **Do not write your answers on the examination itself.**

You will be graded both on your ability to spot the issues of law, fact, and policy presented and on the quality of your analysis of those issues. Organize your answer before you begin to write. Concise expression and clarity of analysis will be rewarded in grading.

The essay questions may fail to provide some information that you consider important. Should you find it necessary to make assumptions beyond those stated in the question, clearly explain your assumptions and their significance in your answer.

There are 22 pages to the exam, not including this cover sheet. Make sure you have all of them.

When time is called, you must stop working on your exam immediately and turn in your copy of the exam and your answers.

Good luck!

GENERAL INSTRUCTIONS FOR ALL EXAMS:

1. Exams do not leave the exam room! Write your exam number on your copy of the examination questions, and return it to the proctor at the end of the exam.
2. Students may NOT take any bluebooks or scratch paper from the examination room, whether blank or used. Return to proctor.
3. If you are using a bluebook print your exam number, the title of the course and the instructor's name on the front of each bluebook.
4. Number each bluebook (1 of 3, 2 of 3, 3 of 3, etc.) and place all bluebooks and examination questions inside the first numbered bluebook.
5. If the examination utilizes a computer answer sheet (Scantron):
 - You must use **BLACK** or **BLUE INK** only; no pencils
 - You may use **CORRECTION TAPE** only; no liquid paper
 - Print your examination number in the box found in the lower left-hand section of the form. Write the number in the first 4 spaces, and zero-fill any remaining spaces.

For example, if your examination number is 2983:

IDENTIFICATION NUMBER

2	9	8	3	0	0	0	0
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Fill in the bubbles corresponding to the numbers written.

Fact Pattern

It could not get much worse. The celebrities are upset.

In March 2000, the Supreme Court issued a decision in *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000). At issue in *Brown & Williamson* was the question of whether “the Food and Drug Administration (FDA), after having expressly disavowed any such authority since its inception, [had] jurisdiction to regulate tobacco products.” *Id.* at 125. In asserting this authority, the FDA had relied on § 321(g) and (h) of the Federal Food, Drug, and Cosmetic Act (“FDCA” or the “Act”), which the FDA administers.

FDCA § 321(g) gives FDA authority to regulate “drugs,” which the statute defines to include “articles (other than food) intended to affect the structure or any function of the body.” FDCA § 321(h) gives FDA authority to regulate “devices,” which the Act defines, in part, as “an instrument, apparatus, implement, machine, contrivance, . . . or other similar or related article, including any component, part, or accessory, which is . . . intended to affect the structure or any function of the body.”

To regulate tobacco products, the FDA determined that nicotine, which is included in tobacco products, is a drug; that cigarettes and smokeless tobacco products (*e.g.*, chew, snuff, etc.) are “drug delivery devices”; and that, accordingly, the agency had jurisdiction under the FDCA to regulate these products. The Supreme Court, in a 5-4 opinion written by Justice O’Connor, disagreed:

Regardless of how serious the problem an administrative agency seeks to address . . . , it may not exercise its authority “in a manner that is inconsistent with the administrative structure that Congress enacted into law.” *ETSI Pipeline Project v. Missouri*, 484 U.S. 495, 517, 108 S.Ct. 805, 98 L.Ed.2d 898 (1988). . . . [W]e find that Congress has directly spoken to the issue here and precluded the FDA’s jurisdiction to regulate tobacco products. . . .

In its rulemaking proceeding, the FDA quite exhaustively documented that “tobacco products are unsafe,” “dangerous,” and “cause great pain and suffering from illness.” 61 Fed. Reg. 44,412 (1996). It found that the consumption of tobacco products presents “extraordinary health risks,” and that “tobacco use is the single leading cause of preventable death in the United States.” *Id.* at 44398. . . . These findings logically imply that, if tobacco products were “devices” under the FDCA, the FDA would be required to remove them from the market. . . . The Act prohibits “[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.” 21 U.S.C. § 331(a). In light of the FDA’s findings, two distinct FDCA provisions would render cigarettes and smokeless tobacco misbranded devices. First, § 352(j) deems a drug or device

misbranded “[i]f it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.” . . . Second, a drug or device is misbranded under the Act “[u]nless its labeling bears . . . adequate directions for use . . . in such manner and form, as are necessary for the protection of users,” except where such directions are “not necessary for the protection of the public health.” § 352(f)(1). Given the FDA’s conclusions concerning the health consequences of tobacco use, there are no directions that could adequately protect consumers. That is, there are no directions that could make tobacco products safe for obtaining their intended effects. . . .

In fact, based on these provisions, the FDA itself has previously taken the position that if tobacco products were within its jurisdiction, “they would have to be removed from the market because it would be impossible to prove they were safe for their intended us[e].” Public Health Cigarette Amendments of 1971: Hearings before the Commerce Subcommittee on S. 1454, 92d Cong., 2d Sess., 239 (1972) (statement of FDA Comm’r Charles Edwards). . . .

Congress, however, has foreclosed the removal of tobacco products from the market. A provision of the United States Code currently in force states that “[t]he marketing of tobacco constitutes one of the greatest basic industries of the United States with ramifying activities which directly affect interstate and foreign commerce at every point, and stable conditions therein are necessary to the general welfare.” 7 U.S.C. § 1311(a). More importantly, Congress has directly addressed the problem of tobacco and health through legislation on six occasions since 1965. . . . When Congress enacted these statutes, the adverse health consequences of tobacco use were well known, as were nicotine’s pharmacological effects. . . . Nonetheless, Congress stopped well short of ordering a ban. Instead, it has generally regulated the labeling and advertisement of tobacco products, expressly providing that it is the policy of Congress that “commerce and the national economy may be . . . protected to the maximum extent consistent with” consumers “be[ing] adequately informed about any adverse health effects.” 15 U.S.C. § 1331. . . . A ban of tobacco products by the FDA would therefore plainly contradict congressional policy. . . .

The inescapable conclusion is that there is no room for tobacco products within the FDCA’s regulatory scheme. If they cannot be used safely for any therapeutic purpose, and yet they cannot be banned, they simply do not fit.

Partially in response to the Supreme Court’s decision in *Brown & Williamson*, Congress over the last decade repeatedly introduced legislation seeking to give the FDA authority to regulate tobacco products. In June 2009, these efforts finally succeeded. Congress passed, and President Obama signed into law, the Family Smoking Prevention and Tobacco Control Act (the “FSPTCA” or “Tobacco Control Act”). And this is why it cannot get much worse: The celebrities are up in arms.

Immediately following the FSPTCA’s passage, the Hollywood social elite began organizing—and mobilizing. Enraged by what they saw as a clear violation of their personal liberties, a previously little-known nonprofit group called People of Uppity Falutin’ For Tobacco (“PUFFT”) instituted a publicity and outreach campaign under the slogan “We Can Smoke if We Wanna, When We Wanna—and We Wanna!” In this national media effort, PUFFT was headed by its longtime president and founding member, Pauly Shore. It also enlisted three new spokespeople: Katherine Heigl, of *Grey’s Anatomy* fame; Ronnie Wood, of Rolling Stones fame, and Tara Reid, of little fame. Pauly Shore and Ronnie Wood are “Marlboro men,” but Tara Reid enjoys a “heavy” cigar (8 grams of tobacco or more per cigar) on weekends and special occasions, and Katherine Heigl prefers both flavored (*e.g.*, chocolate, gummy bear, or Tiger’s Blood) and high-nicotine cigarettes.



Pauly Shore



Tara Reid

PUFFT filmed a number of television commercials to get out its message. One featured Ms. Heigl and Mr. Wood singing a duet of Rihanna’s *Umbrella* together

onstage, then dancing together in a disco nightclub to the Bee Gees, then taking in a live performance of *Mamma Mia!*, all the while with cigarettes in hand. “Smoking’s fun!,” they chimed in unison at the advertisement’s end. “We’ve always smoked and we always will. Don’t let The Feds take away our right to live our lives the way we want.”



Katherine Heigl



Ronnie Wood

Despite the Hollywood hubbub, the FDA proceeded unabated with implementing the FSPTCA. Section 102 of this new statute states:

SEC. 102. FINAL RULE.

(a) CIGARETTES AND SMOKELESS TOBACCO.—

(1) **IN GENERAL.**—On the first day of publication of the Federal Register that is 180 days or more after the date of enactment of this Act, the Secretary of Health and Human Services shall publish in the Federal Register a final rule regarding cigarettes and smokeless tobacco, which— . . . shall be identical in its provisions to part 897 of the regulations promulgated by the Secretary of Health and Human Services in the August 28, 1996, issue of the Federal Register (61 Fed. Reg. 44615–44618). Such rule shall— . . .

(F) become effective on the date that is 1 year after

the date of enactment of this Act; and

(G) amend paragraph (d) of section 897.16 to read as follows:

“(d)(1) Except as provided in subparagraph (2), no manufacturer, distributor, or retailer may distribute or cause to be distributed any free samples of cigarettes, smokeless tobacco, or other tobacco products (as such term is defined in section 201 of the Federal Food, Drug, and Cosmetic Act).

“(2)(A) Subparagraph (1) does not prohibit a manufacturer, distributor, or retailer from distributing or causing to be distributed free samples of smokeless tobacco in a qualified adult-only facility. . . .

“(C) For purposes of this paragraph, the term ‘qualified adult-only facility’ means a facility or restricted area that—

“(i) requires each person present to provide to a law enforcement officer (whether on or off duty) or to a security guard licensed by a governmental entity government-issued identification showing a photograph and at least the minimum age established by applicable law for the purchase of smokeless tobacco;

“(ii) does not sell, serve, or distribute alcohol;

“(iii) is not located adjacent to or immediately across from (in any direction) a space that is used primarily for youth-oriented marketing, promotional, or other activities;

“(D) Distribution of samples of smokeless tobacco under this subparagraph permitted to be taken out of the qualified adult-only facility shall be limited to 1 package per adult consumer containing no more than 0.53 ounces (15 grams) of smokeless tobacco. . . .

In addition to the command of FSPTCA § 102, the statute bestows the FDA with a number of new powers. Specifically, the FSPTCA gives the FDA the powers to: (1) generally “control” tobacco products, (2) regulate tobacco labeling and advertising, and (3) prescribe standards for tobacco product contents. The FSPTCA effectuates these changes by adding §§ 901, 903, 906, and 907 to the FDCA:

SEC. 901. FDA AUTHORITY OVER TOBACCO PRODUCTS.

(a) **IN GENERAL.**—Tobacco products . . . shall be regulated by the Secretary under this chapter

(b) **APPLICABILITY.**—This chapter shall apply to all cigarettes,

cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary by regulation deems to be subject to this chapter.

(c) SCOPE.— . . .

(2) LIMITATION OF AUTHORITY.—

(A) IN GENERAL.—The provisions of this chapter shall not apply to tobacco leaf that is not in the possession of a manufacturer of tobacco products, or to the producers of tobacco leaf, including tobacco growers, tobacco warehouses, and tobacco grower cooperatives, nor shall any employee of the Food and Drug Administration have any authority to enter onto a farm owned by a producer of tobacco leaf without the written consent of such producer. . . .

(d) RULEMAKING PROCEDURES.—Each rulemaking under this chapter shall be in accordance with chapter 5 of title 5, United States Code. This subsection shall not be construed to affect the rulemaking provisions of section 102(a) of the Family Smoking Prevention and Tobacco Control Act. . . .

SEC. 903. MISBRANDED TOBACCO PRODUCTS.

(a) IN GENERAL.—A tobacco product shall be deemed to be misbranded—

(1) if its labeling is false or misleading in any particular; . . .

(5) if the Secretary has issued regulations requiring that its labeling bear adequate directions for use, or adequate warnings against use by children, that are necessary for the protection of users unless its labeling conforms in all respects to such regulations

(b) PRIOR APPROVAL OF LABEL STATEMENTS.—The Secretary may, by regulation, require prior approval of statements made on the label of a tobacco product to ensure that such statements do not violate the misbranding provisions of subsection (a) and that such statements comply with other provisions of the Family Smoking Prevention and Tobacco Control Act (including the amendments made by such Act). No regulation issued under this subsection may require prior approval by the Secretary of the content of any advertisement

SEC. 906. GENERAL PROVISIONS RESPECTING CONTROL OF TOBACCO PRODUCTS. . . .

(d) RESTRICTIONS.—

(1) IN GENERAL.—The Secretary may by regulation require restrictions on the sale and distribution of a tobacco product, including restrictions on the access to, and the advertising and promotion of, the tobacco product, if the Secretary determines that such regulation would be appropriate for the protection of the public health. The Secretary may by regulation impose restrictions on the advertising and promotion of a tobacco product consistent with and to full extent permitted by the first amendment to the Constitution. The finding as to whether such regulation would be appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account—

(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

(B) the increased or decreased likelihood that those who do not use tobacco products will start using such products. . . .

SEC. 907. TOBACCO PRODUCT STANDARDS.

(a) IN GENERAL.—

(1) SPECIAL RULES.—

(A) SPECIAL RULE FOR CIGARETTES.—Beginning 3 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke. . . .

(3) TOBACCO PRODUCT STANDARDS.—

(A) IN GENERAL.—The Secretary may adopt tobacco product standards in addition to those in paragraph (1)

if the Secretary finds that a tobacco product standard is appropriate for the protection of the public health.

(B) DETERMINATIONS.—

(i) CONSIDERATIONS.—In making a finding described in subparagraph (A), the Secretary shall consider scientific evidence concerning—

(I) the risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the proposed standard;

(II) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

(III) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

(ii) ADDITIONAL CONSIDERATIONS.—

In the event that the Secretary makes a determination, set forth in a proposed tobacco product standard in a proposed rule, that it is appropriate for the protection of public health to require the reduction or elimination of an additive, constituent (including a smoke constituent), or other component of a tobacco product because the Secretary has found that the additive, constituent, or other component is or may be harmful, any party objecting to the proposed standard on the ground that the proposed standard will not reduce or eliminate the risk of illness or injury may provide for the Secretary's consideration scientific evidence that demonstrates that the proposed standard will not reduce or eliminate the risk of illness or injury.

(4) CONTENT OF TOBACCO PRODUCT STANDARDS.—

A tobacco product standard established under this section for a tobacco product—

(A) shall include provisions that are appropriate for the protection of the public health, including provisions, where appropriate—

(i) for nicotine yields of the product;

(ii) for the reduction or elimination of other constituents, including smoke constituents, or harmful

components of the product

(c) PROPOSED STANDARDS.—

(1) IN GENERAL.—The Secretary shall publish in the Federal Register a notice of proposed rulemaking for the establishment, amendment, or revocation of any tobacco product standard.

(2) REQUIREMENTS OF NOTICE.—A notice of proposed rulemaking for the establishment or amendment of a tobacco product standard for a tobacco product shall—

(A) set forth a finding with supporting justification that the tobacco product standard is appropriate for the protection of the public health;

(B) invite interested persons to submit a draft or proposed tobacco product standard for consideration by the Secretary;

(C) invite interested persons to submit comments on structuring the standard so that it does not advantage foreign-grown tobacco over domestically grown tobacco

(4) COMMENT.—The Secretary shall provide for a comment period of not less than 60 days.

(d) PROMULGATION.— . . .

(2) EFFECTIVE DATE.—A regulation establishing a tobacco product standard shall set forth the date or dates upon which the standard shall take effect, but no such regulation may take effect before 1 year after the date of its publication unless the Secretary determines that an earlier effective date is necessary for the protection of the public health. Such date or dates shall be established so as to minimize, consistent with the public health, economic loss to, and disruption or dislocation of, domestic and international trade. In establishing such effective date or dates, the Secretary shall consider information submitted in connection with a proposed product standard by interested parties, including manufacturers and tobacco growers, regarding the technical achievability of compliance with the standard If the Secretary determines, based on the Secretary's evaluation of submitted comments, that a product standard can be met only by manufacturers requiring substantial changes to the methods of farming the domestically grown tobacco used by the manufacturer, the effective date of that product standard shall be not less than 2 years after the date of publication of the final regulation establishing the standard.

(3) LIMITATION ON POWER GRANTED TO THE FOOD AND DRUG ADMINISTRATION.—Because of the importance of a decision of the Secretary to issue a regulation—

(A) banning all cigarettes, all smokeless tobacco products, all little cigars, all cigars other than little cigars, all pipe tobacco, or all roll-your-own tobacco products; or

(B) requiring the reduction of nicotine yields of a tobacco product to zero, the Secretary is prohibited from taking such actions under this Act.

The FDA is headed by its Commissioner, currently Simon Cowell. Structurally, the FDA is located within the United States Department of Health and Human Services (“HHS”). HHS is headed by its Secretary, currently Joaquin Phoenix. FDA’s headquarters are in Silver Spring, Maryland. The agency also has centers and field offices in other locations across the country.



Commissioner Cowell



Secretary Phoenix

Commissioner Cowell is anxious to enforce the FSPTCA. Accordingly, 90 days after the FSPTCA was signed into law, the FDA issued a notice of proposed rulemaking, published in the Federal Register, stating the agency’s intent to promulgate a rule taking

three actions: (1) establishing standards for all tobacco products limiting the nicotine content of the product to 1/500th of 1 percent or less; (2) banning the sale of any cigar that contains more than 3 grams of tobacco; and (3) requiring all manufacturers of tobacco products to obtain a license from FDA for each of their product's packaging and labels.

The FDA's Federal Register notice established a comment period of 60 days. It further specified that all comments must be submitted electronically to the FDA via the FDA's website. During the comment period, the FDA received over 10,000 comments from tobacco companies, public interest groups, doctors, scientists, politicians, law enforcement agencies, and members of the public at large. Most vociferous among these, PUFFT filed comments arguing that, if adopted, the proposed regulations would "violate our God-given right to smoke when we wanna," and that the proposed rules are "forbidden by the statute you are supposedly trying to implement."

Specifically, PUFFT contended that both the nicotine content limit (for all tobacco products) and the tobacco content limit (for cigars) would effectively violate the FSPTCA's prohibition on tobacco product bans. Wrote PUFFT in its comments, "The agency can call its rules whatever it would like, but the fact of the matter is that, in practical effect, these regulations, if ultimately adopted, will entirely foreclose the sale of tobacco products across the United States. That the FDA cannot do. The FSPTCA specifically forbids it." To prove its point, PUFFT attached to its comments public opinion surveys showing that over 90 percent of smokers in the United States do not like tobacco products with less than 1/10th of 1 percent nicotine content, that smokers generally prefer tobacco products more when they contain more nicotine, and that tobacco purchases generally coincide with smoker preferences (rather than price). Moreover, the public opinion surveys showed that 85 percent of cigar sales in the United States currently are made with cigars that have 6 grams of tobacco or more. Finally, PUFFT observed that (1) no tobacco products in the United States are currently available with nicotine content as low as the FDA rules would prescribe, (2) it would take most manufacturers "five years, at the very minimum" to modify their production processes to comply with the proposed rules in a way that would not "severely and deleteriously affect their profit margins," and (3) submitting tobacco makers' labels and packaging to the FDA for "pre-review before they sell any products not only is patently offensive to their professional judgment but will only further slow down their production line and ability to take product to market."

Undeterred, the FDA issued its final rule shortly after the comment period's close. The final rule was a verbatim reproduction of the rule proposed in the NOPR. Included with this final rule was a 500-page preamble explaining the reasons for the rulemaking and addressing the voluminous comments received by the agency. For example, the preamble stated:

The Administration takes exceedingly seriously its obligation to Congress and the Americans at large. This rulemaking clearly advances the goals established by Congress in the FSPTCA. Smoking is a plague upon this nation, a plague that will not be cured absent our forceful action here. While

we recognize the potentially significant economic impacts this rule may have for some manufacturers and distributors of tobacco products, those effects pale in comparison to the public health benefits our rule will achieve. The data clearly show that absent reduction of nicotine and tobacco content to the levels prescribed herein, Americans, and particularly teenagers and even children, will continue to become addicted to tobacco products at an alarming rate. Likewise, current tobacco users will remain addicted to these products at the current, quite troubling rate, absent our action today. Given that tobacco consumption leads to a plethora of health maladies, including cancer, emphysema, stroke, heart disease, and death, just to name a few, we find that our rule promulgated today is clearly in the public interest and necessary for the protection of the public health. The rule is, therefore, effective 180 days from the publication of this Final Rule in the Federal Register.

Essay Question No. 1

Following promulgation of the final rule, PUFFT sued the FDA challenging the rule under APA § 706(2)(C). To support its case, PUFFT’s complaint reiterated the same arguments made in its comments in the rulemaking.

Meanwhile, a different group of celebrities also has sued the FDA on other grounds. Unlike PUFFT, this group, Stars Who Ain’t lighting up at all anymore, Take That!, Inc. (“SWATT”), alleged that the FDA has not gone far enough in implementing the FSPTCA. Specifically, under APA § 706(1), SWATT’s complaint argues that the FDA has shirked its duties by (1) failing to promulgate a rule under FSPTCA § 102, and (2) failing to promulgate a rule implementing FDCA § 907(a)(1)(A). Accompanying SWATT’s lawsuit are affidavits from four of its founding members, Ben Affleck, Jennifer Aniston, Courteney Cox, and Brandon Flowers. Each of the affidavits explains



Mr. Affleck



Ms. Aniston



Ms. Cox



Mr. Flowers

that members of SWATT contribute 1 percent of their income each year to promote SWATT’s objectives, which are to stop smoking, first, among celebrities “because celebrities are the world’s best people, obviously,” and second, among children and teenagers, “who, as studies have shown, are most vulnerable to free and flavored tobacco products.” Indeed, not only do SWATT’s members annually contribute money to promote these goals, they all make public appearances on SWATT’s behalf to advocate against smoking.

You are in-house counsel for the FDA. Your supervisor has asked you to prepare a memorandum addressing three questions:

- (1) What arguments should the agency make to counter the allegations of PUFFT's lawsuit?
- (2) What arguments should the agency make to counter the allegations of SWATT's lawsuit?
- (3) Should the FDA argue that either SWATT or PUFFT lacks standing to sue?

To assist in preparation of your memorandum, your paralegal has furnished you with some additional materials that may potentially be of use. The materials consist of three categories: definitional provisions from the FSPTCA, pages from *The American Heritage Dictionary*, and legislative history of the FSPTCA:

From the FSPTCA:

SEC. 101. AMENDMENT OF FEDERAL FOOD, DRUG, AND COSMETIC ACT.

(a) DEFINITION OF TOBACCO PRODUCTS.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following: “(rr)(1) The term ‘tobacco product’ means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). . . .”

SEC. 900. DEFINITIONS.

In this chapter:

(3) CIGARETTE.—The term ‘cigarette’—

(A) means a product that—

(i) is a tobacco product; and

(ii) meets the definition of the term ‘cigarette’ in section 3(1) of the Federal Cigarette Labeling and Advertising Act; and

(B) includes tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco. . . .

(11) LITTLE CIGAR.—The term ‘little cigar’ means a product that—

(A) is a tobacco product; and

(B) meets the definition of the term ‘little cigar’ in section 3(7) of the Federal Cigarette Labeling and Advertising Act.

(12) NICOTINE.—The term ‘nicotine’ means the chemical substance named 3-(1-Methyl-2-pyrrolidinyl) pyridine or C[10]H[14]N[2], including any salt or complex of nicotine.

(13) PACKAGE.—The term ‘package’ means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers. . . .

(15) ROLL-YOUR-OWN TOBACCO.—The term ‘roll-your-own tobacco’ means 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. . . .

(17) SMOKE CONSTITUENT.—The term ‘smoke constituent’ means any chemical or chemical compound in mainstream or sidestream tobacco smoke that either transfers from any component of the cigarette to the smoke or that is formed by the combustion or heating of tobacco, additives, or other component of the tobacco product.

(18) SMOKELESS TOBACCO.—The term ‘smokeless tobacco’ means any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity.

From The American Heritage Dictionary:

to·bac·co (tə-bāk'ō)

n. pl. **to·bac·cos** or **to·bac·coes**

1. Any of various plants of the genus *Nicotiana*, especially *N. tabacum*, native to tropical America and widely cultivated for their leaves, which are used primarily for smoking.
2. The leaves of these plants, dried and processed chiefly for use in cigarettes, cigars, or snuff or for smoking in pipes.
3. Products made from these plants.
4. The habit of smoking tobacco: *I gave up tobacco.*
5. A crop of tobacco.

cig·a·rette also **cig·a·ret** (sĭg'ə-rĕt', sĭg'ə-rĕt')

n.

1. A small roll of finely cut tobacco for smoking, enclosed in a wrapper of thin paper.
2. A similar roll of another substance, such as a tobacco substitute or marijuana.

ci·gar (sĭ-gär')

n. A compact roll of tobacco leaves prepared for smoking.

prod·uct (prŏd'əkt)

n.

1. Something produced by human or mechanical effort or by a natural process.
2. A direct result; a consequence: "*Is history the product of impersonal social and economic forces?*" (Anthony Lewis).

Chemistry A substance resulting from a chemical reaction.

Mathematics

1. The number or quantity obtained by multiplying two or more numbers together.
2. A scalar product.
3. A vector product.

all (ôl)

adj.

1. Being or representing the entire or total number, amount, or quantity: *All the windows are open. Deal all the cards.* See Synonyms at whole.
2. Constituting, being, or representing the total extent or the whole: *all Christendom.*
3. Being the utmost possible of: *argued the case in all seriousness.*
4. Every: got into all manner of trouble.
5. Any whatsoever: *beyond all doubt.*
6. *Pennsylvania* Finished; used up: *The apples are all.*
7. *Informal* Being more than one: *Who all came to the party?* See Regional Note at you-all.

n. The whole of one's fortune, resources, or energy; everything one has: *The brave defenders gave their all.*

pron.

1. The entire or total number, amount, or quantity; totality: *All of us are sick. All that I have is yours.*
2. Everyone; everything: *justice for all.*

adv.

1. Wholly; completely: *a room painted all white; directions that were all wrong.*
2. Each; apiece: *a score of five all.*
3. So much: *I am all the better for that experience.*

From the FSPTCA's Legislative History:

111TH CONGRESS } HOUSE OF REPRESENTATIVES { REPT. 111-58
1st Session } Part 1

FAMILY SMOKING PREVENTION AND TOBACCO CONTROL
ACT

—————
MARCH 26, 2009.—Ordered to be printed
—————

Mr. WAXMAN, from the Committee on Energy and Commerce,
submitted the following

R E P O R T

together with

DISSENTING AND ADDITIONAL DISSENTING VIEWS

[To accompany H.R. 1256]

Section 907. Tobacco product standards

Consistent with the overall intent of the bill to protect the public health, including by reducing the number of children and adolescents who smoke cigarettes, section 907(a)(1) is intended to prohibit the manufacture and sale of cigarettes with certain “characterizing flavors” that appeal to youth. Examples of these products include, but are not limited to, those introduced in recent years such as “Mandalay Lime,” “Warm Winter Toffee,” “Mocha Taboo,” and “Midnight Berry,” which were the subject of an investigation and subsequent settlement agreement between one cigarette manufacturer and the attorneys general of 40 states in October 2006.

Accordingly, this section prohibits the use of any constituent or additive that causes a cigarette or its smoke to have a characterizing flavor other than menthol or tobacco. Section 907(a)(1) is not intended to prohibit the use of specific ingredients, including those found in some American blend cigarettes, so long as those additives or constituents are not a characterizing flavor (other than tobacco or menthol) of the cigarette or its smoke. A cigarette (including any component of the cigarette) or its smoke should not be determined to have a prohibited characterizing flavor based solely on the presence of an ingredient in the product or its smoke.

The Committee has reviewed the products that will be banned after 90 days under this section and has concluded that the ban will not lead to negative public health effects, because of how the affected products generally are used and because of their low overall use by adult smokers. Specifically, none of the cigarettes cov-

ered by the ban—including those with the characterizing flavors of fruit, chocolate, and clove—is used regularly by a large number of addicted adult smokers. Instead, these cigarettes tend to be used only occasionally, either by regular users of other products, by individuals who are experimenting with tobacco use, or by those who smoke only in certain social settings. Given that few adult smokers ever use the flavored cigarettes that will be banned and that most adult smokers name other products as their regular brand, it is likely that regular use of these products by heavily addicted adult smokers is negligible.

Section 907(a)(3) provides that the Secretary may adopt a tobacco product standard if the Secretary finds that it is appropriate for the protection of the public health. Section 907(a)(3)(B) sets forth certain considerations with respect to that finding and additional considerations with respect to a standard that would reduce or eliminate an additive, constituent (including a smoke constituent), or other component of a tobacco product. In the event that the Secretary has proposed the adoption of such a standard because the Secretary has found that the additive, constituent, or other component is or may be harmful, an objecting party may, in response to such finding, provide for the Secretary's consideration scientific evidence that demonstrates that the proposed standard will not reduce or eliminate the risk of illness or injury. In issuing a final standard as with any rulemaking, the Secretary shall review and consider all information and scientific evidence and data, presented by any party that comments on the proposed standard, including any information, evidence, or other documentation that is submitted concerning the population impact or any other matter related to the proposed standard. The Committee intends the Secretary will base his or her determinations on sound information and scientific evidence and data when issuing the proposed standard that is appropriate for the protection of the public health.

The Committee also intends for the agency to have authority to establish product standards regarding the testing and measurement of products, nicotine yields, constituents, construction, components, ingredients, additives, and all other properties of the tobacco product, including the form and content of the labeling. This authority is limited only by 907(d)(3), which prohibits FDA from banning all cigarettes, all smokeless tobacco products, all little cigars, all cigars, all pipe tobacco, or all “roll your own” tobacco products, or requiring the reduction of nicotine levels to zero.

Essay Question No. 2

Beyond the actions brought by PUFFT and SWATT, various tobacco manufacturers and distributors are considering challenging the FDA's rule in their own lawsuit. Specifically, the national trade organization for such companies, Sell More Awesome, Righteous Tobacco Right-now, Inc. ("SMARTR"), is upset that the FDA did not address various of its concerns expressed in its comments to the NOPR. In those comments, SMARTR argued:

SMARTR, on behalf of tobacco manufacturers and distributors throughout the nation, urges the Administration to consider multiple concerns, developed more fully herein via these comments, about the Proposed Rule:

First, the proposed rule is unduly excessive and burdensome. It will force many tobacco makers to go out of business because the costs of retrofitting their facilities to comply with the proposed nicotine content limitations will be inordinately expensive. Moreover, as the medical clinical studies submitted in conjunction with these comments unequivocally demonstrate, reducing nicotine content to 1/500th of 1 percent will have no meaningful health benefits. Nicotine levels below 1 percent of the average cigarette have no direct connection to cancer, and any amount of nicotine is potentially addictive, so removal to such a low level will not help on that front. Further, these studies show that other components of tobacco smoke may be addictive, not nicotine alone.

Second, the rule will be ineffective, especially as to the tobacco content limitation for cigars. Requiring tobacco content to be eliminated from cigars will merely create incentives for consumers to buy and smoke more cigars to achieve the same effect they would have previously from a single cigar – not to smoke less altogether. In fact, SMARTR's surveys of tobacco consumers show a propensity for such consumptive behavior. Our survey, appended hereto, demonstrates that 4 out of 5 cigar smokers are likely to simply consume more cigars to get the same amount of tobacco.

Third, the rule will create perverse incentives. SMARTR's customer surveys show that the American public will not abide tobacco products with such little nicotine, nor cigars with such little tobacco. Instead, the result will be one akin to the prohibition of alcohol in the early Twentieth Century: Consumers will create and purchase black market tobacco products possessing the content they

want. Thus, while the FDA will have effectively banned tobacco products on the face of its rule, the net effect will be unabated consumption of tobacco nevertheless - only in a now-illegal way. In short, the rule will not accomplish its goals, but will merely punish the legitimate tobacco companies operating today, burden local law enforcement with unnecessary costs, and cast a pall of illegitimacy over the FDA's entire regulatory regime.

For all these reasons, SMARTR urges the FDA to rescind the NOPR and, instead, convene a technical conference with the public and the industry to create a rule that will be both workable and effective.

The FDA, in the preamble to its final rule, responded to SMARTR's comments as follows:

The Administration has considered intently all the comments received during the comment period, including all data and materials provided therewith. . . . With respect to SMARTR's comments and submitted studies and surveys, the Administration rejects the argument that the proposed rule will be ineffective due to increased tobacco consumption or the creation of a black market. SMARTR's own evidence shows that at least some cigar users will smoke less (at least 1 in 5 smokers). Moreover, if a black market in tobacco is created, that is beyond the Administration's control. What is admittedly more troubling are the nicotine studies submitted by SMARTR. While the Administration acknowledges the concerns presented by this evidence, it finds more convincing the studies submitted by the American Medical Association. Those studies, which also were performed by medical professionals using clinical subjects, show that not only is nicotine addictive at any level, as SMARTR acknowledges, but that, in addition to lung cancer, smoking also causes diseases such as chronic bronchitis and emphysema, exacerbates asthma, and is associated with cancers of the mouth, pharynx, larynx, esophagus, stomach, pancreas, cervix, kidney, ureter, and bladder.

SMARTR has retained you as its counsel. SMARTR has informed you that for strategic and public relations reasons, it does not want press the statutory and jurisdictional arguments in PUFFT's lawsuit, although it is happy to let PUFFT pursue those claims. SMARTR would, however, like your advice on (1) other arguments it might lodge to challenge the FDA's rule based on the FDA's treatment of SMARTR's comments in the rulemaking, and (2) the likelihood of prevailing on those arguments.

(Assume that you may ethically provide such advice despite your prior representation of the FDA in the first essay question.)