

**Sample Answers**

**Administrative Law – Final Examination**

**Summer 2009**

**Professor Davies**

**NOTE: The answers contained herein are samples only. They are disjointed from reality in that they (or at least some of them) exceed what anyone likely could produce in the amount of time allotted.**

**Nevertheless, the answers also are not ideal, model, or perfect. Different portions of the questions could be approached in different ways; the key is not necessarily the conclusion reached but the analysis undertaken.**

**Students are thus well advised to see these answers as study tools rather than talismans. The prudent reader will first use the *questions* for a practice run through the semester's material. Only *after* this would the student review the sample answers provided here, which can be used to identify potential areas for improvement.**

## Essay Question No. 1

This memorandum addresses three issues: (1) what defenses we might lodge to PUFFT's lawsuit, (2) what defenses we might lodge to SWATT's lawsuit, and (3) whether we should challenge either group's standing to be in court. Because it is a jurisdictional question, the memorandum addresses standing first. The memorandum then discusses potential counterarguments to PUFFT's and SWATT's lawsuits, respectively.

### I. Standing

There are two separate sets of standing requirements that one must establish to sue in federal court: Article III, or constitutional, standing and prudential standing. Article III standing demands that a party (a) has incurred a concrete, imminent injury-in-fact that is (b) proximately caused by the action challenged and that (c) is likely to be redressed by the judicial relief sought. *Lujan v. Defenders of Wildlife*. Article III standing, because it derives from the Constitution, is jurisdictional and cannot be waived. Prudential standing is judicially self-imposed. This requirement mandates that a party (a) assert its own interest, rather than that of a third party, (b) assert an interest that falls within the zone of the statute's interests, and (c) assert a claim that is not a generalized grievance better resolved by the political branches of the government. *See Elk Grove*. Moreover, when a trade organization or public interest group such as PUFFT and SWATT sue in federal court, they may show standing in an "associational" rather direct capacity. That is, they may sue in their own name by relying on their members' interest in the suit. To do so, the organization must show (a) that a member would have standing to sue on their own, (2) the interests pursued by the lawsuit are germane to the organization's interests, and (3) the individual participation of the organization's member is not necessary (that is, the lawsuit pursues equitable rather than monetary relief). *See Hunt v. Washington Apple Advertising Comm'n*.

Based on these criteria, we may want to consider challenging SWATT's standing. By contrast, attacking PUFFT's ability to sue likely will be futile—and could potentially damage our credibility with the court.

#### A. PUFFT's Standing

It should be clear that PUFFT satisfies the second and third prongs of the *Hunt* test for associational standing. The very purpose of the organization is to promote tobacco consumption, and that is the purpose of their lawsuit as well—to challenge the FDA's new restrictions on smoking tobacco. Nor does the lawsuit require the participation of any individual PUFFT members; it asks for the FDA's new rule to be overturned as outside the agency's statutory authority, not for any monetary relief.

The only potential question, then, is whether a member of PUFFT satisfies standing herself. The answer to this question seems rather straightforward. Multiple members of PUFFT should have standing to sue. As individuals who smoke, they clearly will suffer a concrete injury-in-fact if our rule is upheld. Specifically, Tara Reid enjoys consuming the very kind of cigar that the Final Rule prohibits, and Katherine Heigl enjoys the very kind of cigarettes (high

in nicotine) that the Final Rule will foreclose. These injuries also are not generalized; different consumers enjoy different types of tobacco, as evidenced by PUFFT's affidavits. Not everyone likes the types of tobacco subject to the provisions of the Final Rule, but at least some members of PUFFT do. Moreover, these same injuries are directly caused by the rule; without the rule, the products used by these two PUFFT members would still be readily available. And a court order overturning the Final Rule would thus restore Mss. Reid and Heigl's ability to buy the products they desire.

By the same token, there should not be any prudential standing concerns. A third party's interest is not being asserted, nor is this a generalized grievance but rather one specifically about the Final Rule. Nor is there a claim that the interest asserted falls outside the statute's zone of interests. PUFFT has sued under the APA, and APA § 706 specifically seeks to ensure that agencies act only within their statutory powers. Accordingly, it likely is not advisable to challenge PUFFT's standing to sue.

Of course, there is an argument that the Final Rule causes PUFFT no injury because rather than harming any member of the public, it expressly protects them by ensuring they will have better health. Given, however, that consumers remain free to purchase tobacco products—and especially in light of the fact that Congress dictated such a result in the Tobacco Control Act—it would be difficult to maintain a position that consumers suffer *no injury* whatsoever from the Final Rule. The Final Rule clearly limits their choices to purchase tobacco, and so long as tobacco remains a legal product, a claim that consumers who enjoy tobacco varieties targeted by the Final Rule are not harmed seems questionable at best. These consumers enjoy using the product, but now they cannot use it.

#### B. SWATT's Standing

SWATT's standing to sue is somewhat more tenuous. Accordingly, even if we ultimately decide not to press a standing challenge, we should at least consider doing so.

SWATT satisfies the second and third prongs of the *Hunt* test just as PUFFT does. SWATT is dedicated to preventing smoking, and that is the goal of their lawsuit. They seek to spur the FDA on to additional action that will reduce both the tobacco products available on the market and the groups of individuals likely to buy them. Indeed, one of SWATT's key objectives is reducing access to tobacco for children and teenagers, and the two rules they seek to have promulgated—banning free tobacco samples and banning flavored tobacco products—would do just that. Nor is the involvement of an individual member of SWATT necessary; they seek only the promulgation of rules, not any damages.

Where, however, SWATT may be vulnerable to a standing challenge is on the first *Hunt* prong: that an individual member of the group must have standing on his own. Specifically, there is at least an argument that no SWATT member is actually harmed by any FDA inaction. Though SWATT members contribute both time and money to help prevent smoking, the fact that the FDA has not yet issued a rule in no way forecloses from them continuing to engage in those activities. In this way, SWATT's alleged standing here is very much unlike, say, an environmental group challenging the BLM's failure to take action to protect an area that the

group's members enjoy using. *Cf. Norton v. SUWA*. Rather, in contrast to such scenarios, SWATT and SWATT's members will be unimpeded in their actions by any delay at FDA. Thus, we might even be able to characterize SWATT's interest in anti-smoking advocacy as akin to a generalized grievance, and thus, improper under prudential standing. While SWATT may have somewhat of a heightened interest in this goal, ultimately the health of the entire public will be promoted by its advancement—not just the health of some of its members.

Moreover, we could make strong arguments that both causation and redressability are lacking here. Causation is lacking because SWATT has made no showing that the problems SWATT seeks to address stem from the lack of an FDA rule. In fact, the problems predate FDA's ability to even regulate this area of commerce. Redressability, even more clearly, seems empty here. SWATT has provided neither evidence nor allegation that an FDA rule would actually reduce the types of smoking it is concerned about. Certainly the Tobacco Control Act itself should give some measure of comfort that an FDA rule limiting flavored cigarettes could help stop children from becoming addicted to these drugs, but as described in greater detail below, the FDA need not issue a rule at all to erect such standards because § 907(a)(1)(A) is self-implementing. Likewise for SWATT's complaint about the rule prescribed by § 102(a) of the Act, there is no evidence that a rule limiting free tobacco samples will actually reduce the number of new tobacco users. Indeed, we might well argue that limiting the nicotine content of tobacco products is much more likely to reduce the number of new users, and it was for that very reason we proceeded along those lines first.

Clearly, SWATT may have counters to these arguments. They might argue that they have spent exorbitant amounts of money on campaigns to help stop the very kinds of smoking the rules they seek would target. They might show how that interest is in fact unique to them and their members, given their members' history of smoking. And they might be able to show that even if the Final Rule will reduce new tobacco users, the rules they seek could further advance the same goal. Together, these factors may help SWATT overcome a challenge to their asserted standing.

However, because SWATT's arguments are not as strong as PUFFT's—and potentially could be overcome by casting them as effectively a political crusade that should be made at a political level—we should at least consider challenging standing. Indeed, the standing argument may well bolster our substantive arguments, which show, as discussed below, that SWATT's suit has little ground to stand on.

## II. Defenses to PUFFT's Lawsuit

The core question raised by PUFFT's lawsuit is whether the Final Rule exceeds the jurisdiction given by the Tobacco Control Act. It is hornbook law that agencies only have the authority given them by Congress, but it does not appear that PUFFT contends we have used powers that do not exist in the statute. Rather, the crux of their argument is that the Final Rule exercises powers in fact bestowed upon FDA by the Tobacco Control Act but that it does so in contravention to what the statute contemplates. Their argument in this regard is threefold: First, they argue that the 1/500th of 1 percent nicotine limitation flouts § 907(d)(3)'s prohibition on “requiring the reduction of nicotine yields of a tobacco product to zero.” Second, they argue that

the 3 grams of tobacco limitation violates § 907(d)(3)'s prohibition on "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." Third, PUFFT contends that the Tobacco Control Act precludes FDA from requiring licensing of tobacco product labels.

Each of PUFFT's arguments is fundamentally a question of statutory construction. With respect to the first argument, it is a question of the meaning of "zero"; for the second, the meaning of "all"; and for the third, whether the Tobacco Control Act speaks to our ability to control tobacco product labels. The nicotine content question is not open and shut. We have good arguments, and can attempt to invoke *Chevron* Step 2 deference, but it is certainly possible that PUFFT may be able to convince a court we have exceeded our authority. On the tobacco content and label licensing questions, however, we should be on rather firm ground.

#### A. Applicable Law

Statutory interpretation questions at the agency level are governed by the familiar *Chevron* test. In this analysis, the opening question is whether Congress has intended the agency to interpret the statute and, if so, whether the agency acted with the force of law. *See Mead* and *Barnhart*. If the answer to both these inquiries is yes, and if the statutory provision in question is ambiguous or if the statute does not speak to the specific question at issue, then the agency's interpretation will be upheld if reasonable. This is the so-called *Chevron* Step 2 analysis. If, however, the statute is unambiguous on a question or Congress has clearly spoken to the specific issue at hand, Congress' manifested intent controls and no deference is afforded the agency's interpretation. This is the so-called *Chevron* Step 1 analysis. To ascertain whether Congress has spoken to an issue, traditional tools of statutory construction must be utilized. These are, first, to assess the plain meaning of the statutory text; second, to utilize intrinsic aids, such as grammar, punctuation, and the internal structure of the statute; third, to apply, where necessary and useful, canons of construction; and finally, to assess the legislative history. Of course, there is no clear order to these steps, other than to begin with the plain text itself. Court decisions run many ways, and direct and clear legislative history, for instance, might supplant the need for application of canons of construction, for instance.

Here, it is clear that the Tobacco Control Act gives FDA general rulemaking authority to implement the Act's provisions. *See* § 901(d). Inherent in that authority is the power to fill the gaps of the statute—to say what the statute means. Thus, as the Final Rule was an exercise of that authority, the question is not a *Chevron* "Step 0" one of whether we might receive deference at all (or whether we might receive the lesser deference of *Skidmore*), but rather, whether the statute must be interpreted at *Chevron* Step 1 or Step 2.

#### B. The Nicotine Limitation

Our strongest defense to PUFFT's argument on the nicotine rule is that the limitation is clearly permissible under the unambiguous meaning of the Act. The beginning premise here is that the Act gives FDA clear and broad authority to regulate tobacco products and their contents. Section 907(a)(3) bestows wide authority for us to "adopt tobacco product standards" so long as we make a finding that the standard "is appropriate for the protection of the public health." The

Act then makes clear that these standards may be far-reaching. They may include any “provisions that are appropriate for the protection of the public health.” They may apply to product “constituents” as well as “smoke constituents.” They also may target any “harmful components” of the product. And, most critical here, they may specifically address “nicotine yields of the product.” All of this language shows just how searching Congress expected this authority to be. Not only did Congress anticipate that we might constrain how tobacco products are made, Congress knew that we might irrevocably alter the very contents of those products. More to the point here, Congress clearly and unequivocally recognized that a target of these standards could be nicotine. That is precisely what the Final Rule did—regulate the very thing Congress gave us the authority to regulate.

Congress put only two restrictions on this far-reaching authority. First, it required that any standards be promulgated on the basis of a finding that, under the relevant scientific evidence concerning the risks and benefits to the population as a whole and the likely impact on existing and potential smokers, the standards be “appropriate” for the public health. *See* § 907(a)(3)(B). The Final Rule, of course, did exactly that—and then took it a step farther. Not only did the Final Rule find that the standards would be “appropriate” based on their likely effect for existing smokers and potential smokers, it found the nicotine standard “necessary”: “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.*” This conclusion was based on FDA’s findings that tobacco addiction would continue unabated unless nicotine content was reduced in the way the Final Rule mandates. PUFFT does not appear to challenge any of these findings, and thus, its argument reduces to a claim that the Final Rule flouts § 907(d)(3)’s prohibition on regulations mandating manufacturers to eliminate the nicotine content of their products to “zero.”

From at least one vantage, PUFFT may be tilting at windmills. Congress said only that nicotine cannot be limited to a level of “zero,” and the Final Rule clearly does not mandate that result. “Zero” means zero, nothing more, nothing less. That word carries a clearly defined meaning in our society—one of the complete *absence* of value or content. Yet the Final Rule’s nicotine standard, while mandating an admittedly very low level of nicotine in tobacco products, still allows some nicotine to be present. If PUFFT’s interpretation of the statute were adopted, it would obliterate Congress’ use of the term “zero.” No measurable limitation on nicotine would be safe, because PUFFT could always argue that a low limit was “close enough” to zero that it triggers § 907(d)(3). Indeed, not only does PUFFT’s construction contravene the plain meaning of a commonly understood term, it would undermine Congress’ obvious intent. Congress adopted § 907 for the very purpose of giving the FDA authority it previously did not have under the Supreme Court’s decision in *Brown & Williamson*: to regulate tobacco products to protect the public health. That is what FDA has done here by limiting nicotine content, but PUFFT would have the courts utilize a very narrow limitation to gut a very broad power. If FDA cannot set the “nicotine yield” limitation contemplated by § 907(a)(4)(A) at whatever level above zero it deems “appropriate” for protecting the public health, the courts—not the agency—become the regulator of tobacco products under the Act.

From another perspective, however, PUFFT has at least a viable claim that § 907(d)(3) forecloses the Final Rule's nicotine limit. That argument is the one it made in its rulemaking comments, namely, that a limit as low as 1/500th of 1 percent is the practical equivalent of a ban on nicotine. The reasoning here is straightforward. Clearly Congress in the Tobacco Control Act sought to give FDA authority to "control"—to limit, to regulate—tobacco. But Congress did not want FDA to actually ban tobacco products. Thus, § 907(d)(3) not only prohibits requirements that would reduce nicotine levels to "zero"; it forbids the "banning" of virtually every class of tobacco product. The House Report, though perhaps not as helpful as some legislative history, reiterates this point. It states that FDA's authority to regulate tobacco contents 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 *requiring the reduction of nicotine levels to zero.*" In other words, while Congress intended for FDA to limit the production of tobacco in some ways, it unequivocally did not want us to remove these products from the stream of commerce altogether. PUFFT's argument is that the Final Rule effectively does that, regardless of whether it still technically allows some trace amounts of nicotine in tobacco.

The problem with PUFFT's argument, separate and apart from its apparent conflict with both the plain meaning and overarching intent of § 907, is that the Final Rule clearly does not impose a ban on nicotine. Even under PUFFT's own evidence, 10 percent of smokers are agnostic on consuming tobacco products with nicotine levels as low as the Final Rule requires. Moreover, PUFFT's evidence does not speak to whether even those smokers who do prefer products with much higher nicotine contents will in fact stop buying tobacco simply because it has less nicotine. Nor has PUFFT provided any evidence that tobacco makers cannot comply with the Final Rule's mandate. Thus, even if PUFFT prevailed in contending that the intent of § 907 is to stop a ban on tobacco products, we have a strong defense. PUFFT can claim an unambiguous interpretation of "zero," but so can we. Thus, at the least, we have a backup argument that Congress' use of "zero" is ambiguous and because we have not adopted an actual ban, our interpretation is a reasonable one at *Chevron* Step 2.

### C. The Tobacco Content Limitation

PUFFT's argument as to the Final Rule's tobacco content limit is similar to its nicotine argument, but not as strong. Again, we can counter with an argument that the Final Rule is authorized by the unambiguous intent of the statute, but here we may not need worry about a claim that the Final Rule accomplishes in practical effect what § 907(d)(3) forbids. True, PUFFT will argue that what the Final Rule does is effectively remove from the market an entire class of cigars (those with more than 3 grams of tobacco content per cigar), and that is precisely what § 907(d)(3) forbids. The difference, however, is that § 907(d)(3) speaks in clear terms that the FDA actually may ban some classes of tobacco products. The provision does not say that FDA cannot ban "any" tobacco products, as it well could have. Congress knows how to impose a limitation when it wants to. Rather, in stark contrast, § 907(d)(3) says that FDA cannot ban "all" cigarettes, that it cannot ban "all" smokeless tobacco products, that it cannot ban "all" little cigars, that it cannot ban "all" cigars other than little cigars, that it cannot ban "all" pipe tobacco, and that it cannot ban "all" roll-your-own tobacco products.

In other words, § 907(d)(3) is not a prohibition on the banning of tobacco products, but instead, a prohibition on banning certain categories of tobacco products. That is the very structure of the provision. It enumerates each category that cannot be banned. And, under the canon *expressio unius*, the enumeration of these categories implies that others might be banned.

If this structure alone is not enough, Congress' careful qualification of each category with the adjective "all" should be dispositive. "All" denotes the "total number" or total "amount," the "whole," the "utmost possible"—as *The American Heritage Dictionary* puts it, "every." By qualifying each of the prohibited categories with this adjective, Congress clearly indicated that while it sought to foreclose the banning of a whole category of tobacco products, it contemplated that the FDA might ban some sub-classes of products within those categories. Otherwise, the word "all"—repeated six times—would be rendered surplusage. And such a reading would itself violate a critical canon of construction. Statutes must be read to give meaning to every term.

In fact, what the Final Rule did is exactly what Congress contemplated. It bans a subclass of cigars within the broader category of cigars—not "all" cigars as § 907(d)(3) would prohibit. The only qualification on this is if "little cigars" are defined by § 3(7) of the Federal Cigarette Labeling and Advertising Act as cigars with 3 grams of tobacco content or less. See FDCA § 900(11)(B). If they are, PUFFT's argument might actually gain merit, because it would mean that the Final Rule in fact bans "all" cigars "other than little cigars." If, however, little cigars are defined as having any amount of tobacco that is a quantity starting below 3 grams, this militates in our favor. It means that, by definition, the Final Rule bans only a portion of "all cigars other than little cigars"—again, something clearly contemplated by § 907(d)(3). Indeed, because of the provision's repeated use of the qualifier "all," and because § 907(d)(3) relies on another statutory definition of "little cigar," it will be hard for PUFFT to argue that anything other than a *Chevron* Step 1 interpretation controls here. Moreover, we should be able to make something before the court of PUFFT's own evidence. PUFFT stated in its rulemaking comments that 85 percent of cigar sales in the United States currently are made with cigars that have 6 grams of tobacco or more. This has a clear, and important, implication: PUFFT concedes that many cigars still can be made even with the Final Rule in place (a fact that would also seem to indicate that the "little cigar" threshold is not at 3 grams).<sup>1</sup>

#### D. Label Licensing Requirement

Least powerful of PUFFT's arguments is its claim that the Tobacco Control Act somehow limits FDA's authority to require the licensing of tobacco product labels. Even the way PUFFT makes this argument is weak. The group claims merely that the licensing requirement is "offensive" to tobacco makers' "professional judgment" and that it will "slow down" production of tobacco products. Whether true or not, these arguments are immaterial to a statutory contention that the Final Rule exceeds FDA's jurisdiction. Section 903(b) of the Tobacco Control Act unambiguously bestows FDA with label approval authority: "The

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<sup>1</sup> *N.B.* Although not provided in the fact pattern, the Federal Cigarette Labeling and Advertising Act defines "little cigars" as "any roll of tobacco wrapped in leaf tobacco or any substance containing tobacco (other than any roll of tobacco which is a cigarette within the meaning of subsection (1)) and as to which one thousand units weigh not more than three pounds." 15 U.S.C. § 1332(7). Three pounds divided by 1000 is .003 pounds, which is roughly equivalent to 1.36 grams.

Secretary may, by regulation, require prior approval of statements made on the label of a tobacco product . . . .” That is precisely what a licensing requirement is, one of prior approval by the agency for the content of the labels. Nor does PUFFT seem to argue that the other limitations of this provision apply here. Section 903(b) does forbid FDA approval of “any advertisement” for tobacco products, but the Final Rule does not apply to advertisements. It applies only to labels and packaging, which FDCA § 900(13) clearly limits to the materials in which the products are sold—not advertisements. PUFFT also does not claim that the Final Rule exceeds the grounds on which § 903(b) allows FDA to regulate labels, to ensure compliance with the Tobacco Control Act’s misbranding and other provisions. Indeed, ensuring compliance with these provisions should be the presumptive purpose of this requirement.

The only claim that PUFFT appears left with, then, is a contention that § 903 gives FDA authority over only the “labels” of tobacco products, and thus, the Final Rule exceeds the scope of FDA’s authority by applying not only to tobacco “labels” but also “packages.” Lending merit to this contention is the fact that the statute defines “package,” and nowhere in that definition is a mention of labeling: “The term ‘package’ means a pack, box, carton, or container of any kind or, if no other container, any wrapping . . . , in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers . . . .” Obviously, similar to our arguments on nicotine above, PUFFT could claim that Congress could have afforded the power to regulate packages if it so chose—especially since Congress recognized the issue of packaging in the statute. Potentially, PUFFT could go far with this argument, though there are a few problems with it. Foremost, PUFFT does not appear to make it. Second, we could claim that the power to regulate the “label” includes the power to regulate the package by definition, because the label must appear on the package somewhere. Third, we could attempt to invoke *Chevron* Step 2 to contend that because information presented on the packaging of tobacco contents could circumvent or dilute what we require in the label, Congress’ use of the term “label” in § 903 was ambiguous, and our interpretation that we need to regulate both to give effect to § 903 is eminently reasonable.

### III. Defenses to SWATT’s Lawsuit

SWATT’s lawsuit is far weaker than PUFFT’s. There are four clear defenses we can raise to SWATT’s suit, three of which should be dispositive of the entire suit and one of which should be dispositive of half the suit. Moreover, we likely can use the SWATT suit “atmospherically” in the PUFFT suit. That is, we might allude to it to show the court that while PUFFT thinks we have gone too far, others think we have not gone far enough, the implication being that what we have done is strike an eminently reasonable balance in the Final Rule. Because the targets of the two suits are somewhat different, even if both tie to implementation of the Tobacco Control Act, we should be careful in assessing whether, and how hard, to press this tactic. While one characterization of the two suits is reason, another could be an assertion of incompetence. This assessment aside, our substantive defenses to SWATT’s suit are:

First and most fundamentally, we have a defense that there is no requirement to have promulgated the rules in question yet. SWATT complains of delay on the “free sample” rule required by § 102(a)(1), but that provision requires promulgation of a rule “180 days or more after the date of enactment of this Act.” From the fact pattern, it is unclear whether 180 days have yet passed: The NPR on the Final Rule was issued 90 days after enactment, and the

comment period for that was 60 days. Potentially, then, it is not even permissible for us to promulgate a rule yet. And even if it were, the statute simply does not mandate that it occur on the 180th day or any immediate time thereafter. The statute clearly states a timeframe that is “180 days *or more*.” Likewise for § 907(a)(1)(A)’s prohibition on certain flavored cigarettes, the provision contains no timetable for the publication of a rule. Thus, SWATT’s claim is at best not yet ripe for adjudication, based on the plain language of these provisions.

Second, there is no indication that SWATT has filed a petition for rulemaking on either of the rules it now seeks. If that is in fact the case, it may be that SWATT does not have the right to be in court under the APA because no challengeable agency “action” has occurred. In the recent Supreme Court case *Norton v. SUWA*, the majority clearly limited the definition of challengeable agency non-action to the denials of those specific acts included in the APA’s definition of agency “action.” Here, that would be a petition for rulemaking—which it appears SWATT has not filed. Accordingly, if so, SWATT cannot be in court under *SUWA*.

Third, even if SWATT’s claims were ripe and satisfied the APA’s justiciability requirements, it would have no ground to argue that FDA must promulgate a rule at all to implement § 907(a)(1)(A). That provision is self-implementing. It clearly states that “a cigarette or any of its component parts . . . shall not contain” the prohibited flavors and flavor-causing agents. FDA need do nothing to make this prohibition effective. While certainly FDA has general rulemaking authority under the Act to promulgate regulations on this provision if we deem it necessary, there is nothing in the statute mandating that we do so. Accordingly, SWATT’s claim as to § 907(a)(1)(A) should fail.

Finally, even if these arguments are not dispositive of SWATT’s claims, we have a very strong argument that any delay incurred thus far is permissible. The APA does prohibit agencies from either unlawfully withholding or *unreasonably* delaying actions. *See, e.g.*, APA § 706(1). Nevertheless, courts grant agencies wide berth in determining when something becomes too unreasonable. The D.C. Circuit’s decision in *TRAC v. FCC* is emblematic of the analysis. There the court acknowledged that claims of unreasonable delay can be won only if the agency’s delay is “so egregious as to warrant mandamus.” In short, while agency inaction can be reviewed, the agency’s discretion is broad. The *TRAC* line of cases measures that discretion by applying five factors to create a “rule of reason” for the time in which the agency must act: (1) the timetable set by Congress, (2) delay in economic regulation rather than public health regulation, (3) the effect of judicially-imposed expedition on other agency priorities, (4) the nature and extent of the interests prejudiced by the delay, and (5) the fact that the court need not find impropriety to find undue delay.

Here, it seems clear that FDA has not breached this rule of reason. First, as noted, there is no congressional timetable to act under § 907(a)(1)(A), and the timetable for § 102(a)(1) either has not yet been triggered or only recently was. Likewise, while the regulations sought by SWATT are admittedly for the public health, they also bear economic effects. And, there is no real prejudice from the delay. SWATT seems to be complaining that we have not acted *fast enough*, not that any inaction to this point is *unduly delayed*, much less deleterious. Tobacco makers were required to comply with § 907(a)(1)(A) the moment the Act was signed into law, and Congress appears to have left it to our discretion to decide how quickly to promulgate rules

under § 102(a)(1). In fact, in adopting the Act, Congress clearly was concerned not only about public health but also economic effects. Section 907(d)(2), for instance, plainly mandates that the FDA take into consideration economic effects in promulgating tobacco content standards. Add to this the fact that the FDA clearly has been busy attempting to expeditiously implement this new statute—including by promulgating an extensive rulemaking with a 500-page preamble—SWATT hardly can claim “egregious” delay mandating a court to step in and reprioritize how FDA is carrying out Congress’ objectives.

## **Essay Question No. 2**

This memorandum addresses possible arguments SMARTR might raise in a lawsuit challenging the FDA's Final Rule imposing (1) a nicotine content limitation of 1/500th of 1 percent on all tobacco products, (2) a tobacco content limitation of no more than 3 grams for cigars, and (3) licensing requirements for all tobacco product labels and packaging. You have asked primarily about the FDA's treatment of SMARTR's rulemaking comments; the memorandum addresses potential arguments that might be made on those grounds. In addition, the memorandum also addresses other potential arguments not necessarily based on arbitrary and capricious review.

### I. Statutory Arguments

It is our understanding that SMARTR has made a business decision not to press any arguments that the FDA has exceeded its statutory authority, but rather, to leave those challenges to PUFFT's lawsuit. It may, however, be worth considering making some of those same arguments on our own, or making a filing in PUFFT's suit bolstering their claims. In particular, there is a reasonably strong argument that FDA violated the Tobacco Control Act's prohibition on nicotine bans. Should you decide to reconsider making statutory arguments, we will be happy to discuss our views of those arguments' strengths, and the procedural and strategic considerations for how best to make them.

### II. Arbitrary and Capricious (Substantive) Arguments

The Administrative Procedure Act ("APA") mandates that agency actions not be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). This so-called arbitrary and capricious standard holds agencies to a requirement that their decisions be reasoned. Courts, in other words, defer to agency decisions because of agency expertise on the subject matter, but examine those decisions nevertheless to ensure that the agency has "articulate[d] a satisfactory explanation for its action." *Motor Vehicle Manufacturers Ass'n v. State Farm*. Courts express this mandate different ways, but it has become known as the "hard look" doctrine—courts must examine agency actions to ensure the agency took a hard look at the problem. The Supreme Court's decision in *State Farm* has become the standard recitation of the rule: "Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Id.*

Here, there are at least three ways in which we could argue that the FDA's action was not reasoned, though only two of the three are likely to have much chance of succeeding, and even those arguments are not particularly strong. Moreover, it is important to note that even if we are able to prevail on an arbitrary and capricious argument, the typical judicial recourse is to remand for further consideration by the agency. In other words, winning on an arbitrary and capricious argument is likely only to place us back before the FDA, with the FDA free to adopt the same conclusion it reached before—so long as it provides sufficient justification for doing so.

## A. Nicotine Levels

The first argument is likely the strongest. It is that the FDA was inconsistent in its treatment of the evidence presented on nicotine, and thus, the Final Rule is arbitrary and capricious because the findings FDA made on the nicotine are irreconcilable.

The FDA rulemaking, in fact, seemed to speak from both sides of its mouth. On one hand, the agency insisted that the “plague” of smoking “will not be cured absent our forceful action here.” Even more pointed, the agency asserted that “absent the reduction of nicotine” prescribed by the rule, “Americans . . . will continue to become addicted to tobacco products at an alarming rate” and “current tobacco users will remain addicted to these products at the current, quite troubling rate.” In other words, the FDA clearly claimed that the Final Rule would *reduce* smoking addiction rates *by reducing nicotine levels*. In contrast, when addressing SMARTR’s evidence, the FDA seemed to implicitly acknowledge that nicotine level reductions might not alleviate smoking addiction. It admitted that nicotine is “addictive at any level.” This acknowledgment potentially renders the rulemaking arbitrary and capricious. If the rule relies on nicotine reductions to instigate smoking reductions, but nicotine is addictive regardless of its amount, the very premise of the rule is invalid. That is arbitrary by definition.

Indeed, rather than directly refuting SMARTR’s evidence making that very point, the FDA simply noted various health maladies linked to smoking. Crediting the AMA studies over those provided by SMARTR, the agency wrote: “[The AMA studies] show that not only is nicotine addictive at any level . . . but that, in addition to lung cancer, smoking also causes diseases such as chronic bronchitis and emphysema . . .” This effectively was a deflection of SMARTR’s argument, not a meaningful grappling with it. But the hard look doctrine requires agencies to actually address evidence presented to them. Arguably, the FDA did not do that here. Of course, the FDA’s retort likely will be that regardless of whether it discussed the direct correlation of nicotine levels and addiction levels, the clear implication of its statements—and its rule—is that more nicotine is more likely to cause addiction, even if nicotine is addictive to *some degree* at all levels. Case law in fact acknowledges that agencies need not describe their logic perfectly. “We will . . . ‘uphold a decision of less than ideal clarity if the agency’s path may reasonably be discerned.’” *State Farm*. Likewise, we should expect the FDA to invoke the line of cases acknowledging broad discretion to agencies when they choose among evidence, especially evidence on questions within their expertise. Nevertheless, the FDA nowhere made a finding that products are more addictive when they contain more nicotine content. Nor did it appear to acknowledge that its alleged crediting of the AMA evidence over SMARTR’s was not even on the same question.

## B. Ineffectiveness of the Rule

The second arbitrary and capricious argument is similar to the first, and may bolster the first if we choose to make it. The argument is that the FDA effectively ignored the various evidence and arguments made by SMARTR that the Final Rule is unlikely to be effective at all, and in fact may backfire by creating black markets for tobacco products with higher nicotine and tobacco levels, or by increasing smoking.

The only direct response the FDA made to the first argument was that black markets would be outside its jurisdiction. This was not sufficient. If the evidence is true, simply pointing out that the agency does not have the legal power to deal with a problem its rule creates does not inoculate its decision as reasoned. Rather, the evidence proves the rules unreasonableness, and because of that, the agency had an obligation to address the evidence. The reason is simple: a black market carries the potential to gut the rule of the very aim it seeks to achieve, less smoking. “The requirement that agency action not be arbitrary and capricious includes a requirement that the agency adequately explain its result, and respond to ‘relevant’ and ‘significant’ public comments.” *NLRB v. Beverly Enterprises*. Here, by failing to address the substance of the evidence on black markets, the FDA did not do so.

Nor did the FDA sufficiently explain why reducing nicotine levels would be acceptable if a likely consequence was that many individuals would simply smoke more to achieve the same kind of chemical reaction as they did when more nicotine was allowed. There was evidence plainly on the record showing that smokers in the United States generally prefer tobacco products with more nicotine. A natural conclusion from this would be that smokers thus might consume more tobacco to make up for the lack of nicotine prescribed by the Final Rule. Yet the FDA failed to address this question. Potentially, depending on how pointedly the argument was presented to the agency (it is somewhat unclear from the fact pattern), that failure could render the agency’s decision arbitrary, especially when the very purpose of the Final Rule is to promote public health. Evidence showing that the Final Rule actually may harm public health must be dealt with by the agency. Yet the FDA offered no comparison of which we are aware of the likely health effects of (a) reduced addiction rates from nicotine loss and (b) increased smoking quantity rates by existing smokers under the new rule.

In fact, this brand of argument was made to the agency very clearly in a separate context. SMARTR pointedly made the contention with respect to cigars (rather than tobacco products generally). Again, SMARTR argued that the proposed rule would be ineffective. It did so by relying on data showing that 4 out of 5 consumers are likely to consume more cigars to obtain the same amount of tobacco as they would have before the rule was promulgated. Regardless of how well the general tobacco point above was made, this cigar contention was quite pointed. Thus, the FDA had an obligation to deal with it. The problem here, however, is that the FDA actually did address this argument. It noted that evidence showing that 4 out of 5 smokers will consume more tobacco implies that at least 1 in 5 smokers actually will end up consuming less tobacco. That retort is certainly the one the agency will lodge again. The problem for the agency is that it is only half right. It is true that *how* effective to make a rule is well within the agency’s discretion, *cf. State Farm*, and so the FDA’s reasoning may *ultimately* justify the promulgation of the rule *from a substantive perspective*. What it does not do, though, is justify the agency’s failure to address this argument by quantifying, respectively, the public health benefits from having 1 in 5 smokers smoke tobacco with less nicotine and 4 in 5 smokers consume more tobacco overall. This balance could sway either way, especially since there is also evidence on the record that tobacco ingredients other than nicotine are addictive. But without an assessment from the agency, we do not know. And if we do not know, quite likely, the agency’s decision is not reasoned.

### C. Economic Considerations

A final argument that might be made asserting the Final Rule's capriciousness is that the FDA failed entirely to address the economic impacts of its rule. Because the fact pattern is not clear about what determinations, if any, the FDA made on this question, the merits of this argument are difficult to determine. Unless the agency dealt with the question head-on, however, it may be worth making the argument. The statute at issue clearly anticipates the need for the FDA to take economic impacts into consideration, even providing for longer minimum lag times for regulation effective dates when economic impacts are particularly acute. Courts also have recognized that failure to consider factors contemplated by the statute can render a decision arbitrary and capricious. Moreover, although the fact pattern is unclear on the point, the fact that the FDA published a Final Rule identical in content and form to the rule proposed in its NOPR may bolster an argument that the agency shirked its duty to take these considerations into account, particularly when there was strong evidence on the record that the stringent regulations adopted could wreak havoc on the tobacco industry unless given much longer lead times than the Final Rule allows.

### III. Procedural Argument

In addition to the potential statutory and substantive arguments addressed above, there is at least one procedural argument SMARTR could lodge, though it is rather limited in merit. Moreover, even if we are able to prevail on this argument, it would, again, not prevent FDA from promulgating the same or effectively the same rule following remand. It would merely require the agency to go through more steps before doing so.

The argument would be that the FDA violated the time limitations prescribed by the Tobacco Control Act. The FDA promulgated its nicotine and tobacco content limitations under new § 907 of the FDCA. Subsection (d)(2) of that provision, however, clearly prohibits rules promulgated under § 907 from taking effect "before 1 year after the date of its publication." On its face, then, the FDA seems to have violated this requirement. The agency made the rule effective 180 days after its publication—not 365 days. Thus, the rule may be effective roughly 6 months before it is statutorily allowed. However, this argument may not be worth making for two reasons, despite its apparent ease. First, if the rule is effective only 6 months early, the likely relief, if any, will be minimal. Second, § 907(d)(2) does allow for earlier enactment if the agency "determines that an earlier effective date is necessary for the protection of the public health." It is not clear whether the FDA actually made such a determination, but it is likely that it would on a remand made due to the rule's prematurity. However, if those 6 months of inapplicability are sufficiently valuable to industry, this argument may be worth pressing. That is a business / strategic calculation, not a purely legal one.