

**Sample Answers**

**Administrative Law – Final Examination**

**Spring 2009**

**Professor Davies**

**NOTE: The answers contained herein are samples and 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, and the key is not necessarily the conclusion reached but the analysis undertaken.**

**Students are 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 whether PYHI can challenge in court the FDA's detainer of PYHI's deep-fried candy bar stock. As detailed below, we advise that (1) PYHI can in fact use judicial proceedings in response to the FDA's actions, (2) PYHI has numerous grounds upon which it can base such a challenge, most strongly by contending that the excessively fat-heavy food ("EFHF") regulations exceed the FDA's authority and failed to follow proper notice and comment procedures, and (3) the relief likely available to PYHI depends on which arguments are pressed, though much of the possible relief is simply additional process before the agency. Only the statutory arguments and one brand of the unreasoned decisionmaking arguments may provide more substantive relief.

### I. Availability of Judicial Review

Agency actions can be challenged in two circumstances: where the enabling act under which the agency is proceeding grants a right of judicial relief, and under the APA. In addition, to appear in federal court, parties must establish both Article III and prudential standing.

#### A. Standing

There should be no question that PYHI has standing here. Article III standing is established when three elements are met: (1) the suing party has suffered a concrete and particularized injury-in-fact (2) caused by the agency's action that (3) can be redressed by the judicial relief sought. *See Lujan*.

Where parties are themselves the subject of the agency's action, courts typically deem the party's standing self-evident. That should be the case here. The FDA's detainer of PYHI's product stock clearly is harming PYHI; the company is losing profits daily as a result of the detainer. Indeed, this kind of economic harm is the paradigmatic example of an injury-in-fact. Likewise, it is plain that this injury is both caused by the FDA's action and redressible by judicial intervention. If the FDA had not detained PYHI's product, the company would not be facing diminished profits. If the court overturns the agency's action, PYHI's product will be released.

By the same token, prudential standing should not be in doubt. Prudential standing aims to ensure that the interest asserted falls within the purposes of the statute, that the suing party is not asserting a third party's interest, and that the challenge is not a generalized grievance that should be resolved in the executive or legislative, not judicial, branches. PYHI is asserting its own interest—its interest in its product and its profits. And the question of its product's eligibility for detainer clearly falls under the FDCA's objectives of ensuring food safety, just as it clearly is about a specific dispute over the EFHF regulations and the FDA's detainer of PYHI's product, not something generalized such as a challenge to the expenditure of tax funds.

## B. Right of Judicial Review

The slightly more difficult question is whether the FDA has engaged in a judicially reviewable action, though that inquiry too is not particularly troublesome. The FDA might attempt to argue otherwise, but the question is relatively straightforward.

We do not have available the judicial review portion of the FDCA, so it is not possible to comment substantively on the availability of review under that statute. It bears noting, however, that review potentially could be available under the FDCA; that route to court should not be assumed as foreclosed. We must locate the statute and assess the possibility.

Nevertheless, judicial review should be available under the APA. Section 704 of that statute provides judicial review for any “final agency action for which there is no other adequate remedy in a court.” Thus, assuming that FDCA review is not available, APA review will be so long as the FDA’s actions qualify as “final” under the APA.

Most likely, the FDA’s actions are final for APA purposes. Section 704 contrasts “final” action with “preliminary, procedural, or intermediate” agency actions. Thus, final agency action is somewhat comparable to finality in the civil procedure context; conceptually it can be thought of as the agency’s full termination of a matter. The point, in other words, is to protect against piecemeal litigation in the courts when further proceedings before the agency remain available.

Here, there is one action taken by the FDA that clearly qualifies as “final” for APA purposes and another that potentially qualifies. Both, however, are subject to an important caveat: the possibility that administrative remedies have not been exhausted. First, the FDA has promulgated a rule in the Federal Register—the EFHF rules. Presumably, PYHI can challenge this as a final agency action. Promulgation of a substantive rule that establishes new rights or duties—here, the automatic qualification of EFHFs as “adulterated”—is the epitome of a final agency action. Nothing is left for the agency to do but enforce the rule. Its substance is finalized when published. Indeed, the FDA itself denominated the EFHF rules “final.”

Second, PYHI may or may not be able to challenge the FDA’s letter order as a final agency action. Effectively what the FDA has done here is undertake an informal adjudication: It applied the new EFHF prohibition to PYHI’s product, found that product in violation of the prohibition, and then ordered various recourse, including product detainer, for that violation. This seems remarkably final on its face, but there is a problem. FDCA § 304(h)(4) establishes an appeals process to challenge a detainer order before the Secretary of Health and Human Services. The facts do not state whether PYHI pressed for such recourse. If it did, letter order likely is final, unless FDA regulations or another portion of the FDCA require other steps. If PYHI did not exhaust the administrative appeal remedy, there is a possibility that the letter order is not yet final and further steps at the agency would need to be taken before judicial recourse is available.

In the same vein, there is some chance that even the EFHF rules are not yet challengeable due to exhaustion failure. APA § 704 limits the scope of what is “final” with the proviso that “agency action otherwise final is final . . . unless the agency otherwise requires by rule and provides agency authority.” We lack sufficient information here to ascertain whether the FDA

has such rules in place, but we know that these kind of rules are not uncommon in other agencies. Parties often may be required, for instance, to seek agency rehearing or reconsideration of a new rule prior to challenging it in court.

Nevertheless, recognizing both these possibilities for necessary further action at the agency before moving to court, we assume for purposes of this memorandum that PYHI has taken (or will shortly take) the necessary actions at the agency, that both the EFHF rules and the letter order are consequently final, and thus, judicially reviewable under APA §§ 702 and 704.

## II. Grounds for Judicial Challenge

Having determined that the FDA's actions here are presumably reviewable, the next inquiry is determining potential avenues for attack and, correspondingly, the likely merits of each such argument.

The APA contemplates six possible types of challenges to agency actions. Under APA § 706, a court may set aside an agency action as (1) unlawfully withheld or unreasonably delayed, (2) arbitrary and capricious, (3) unconstitutional, (4) outside the agency's statutory authority, (5) procedurally improper, and (6) unsupported by substantial evidence, if a formal adjudication or rulemaking is required. Here, PYHI has potential challenges under (2), (3), (4), and (5).

### A. Procedural Impropriety

There are numerous procedural errors in the FDA's actions. Most obvious was the agency's failure to use notice and comment rulemaking to issue the EFHF regulations, but others are also problematic.

#### 1. Notice and Comment Rulemaking

APA § 553 requires agencies to use notice and comment for all non-formal rulemakings that are not specifically exempted from this requirement. The EFHF regulations clearly fall within the APA's definition of a "rule." A "rule" under the Act is "an agency statement of general or particular applicability and future effect designed to implement . . . law or policy . . ." That is exactly what the EFHF rules do. They apply universally to any foods that fall within their ambit, they are effective going forward, and they impose a substantive legal requirement, namely, a duty not to sell EFHF. Indeed, publication of generally applicable rules in the Federal Register for codification in the C.F.R. is strong evidence of a rule under the APA, for this is standard procedure for most agencies. This only further bolsters the clear substantive effect of the EFHF rules.

Thus, the question of whether notice and comment rulemaking had to be used for the EFHF rules turns on whether they fall within an enumerated exception under Section 553. Section 553 creates six exceptions to its notice and comment requirements: (1) military or foreign affairs, (2) agency management or public property, loan, grant, benefits or contracts administration, (3) interpretative rules, (4) general policy statements, (5) agency organization or

procedural rules, and (6) when notice and comment is impracticable, unnecessary, or contrary to the public interest.

There is no argument that military, foreign affairs, or agency or public property management is the focus of the EFHF rules. Nor should the FDA have any claim that the EFHF rules are a policy statement or interpretative or procedural rule. As noted above, the EFHF rules clearly seek to have a substantive, binding effect—the very definition of the difference between a “rule” and a policy statement or interpretative rule. Likewise, although 21 C.F.R. § 9999.003 might be fairly cast as procedural, it governs not how the agency operates but how others will be treated by the agency, and thus, should not be considered procedural. *See, e.g., Am. Hosp. Ass’n v. Bowen*. In any event, even if § 9999.003 were deemed procedural under APA § 553(b)(3)(A), that would not exempt the other provisions of the EFHF rules from § 553’s notice and comment requirement.

The question of whether the EFHF rules can be exempted from notice and comment rulemaking thus reduces to whether they qualify under § 553(b)(3)(B) as making notice and comment impracticable, unnecessary, or contrary to the public interest. The FDA can be expected to make this argument, particularly given its denomination of the EFHF regulations as an “emergency” rule, but this should be a difficult position to take.

Courts “narrowly construe[] and only reluctantly countenance[]” the § 553 exceptions. *Am. Fed. Government Employees v. Block*. These exceptions are not intended to create broad categories where notice and comment is not used but, rather, merely to delineate limited circumstances where the purposes of notice and comment need not be advanced. Thus, APA legislative history indicates that “impracticable” contemplates situations in which advance notice of a rule would defeat an agency’s regulatory objectives, or where immediate action is necessary to protect public health or safety. “Unnecessary” indicates a very minor or technical amendment. And “contrary to the public interest” encapsulates these other concepts.

The FDA can hardly claim that the EFHF rules would be ineffective had prior notice and comment been used, or that they are merely minor or technical. Providing notice and comment here would have satisfied the very purposes for which the APA mandates it. It would have allowed the regulated parties—and the public—to give the agency better and more information about the likely effect of its proposal and, possibly, better ways to achieve it. If the FDA so chose, it still could have regulated EFHFs; it is just that with public comment, the scope and content of those regulations might have changed. Nor can the FDA claim that these regulations are merely technical or clarifying. They open up the FDCA’s scope to an entirely new class of foods—those heavy in fat content—that the FDA has never regulated before. Technical amendments merely clarify or correct a rule, not reinterpret an entire statute’s meaning.

The FDA’s strongest argument is that notice and comment need not have been used because immediate promulgation of the EFHF regulations was necessary to protect public health. The problem with this argument is twofold. First, § 553(b)(3)(B) clearly requires the agency to actually find that notice and comment was impracticable, and it is not clear from the facts that the FDA did so here. Even more problematic, the EFHF rulemaking carries heavy indicia of being motivated by President Simmons’ political agenda, *cf. State Farm*, not by, say, the

discovery of spoiled food on the market that was unexpectedly causing a health crisis. Section 553's legislative history indicates that the emergencies contemplated by the "impracticable" exception are those that require immediate action because of a sudden or imminent threat. Certainly the FDA can argue that 821 American deaths per day is a national health crisis, but the agency can hardly claim it as an imminent result of EFHFs. Many other factors cause obesity, including the quantity of EFHFs consumed, not just the amount of fat in a food serving; an individual's activity and exercise habits; environmental factors; and genetics. Moreover, even if obesity were caused primarily by EFHF consumption, the deleterious health effects cited by the FDA are not immediate. It takes time—years and decades—for EFHF consumption to lead to obesity, much less the associated health ills (or death). Indeed, as detailed further below, the EFHF regulations are likely arbitrary and capricious for their failure to adequately tie the harm they attempt to regulate (obesity's health effects) to the "cause" they actually regulate (EFHF).

Accordingly, PYHI has a very strong argument that the EFHF regulations are invalid for failure to use notice and comment procedures.

## 2. Mandatory Effective Date Delay

PYHI's second strongest procedural argument challenging the new EFHF rules is related to the first. Section 553(d) specifically precludes agencies from making regulations effective any sooner than 30 days following publication in the Federal Register. The purpose of this is to give parties the chance to challenge a rule before its application causes immediate harm. Here, the FDA clearly violated this principle. It made the EFHF rules effective "immediately." Granted, Section 553(d) allows for waiver of the mandatory wait period for "good cause found and published with the rule." Presumably, however, the only good cause the FDA could cite for waiving the effective date delay requirement would be the same "emergency" assertions it might raise to justify foregoing the notice and comment process. And, it is not clear the FDA even articulated such reasons. Moreover, while it is not inconceivable that a court would countenance such an attempted justification, particularly since the likely harm from the EFHF rules' immediate effectiveness may be less than the total lack of notice and comment, it seems most likely that if the court does not accept the justification for the agency's failure to use notice and comment, it will not accept it for failure to follow § 553(d) either.

## 3. Ex Parte Contacts

A third argument that might be used to challenge the EFHF rules is that they were improperly promulgated based on inappropriate political influence from the Simmons administration. Specifically, we could argue that the Five Guys meeting—and not a rational execution of the statute's purposes—was what gave rise to the EFHF rules.

The APA places express limits on ex parte contacts. For three reasons, however, these limits likely do not preclude the contacts that occurred here. This argument is thus likely limited in its utility; unless it we strategically decide that it could be used to bolster another argument, or unless we obtain more evidence about the contacts focused on, I would suggest not using this as a primary way to attack the EFHF rules.

The first problem foreclosing application of the APA's ex parte contacts ban is that those limits apply only to formal adjudication and rulemaking proceedings. *See* APA § 557(d). There is no indication that this was a formal rulemaking. Rather, it seems clear that the FDA intended the proceeding to be an informal rulemaking, albeit without some of the process required for even that.

Second, there is no evidence of what the Five Guys meeting was actually about. While both the proximity of the meeting to the rules' issuance and the political responsibilities of Mr. Seacrest may provide indicia of attempted political influence, certainly neither rises, without more, to proof of procedural impropriety. The meeting could have been about anything, especially given the broad scope of FDA's responsibilities.

Third, and even more problematic for the ex parte contacts argument, the very timing of the Seacrest meeting likely forecloses reliance on a claim of procedural impropriety. The purpose of the APA's ex parte limitations is to ensure full public participation and open decisionmaking in the formal adjudication and rulemaking process. Part of this purpose ties to the APA's notion of how public participation ensures better decisionmaking; part of it ties to due process concerns over fairness. Presumably, it is largely because of these fairness concerns that the statute forbids ex parte contacts in the formal rulemaking and adjudication context but says nothing about ex parte participation in informal proceedings. The FDA thus would have a strong argument based on *Vermont Yankee* that since the APA fails to prohibit ex parte contacts for informal rulemakings, a court could not graft that prohibition on itself. It might be possible, depending on the case law, to counter such a *Vermont Yankee* defense with a Due Process Clause argument, but one fact here makes that unlikely. Even Section 557(d)'s prohibition on ex parte contacts is not triggered until a proceeding begins, or it is clear a proceeding is about to begin. *See* APA § 557(d)(1). It would be difficult to argue that a *more stringent* prohibition should apply to *less formal* proceedings, particularly where, as here, the contact occurred a full month before the rule was issued.

#### 4. FDCA Informal Adjudication Requirements

Another, and stronger, procedural argument is that the FDA failed to follow the FDCA's requirements for informal adjudications. Although the APA establishes baseline procedures that agencies generally must follow, Congress can, and often does, prescribe additional procedures for certain agencies or types of cases. For the FDCA, Congress has defined "informal hearings" to include a bevy of requirements to which informal adjudications under the APA are not subject. These include, for instance, a neutral arbiter with no involvement in the proceeding, the right to present oral or written information, and the right to question the agency's information or witnesses. *See* FDCA § 201(x). The FDA's new EFHF rules, in turn, make enforcement actions brought against allegedly adulterated foods subject to these "informal hearing" requirements. *See* 21 C.F.R. § 9999.003.

The FDA's action against PYHI, however, followed none of these procedures. Instead, Commissioner Griffin merely emailed the corporation informing it that it, allegedly, was in violation of the FDCA's adulterated foods ban and ordering it to recall its entire product line. None of the process mandated by FDCA § 201(x) was followed. There was no hearing at all, let

alone one in which PYHI was afforded the right to submit its own or challenge the FDA's evidence. This seems to qualify as a flat breach of the FDCA's procedural requirements, and the agency's own rules requiring adherence to those procedures.

A counterargument the FDA could make is that, on one hand, its regulations exempt detainer actions from 201(x) procedures or that, on the other hand, its action was not an adjudication at all. Clearly there was a detainer here. But PYHI should have a strong argument that the FDA engaged in two separate actions here, the first of which qualifies as an enforcement action under FDCA § 301 and thus is subject to FDCA § 201(x)'s heightened procedures. The FDA's first action was Commissioner Griffin's issuance of the "formal notice" letter ordering PYHI to recall its product; the second action was the detainer. Although it is possible the FDA could contend otherwise, the notice letter appears in fact to be an enforcement action under the statute. It expressly declares PYHI in violation of the FDCA. It specifies the reasons for that violation (manufacture of deep-fried candy bars). And it indicates the legal consequences of that alleged violation, namely, the orders to recall and cease and desist from further manufacture. Indeed, the letter itself appears to view this finding of an FDCA violation and the detention action as separate, for it uses the penalty of detention as a threat for failure to comply. This would seem to fit squarely within the APA's definition of an adjudication, which the statute sees as a specific application of law to a specific party or parties under a specific set of facts. Further, the FDA should have difficulty contending that this was not an enforcement of FDCA § 301 and its EFHF regulations, because to so argue would undermine its justification for detainer.

## 5. Time Limits for Detainers

A final procedural problem with the FDA's actions is that the agency appears to have breached its own limitations on detainer actions. The agency's own regulations state that the "FDA may detain an article of food for a reasonable period that may not exceed 20 calendar days after the detention order is issued," and that this 20-day period can be extended by 10 days only where "required to institute a seizure or injunction action" in court. While agencies may modify self-imposed procedural requirements over time, they cannot stray from their own regulations without giving a reasoned basis for doing so. Here, the agency's 35-day (and running) detainer of PYHI's product exceeds both the FDA's standard limit of 20 days and the potential "extension" of 10 further days. Without an explanation of any kind from FDA why this is necessary and appropriate, a court should consider it clearly procedurally improper.<sup>1</sup>

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<sup>1</sup> There is also a potential argument that the FDA failed to show "credible evidence or information" that PYHI's product poses "a threat of serious adverse health consequences" justifying detainer, as both the FDCA and FDA regulations require. Most likely, however, the viability of this argument will depend on the FDA's claim that EFHF qualify as adulterated under the Act.

## B. Statutory Authority

In addition to the numerous procedural arguments PYHI might use to challenge the FDA's actions, there are also some generally strong statutory arguments the company could lodge.

### 1. Interpretation of "Adulterated"

The most potent statutory argument at PYHI's disposal is that the FDA improperly interpreted the FDCA by issuing regulations deeming EFHFs "adulterated." When an agency interprets the statute it is charged with administering, courts use the familiar two-prong analysis of *Chevron*. At step one of this analysis, courts afford the agency no discretion if the statute is unambiguous. If, however, the relevant statutory term is open to different interpretations, courts will uphold the agency's choice so long as it is permissible within the statute's bounds. Courts apply this two-part analysis when Congress intended the agency to interpret that portion of the statute and the agency's action carries the force of law. The FDA's actions in this case should satisfy these requirements, as the FDA administers the FDCA and the FDCA clearly gives the agency the rulemaking authority it used here.

#### a. *Chevron* Step One

PYHI could fairly forcibly argue that, at *Chevron* step one, the FDCA's plain text forecloses the FDA's interpretation of "adulterated." FDCA § 402 defines "adulterated" to mean foods that are defective or contaminated in a way that render them, effectively, public health hazards. In describing adulterated foods, the FDCA uses words such as "poisonous," "insanitary," and "deleterious." FDCA § 402(a). It expands on these adjectives by denominating a list of food categories that are deemed adulterated: foods that include "filthy, putrid, or decomposed" substances, that have been "prepared, packed, or held under insanitary conditions" or that "have become contaminated with filth," or that have been subjected to excess radiation. FDCA § 402(a)(1).

The only of these categories that EFHFs might fall into is food that "bears or contains any poisonous or deleterious substance which may render it injurious to health." *Id.* PYHI could well argue, perhaps successfully, that this category must be construed not alone but in conjunction with the FDCA's other definitions of adulterated foods. Those categories militate for a narrower than broader definition of adulteration, one that contemplates complete defiling or contamination of food rather than merely unhealthy foods.

Indeed, had Congress wanted to make all unhealthy foods "adulterated" under the statute, it clearly could have said as much, particularly since its enumeration of what counts as adulterated both is lengthy and seems more than simply exemplary in nature. But it did not. Reading the statute otherwise, as the FDA has here, would elevate a single phrase—"injurious to health"—over the entire statute's scheme in how it sees adulteration. Since such a broad interpretation of the statute would have sweeping effects for all society, Congress should be required to speak plainly on the matter rather than having courts infer it from a single three-word phrase in a lengthy statute. Congress does not hide tanks in mouse holes.

To be sure, this narrower construction of “adulterated” fits much more closely with the standard definition of adulteration. “Adulterate” typically means to debase or make impure by adding inferior elements. Under this definition, an EFHF such as, say, a premium ice cream brand would not be deemed adulterated because nothing impure or inferior has been added to it. So long as the product is made with sufficient safety precautions, it will be precisely what it is supposed to be: ice cream. Only when poison or filth or something of the sort makes its way into the manufacturing process could the ice cream be deemed “adulterated”—that is, debased or made impure by the poison or filth—under the FDCA. The FDA’s EFHF rules turn this plain English definition on its head. They deem foods that may have been perfectly made “adulterated” even though the end product is exactly what it is supposed to be. *See Massachusetts v. EPA.*

Under this logic, PYHI thus has a strong argument that the FDA’s EFHF regulations—and all of its enforcement actions against PYHI based on those regulations—are invalid because they are foreclosed by the FDCA’s plain meaning.

#### b. *Chevron* Step Two

If the FDA is able to convince a court that “adulterated” is open to multiple meanings—made impure *or* made in a way that is unhealthy or inferior, for instance—it is likely that the agency’s interpretation will be upheld. At this stage of the analysis, agencies receive deference in how they read their statute, and the FDA’s interpretation appears to fall within the reasonable meanings “adulterated” can be assigned, if a court assumes the term is flexible. PYHI could still argue that the mere inclusion of fat should not rise to the level of adulteration, but if the court is willing to accept that adulteration can equate with unhealthiness, this will be a difficult argument. It is, instead, an argument that may have more force in contending that the *way* the FDA decided to implement this definition is arbitrary and capricious, not that the *definition itself* is unreasonable.

### 2. Recall, and Cease and Desist Powers

A related, and perhaps even stronger, argument is that the FDA exceeded the scope of its statutory authority by ordering PYHI to (1) recall its products and (2) cease and desist from manufacturing any further deep-fried candy bars. It is hornbook law that agencies only have the authority Congress gives them. Here, the FDA has multiple powers to enforce the FDCA, but none of them appear to include the injunctive powers either to compel a product recall or to order a company to stop manufacture altogether. Rather, FDCA § 303 delineates specific penalties for violation of Section 402’s ban on selling adulterated foods. These penalties include monetary fines and potential jail time. They do not include bans on making products, or an authorization for FDA to recall products that violate § 301. Likewise, FDCA § 304 gives the FDA the ability to detain food, but requires the agency to go to court if it is going to actually seize it. Given that nowhere in the statute is the FDA given injunctive powers, and given that both recall and cease and desist orders are more akin to the court-based seizure procedures than mere detainer (which itself contemplates impending court involvement), there is a strong argument that the recall and

cease-and-desist portions of the FDA’s letter order are invalid as outside the scope of the agency’s jurisdiction.

### C. Unreasonable Decisionmaking

Both the EFHF regulations and the letter order issued to PYHI appear to contain significant gaps in logic that can be challenged under APA § 706(2)(A) as “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” Although courts give wide deference to agencies’ factual findings and policy choices, they repeatedly have held that this does not eliminate the need for a careful, searching review of agency decisions—a philosophy known as the “hard look” doctrine.

#### 1. The Alleged Link to Obesity

Most critical here is the apparent dearth of evidence linking the harm the FDA is trying to prevent—obesity-related disease and maladies—to the subject matter the EFHF regulations actually control—fat-heavy food. Certainly PYHI cannot challenge the fact that excess consumption of fat-heavy foods can lead to obesity. But what PYHI can point out, and what the FDA appears to have failed to show, is how the EFHF regulations actually prevent obesity. One might call this a question of appropriate regulatory scope or of adequate regulatory match, but either way the problem persists: Even if all EFHFs were eliminated from the market, the plague of American obesity could still persist. The reason is simple. Many other factors, above and beyond the fat content of foods, are linked with obesity. Individual genetics play a role, as does exercise habits to a very important degree. Even low-fat and fat-free foods easily can lead to obesity if they are over-consumed. Quantity, in other words, may matter just as much as, if not more than, fat content. Indeed, many foods that are low-fat can be calorie-heavy. The FDA, however, appears to have failed to account for this fact. PYHI accordingly can make a strong attack on these grounds.

It is true that agencies have broad discretion to choose how they will go about implementing their objectives, and the FDA will likely counter with this argument. But the fact that agencies are not required to solve all of a problem at once does not absolve them of ensuring the reasonableness of the solutions they do choose. It is not entirely clear from the fact pattern, but it appears that the core focus of the EFHF rules’ preamble is not on health problems caused by EFHF but, rather, by obesity. If this is true, and if the FDA failed to provide a sufficient evidentiary link from EFHF to such health problems, as appears to be the case, the agency’s promulgation of the EFHF rules arguably was arbitrary and capricious.

#### 2. The Alleged Link to PYHI’s Deep-Fried Candy Bars

A similar argument available to PYHI is that the FDA was arbitrary and capricious in finding PYHI’s products adulterated, even if the EFHF rules are upheld. The FDA’s letter order deemed all deep-fried candy bars EFHF, regardless of the flavor, brand, or content. Obviously, however, candy bars differ. Some have more fat content than others. Thus, to the extent that PYHI can argue that some or all of the deep-fried candy bars it sells do not exceed the 1-to-20 fat-to-calorie per serving ratio specified by the EFHF rules, a strong argument would exist that

the FDA's findings were arbitrary and capricious as applied to PYHI. PYHI could make arguments in the same vein if, for example, the type or quantity of oil used to deep-fry the candy bars might vary violation of the 1-to-20 ratio, or if there are nutritional counter-arguments for why PYHI candy bars do not pose obesity-related health risks or offer obesity-related health benefits irrespective of their violating the 1-to-20 limit.

### 3. The Recall Order

Finally, PYHI potentially could challenge the FDA's action as arbitrary and capricious for failing to follow its own policy on recalls. This argument is a long shot and, though ultimately probably not worth pursuing, should at least be considered.

The FDA's recall policy is plain that it is "voluntary" and not mandatory. "Recall is a voluntary action . . ." 21 C.F.R. § 7.40(a). "Recall may be undertaken voluntarily and at any time by manufacturers and distributors, or at the request of the Food and Drug Administration." *Id.* § 7.40(b). Nevertheless, the letter order issued to PYHI clearly *mandated* recall of all PYHI deep-fried candy bars. While the FDA's recall regulations appear to be a mere policy statement that is not legally binding—the regulations themselves attest to being nothing more than mere "guidance," *id.* § 7.40(a)—at least some cases have been willing to bar agency actions based on the public's detrimental reliance on agency interpretations or policy statements. *See Alaska Professional Hunters Ass'n v. FAA*. In such cases, however, the public's reliance typically has been substantial and detrimental, and the agency's interpretation has been longstanding and formalized. Although the FDA formalized its recall policy here by codifying it in the C.F.R., the other factors typically critical for these cases are not present. A mere expectation by PYHI that the FDA would not compel a recall hardly qualifies as substantial or detrimental reliance, and there is no evidence available either way on whether the FDA has compelled recalls in the past.

PYHI similarly could argue that the FDA failed to abide by the substance of its recall policy. That is, the policy indicates that recalls should be "reserved for urgent situations." Potentially, PYHI could argue that there is nothing urgent about preventing any ill health effects from its candy bars. First, nothing changed from the day before the EFHF regulations were issued to the day after; at both points in time, obesity was a large problem in America. Indeed, as noted, this entire action seems motivated by President Simmons' political agenda rather than an administrative attempt to better effectuate the FDCA's purposes. *Cf. State Farm*. Second, any ill health effects that do arise from PYHI deep-fried candy bars do not arise immediately, much less urgently. They become more likely over time as fat accumulates from prolonged and excessive consumption of calories and fat, combined with insufficient exercise. Nevertheless, despite the logic of these arguments, they suffer from the same deficiency as above. PYHI can hardly claim substantial and detrimental reliance on the substance of the FDA recall policy any more than it can on that policy's compulsoriness.

#### D. Due Process

Finally, PYHI may challenge the FDA's actions as unconstitutional for violating the Due Process Clause of the Fifth Amendment. Even though *Vermont Yankee* precludes courts from imposing new procedural requirements not embodied in the APA or an organic act, the Constitution still provides procedural restraint. Here, the FDA's detainer of PYHI's product potentially violates the Due Process Clause, separate and apart from any statutory or other procedural problems the letter order poses.

Due process applies when (1) an agency engages in an individualized proceeding and (2) the agency's action impinges on a protected interest, *i.e.*, life, liberty, or property. A court should have no difficulty finding that the FDA's action here is individualized for PYHI. The letter order specifically addressed only PYHI and its product. That is precisely the type of adjudicative proceeding that courts consistently have found to be individualized for due process purposes. *Compare Londoner with Bi-Metallic*. Likewise it should be obvious that the FDA's action impinges on a protected interest. While an argument that the FDA's denomination of PYHI's product as "adulterated" under the FDCA somehow qualifies as a breach of PYHI's liberty interest would be difficult to make, *see Board of Regents v. Roth*, the FDA's detainer of PYHI's candy bars clearly is an infringement on the company's property.

The due process question thus turns on whether the FDA afforded PYHI sufficient process before it detained the candy bars. This is a closer question. The Supreme Court has held that the amount of process due depends on a balancing test that weighs a party's interest against the government's. "Due process is flexible and calls for such procedural protections as the particular situation demands." *Mathews v. Eldridge*. The test applies three factors to determine if due process has been violated: (1) the private interest affected by the outcome, (2) the risk that an erroneous deprivation will result absent the procedures requested, and (3) the fiscal and administrative effect of requiring additional procedure.

PYHI has a fairly strong argument on the third prong, but its ability to prevail on the first and second is more questionable. The extent to which PYHI's property interest has been impinged is uncertain. If the FDA's action truly is a detainer, any effect on the property is only temporary. Moreover, monetary effects typically do not qualify as a heightened interest, for money is the ultimate in fungibility. If, however, the FDA's action is longer-lasting or more permanent than a mere detainer, as the fact that the withholding of PYHI's stock already has extended more than the 30-day maximum may indicate, the effect may have greater weight.

Similarly, the second factor may play different ways. If the FDA's EFHF rules are valid and if deep-fried candy bars in fact universally (or almost universally) exceed the rules' 1-to-20 ratio, then there is little chance of an improper deprivation. But if the regulations are invalid, or if the fat content of deep-fried candy bars sometimes dips below the 1-to-20 ratio, this factor may militate more in PYHI's favor.

With respect to the third factor, PYHI has a stronger argument. Determining whether deep-fried candy bars exceed the 1-to-20 ratio should not be particularly time-consuming or expensive for the government, though the FDA could argue that it needs to act immediately to

prevent public health harms. That argument, however, should be difficult to prevail on, as noted above.

In short, PYHI has a strong argument that due process applies here, but a strategic decision will need to be made whether to press the claim that not enough process was afforded. Given the strength of PYHI's other arguments, due process ultimately may not be worth pursuing.

### III. Potential Relief

Part of our ultimate analysis in determining what arguments to use for actually challenging the FDA's actions must depend on the type of relief we potentially could obtain. Not only do the different arguments have varying levels of strength, they hold potential for different kinds of relief.

In this regard, the two statutory arguments are potentially the most powerful. If we can prove to the court that the FDA's interpretation of the FDCA is impermissible under the plain language of the statute, its entire action here will be eviscerated—and foreclosed going forward. Likewise, if we can show that the agency does not have mandatory cease and desist powers, the FDA will be prevented from taking those actions against PYHI in the future. Given that these arguments are also substantively strong, we recommend pursuing them.

Less powerful are the procedural, reasoned decisionmaking, and due process arguments. Because these arguments basically contend not that the FDA was foreclosed from taking these actions at all, but rather, that it did not take them the right way, prevailing on these contentions is most likely to simply secure PYHI more procedure with the agency. Certainly, some of these arguments are more powerful than the others. If, for instance, we can convince a court that the agency cannot tie the fat content of foods to obesity in a reasonable fashion, that too could foreclose further FDA action in this regard. But the majority of the other arguments more likely will leave the door open for the agency to still adopt EFHF rules, provided that it gives sufficient explanation and uses the right procedures. For this reason, we will need to choose strategically which of these arguments are worth pressing, and which may not be.

## **Essay Question No. 2**

This memorandum addresses whether PYHI can challenge the FDA's enforcement action alleging that PYHI misbranded its deep-fried candy bars based on the new excessively fat-heavy food ("EFHF") regulations. The memorandum concludes that (1) PYHI can challenge the FDA's action, and (2) PYHI has numerous arguments it may lodge against the FDA's decision in this case.

### **I. Reviewability**

As detailed in our prior memorandum, agency actions are challengeable in court where either the organic statute or the APA provides a right of relief. Though we are unaware from the facts given, the FDA's "misbranding" enforcement action should clearly qualify for review under the APA. This action is "final" for APA § 704 purposes because there is no other relief that PYHI can seek with the FDA. Indeed, PYHI has already challenged the ALJ's decision to the full agency, the agency denied that appeal, as it did PYHI's subsequent request for rehearing of that decision. The FDA has made clear that it will not accept any further challenges in this case. Likewise, PYHI should clearly have standing. It is harmed by the FDA's action, both reputationally and monetarily (\$1,000 per day fines). The FDA's order deeming PYHI to have misbranded its products is the direct and proximate cause of this harm. And court action can redress that harm. The more difficult question in this "misbranding" challenge is assessing which arguments to use to attack the FDA's decision.

### **II. Avenues of Challenge**

We see at least five arguments for challenging the FDA's misbranding action, four of which are potentially quite strong. We address them in descending order of their likely strength.

#### **A. Statutory Prohibition on Misbranding Penalties**

The most straightforward argument here is that the penalties imposed by the FDA are not permitted under the statute. FDCA § 303(d) specifically forecloses monetary and criminal penalties for misbranding based on advertising. It states, "No person shall be subject to the penalties of subsection (a)(1) [which permits fines of not more than \$1,000 or imprisonment for up to a year] for a violation of section 301 involving misbranded food if the violation exists solely because the food is misbranded under section 403(a)(2) because of its advertising." Although the fact pattern does not provide us with the text of FDCA § 403, it seems relatively clear that such misbranding is precisely what the FDA's enforcement action here is all about. The agency claims that PYHI's use of its logo on its deep-fried candy bars is false advertising because that logo implies health benefits when, in fact, the FDA sees deep-fried candy bars as adulterated. If § 403(a)(2) is in fact the basis of the FDA's action in addition to § 301(b), as it appears to be, the FDA's imposition of the \$1,000 per candy bar penalty is unlawful. FDCA § 303(d) specifically precludes it.

## B. Retroactivity of Misbranding Test

PYHI's second strongest argument is that the agency impermissibly applied a new test for determining whether a product is misbranded, when PYHI had relied on the agency's longstanding, old test.

Courts have long accepted agencies' use of adjudicative proceedings to change their policies, *see NLRB v. Bell Aerospace*, but two restrictions limit how agencies may do so. First, the agency must adequately explain the reasons for its policy change, or the change will be arbitrary and capricious. Second, only in some circumstances can the agency apply its new policy to the party in question, because doing so raises retroactivity, and thus, fairness, concerns. Arguably, the FDA violated both of these restrictions here. We address the former below, the latter now.

The Supreme Court acknowledged long ago in *SEC v. Chenery Corp.* that the APA does not foreclose agency policy changes via adjudications. Nevertheless, the Court also held that not all such retroactive policy changes are acceptable: "Every case of first impression has a retroactive effect, whether the new principle is announced by a court or by an administrative agency. But such retroactivity must be balanced against the mischief of producing a result which is contrary to a statutory design or to legal and equitable principles. If that mischief is greater than the ill effect of the retroactive application of a new standard, it is not the type . . . which is condemned by law." To determine whether the "mischief" of retroactivity outweighs the mischief of results contrary to statutory purposes, courts have applied numerous factors. The D.C. Circuit's in *Retail, Wholesale, and Department Store Union v. NLRB* are particularly helpful. That court examines (1) whether the case is one of first impression, (2) whether the new rule is an "abrupt departure" from settled practice or merely "fill[ing] a void," (3) the extent of reliance on the old rule by the party in question, (4) the degree of burden imposed by the retroactivity, and (5) the statutory interest in applying a new rule.

Here, PYHI has a strong argument that the FDA's new misbranding rule, adopted for the first time by an ALJ without the FDA's own involvement, fails the *Chenery* balancing test. The ALJ's order itself acknowledges that the "product-specific" misbranding test is the FDA's longstanding, "traditional" test to assess whether misbranding has occurred. Presumably PYHI relied on this test in formulating how it would label its deep-fried candy bars, since the company logo on the label is accompanied by specific and accurate nutrient information. Under the old "product-specific" rule, that would have inoculated PYHI from any misbranding enforcement actions, regardless of whether the FDA decided that its candy bars qualified as EFHF. Moreover, the burden of applying the new test retroactively will be extraordinarily burdensome for PYHI. Even if the monetary penalties imposed by the agency are struck down, PYHI will be forced either to repackage its vast deep-fried candy bar stock already in transit and on shelves across the country or to forego selling them at all. And if the penalties are upheld, the total amount of fine would be crushing for the company—\$1,000 for each bar, when a bar normally likely would not sell for more than a few dollars.

The FDA's strongest defense against these contentions is that the new test is merely incremental or, alternately, that it is needed to ensure fulfillment of FDCA objectives. The

“incremental” argument will be a difficult one to make. Certainly the FDA can allege that this is a case of first impression, as the ALJ did, due to the new EFHF regulations. But nothing about the EFHF regulations changes the way the FDA deals with *misbranding*. Those regulations create a new category of what is *adulterated*. The misbranding is about the *information* given to the public about a product. Potentially, the FDA could justify the new rule substantively, but that is a separate matter from asserting that it must apply now, to PYHI, before any notice has been given. This is particularly true given that, as the ALJ observed, the FDA has “never” found a product misbranded when accurate nutritional information also was on the package. This shows just how entrenched the old rule was.

The FDA should have a somewhat easier time making the argument that the new rule is necessary to advance the FDCA’s goals but, again, elevating that argument to a level that justifies retroactivity should be fairly difficult. The FDA may have good reason to forbid any claims that a product is “good for your heart” if it qualifies as EFHF; too much fat certainly is not good for one’s heart. However, even if that is the case, saying that such a rule must apply immediately to those who had no notice it would apply is a longer reach. Not only is the legal viability of the EFHF regulations under severe question (see the statutory power arguments in our prior memorandum), but the immense burden on all manufacturers of EFHF to immediately change or destroy vast quantities of product already on the shelves seems quite disturbing when the offending health claims are accompanied by accurate nutritional information, the new rule can be rapidly phased in without imposing such a burden, and the FDA has the power to disseminate information about foods. *See* FDCA § 705. As the ALJ noted, the FDA has long relied on consumers’ ability to discern between truth and advertising hyperbole as long as accurate nutritional information remains in the picture.

### C. Arbitrariness and Capriciousness

There are at least three arguments here that the ALJ’s reasoning and, by extension, the FDA’s, was arbitrary and capricious.

First, there is an argument that the ALJ applied the wrong test to determine whether PYHI’s products are “misbranded” under the FDCA. The ALJ acknowledged that the “ordinarily injurious” test is for determining whether a product is “adulterated,” not whether it is “misbranded.” Yet it discussed, and applied, the “ordinarily injurious” test at length. It is not clear why, nor is the effect of that application obvious. Apparently, the ALJ seemed to think that whether something is adulterated bears on whether it is misbranded. But nothing in the misbranding test, even as the ALJ retooled it for adulterated products, says that a product’s adulteration counts for misbranding purposes. Thus, there is an argument here that the ALJ’s reliance on the “ordinarily injurious” test rendered its decision unreasonable. Indeed, even if the “ordinarily injurious” test had some relevance, the ALJ necessarily misapplied it, because it could not have possibly weighed the alleged deleterious effects of PYHI’s products, for all the reasons about to be discussed.

Second, PYHI has a strong argument that the FDA simply disregarded the evidence it submitted, if the “ordinarily injurious” test somehow applies. That evidence showed, without refutation, that PYHI’s product does not fail the “ordinarily injurious” test. PYHI provided

evidence that most consumers do not over-indulge when eating its product and, moreover, that many people do not gain weight from eating deep-fried candy bars. This evidence specifically contradicts the assertion that PYHI candy bars lead to obesity-related health problems because of their fat content. Rather, it shows that such health problems may never materialize because the obesity that is their direct and proximate cause also might not arise from deep-fried candy bar consumption. Despite this, the ALJ simply ignored the evidence in the record and instead relied on the FDA's findings from the EFHF rulemaking. But those findings are *exactly* what PYHI's evidence undermined. Thus, the ALJ's decision, and the FDA's affirming of it, should be deemed in error.

Third, and possibly most powerfully, PYHI can argue that the FDA's decision here was unreasoned because it failed to explain why it changed its policy. Agencies, of course, are free to change policy so long as they justify the new policy and that policy falls within the scope of their statutory power. But they may not simply rewrite their own tests without explaining how the new policy satisfies what the statute requires. There is no such explanation here. Not only did the ALJ fail to provide an explanation, but the agency also failed to do so in affirming the ALJ. This should not pass APA muster. Especially given the significant impacts the new and far-more restrictive misbranding rule will have on industry, the agency was required to say something about why it made the change. Silence is not enough.

#### D. Procedural Error

Finally, PYHI potentially has an argument that the FDA failed to follow proper procedures here. It is unclear whether this action qualifies as an enforcement action under the new EFHF rules. If it does, however, those rules specifically mandate special "informal hearing" proceedings under FDCA § 201(x). *See* 21 C.F.R. § 9999.003. Those procedures include a requirement of cross-examination, or "reasonable questioning" at least, at the hearing. FDCA § 201(x)(4). Again, it is unclear whether such an opportunity was afforded PYHI at the hearing, but if it was not, or if any of the other procedures mandated by § 201(x) were not followed, PYHI may have a claim that the procedures used were deficient.