Administrative Process
Fall 2020
Prof. Ford

Take-Home Final Exam

This take-home final exam is being given on Friday, December 18, from 8:30 a.m to 4:30 p.m. It consists of one fact pattern and three questions. You must not use more than 4,000 words total for your responses (not including the honor statement discussed below). When finished, convert your responses to a PDF file named "[exam number] final, Admin.pdf." Email the file to registrar@law.unh.edu with the subject "[exam number] final, Admin."

You may consult any existing material you wish while completing this exam. You must write your entire response, yourself, during the exam period; you may not paste any previously written material into your answers. You may not discuss the exam with anyone until everyone has finished taking it. Type the following at the top of your exam (without copying and pasting!): *I promise that I have not discussed this exam with anyone else during its administration. I understand and have complied with the word and time limits and the formatting requirements governing this exam.*

The formatting instructions in this paragraph are very important, and you should follow them or expect to lose points. (I'm not kidding about this. Take some time to double and triple check.) Type your responses. Format them similarly to this document: single-spaced, with 1.5-inch margins (including top and bottom), numbered pages, and space between paragraphs. Use 12-point Book Antiqua, Cambria, Century, Constantia, or another high-quality serif font appropriate for body text. Do not use Times New Roman, which is a terrible font. Do not include your name or any identifying info. Instead, place only your assigned exam number on the top right—that's the top *right*—of your responses. Include your total word count at the end of your exam.

As in legal practice, writing counts, so take time to outline and leave some time for editing and proofreading. Follow standard practices of good writing: organize your answers thoughtfully; use topic sentences and short paragraphs, each focused on a single idea; use short, complete, grammatical sentences.

If any questions are unclear or missing information, draw reasonable inferences from the available information and explain why you draw those inferences or, if no such information is available, state any assumptions you make and explain how your answer depends on those assumptions.

Good luck and have a wonderful winter break!

The Health Claims Labeling Act.

In late 2021, after the COVID-19 pandemic has largely subsided, a team of reporters from *The Washington Post* publishes an investigative series on companies trying to take advantage of fears of the virus to sell things. The series includes stories on food that promises on its packaging that "free radicals" in the food will that prevent illnesses, clothing with silver threads woven into the fabric that is marketed as killing 99% of bacteria, UV-light devices that claim to sterilize dirty smartphones, and hotels that "mist" their rooms between guests with sprays that they say will remove airborne viruses. These claims have varying degrees of truth and falsity: some, like the fabric with silver threads, are technically true but largely irrelevant to preventing illness in the real world, while others, like the food that claims to prevent illness, are exaggerations or just outright lies.

Consumers, furious at companies for trying to monetize a pandemic and aided by a campaign from two nonprofit organizations, Public Citizen and the Center for Science in the Public Interest, write and call their members of Congress in numbers that haven't been seen since the Vietnam War. In a surprising burst of productivity, Congress responds to the outrage by passing the Health Claims Labeling Act, which President Biden signs in early 2022. The law bans certain false and misleading claims and creates a new agency to enforce the prohibition. The Act reads, in relevant part:

> **Section 1. Findings.** It is the sense of Congress that unscrupulous actors are taking advantage of consumers by selling useless protections and fake cures to diseases like COVID-19. These scams are especially heinous because they capitalize upon the legitimate fears of the American people to obtain unwarranted profits.
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> **Section 2. Bureau.** There is established within the Department of Health and Human Services a Bureau of Health Labeling (the Bureau).
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> **Section 3. Director.** The Bureau shall be headed by a Director appointed by the Secretary [of Health and Human Services]. The Director shall have substantial experience in consumer protection, consumer health advocacy, public health, marketing, or related fields. The Director shall serve for a renewable term of five years and may be terminated for neglect of duty, malfeasance, or other good cause.
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> **Section 4. Prohibited Acts.** It is unlawful to label any product or service sold in interstate or foreign commerce with a false or misleading claim that the product or service prevents, cures, or reduces the transmission or spread of a communicable disease.

Section 5. Exceptions. This Act shall not apply to any product or service regulated [by the Food and Drug Administration] as a drug, medical device, or dietary supplement pursuant to the Federal Food, Drug, and Cosmetic Act.

Section 6. Enforcement. The Bureau shall have jurisdiction to enforce this Act through appropriate means consistent with the Administrative Procedure Act and shall have the power to enter declaratory and injunctive orders and to assess fines up to $1 million per violation after notice and opportunity for a hearing. Any final decision of the Bureau ordering relief against any person [which, pursuant to a different federal statute, includes companies] may be appealed to the Secretary for de novo review within 30 days of the decision. Appeal to the Secretary is not a prerequisite to judicial review of a final order of the Bureau.

Section 7. Jurisdiction. This Act shall not be construed to deprive other agencies of authority to enforce other consumer-protection laws.

Once the law goes into effect, the Secretary appoints a director and deputy director, and the Bureau gets to work. First up, the Bureau holds a two-day workshop with representatives from consumer-goods companies, law firms, business-lobbying organizations like the Chamber of Commerce, consumer organizations, and other groups to discuss the scope of labeling problems and possible policy priorities for the agency's initial actions.

The Bureau then begins regulating by publishing a notice of proposed rulemaking. The notice describes a lengthy omnibus rule setting up numerous aspects of the agency and its enforcement of the Act. Some of the details described in the notice include these:

- The rule would define "label," as used in Section 4 of the Act, to include "any description of a product or service's qualities and features provided by its manufacturer or seller, including product packaging; any box, bag, or tag attached to or enclosing the product; a product or service's marketing, including advertisements and websites; and any printed or electronic literature accompanying or relating to the product or service."
- The rule would define "misleading," as used in Section 4, to include "any claim that, while literally true, relates to any claim or feature that does not meaningfully distinguish a product or service from one not making the same health claim."
- The rule would define "communicable disease," as used in Section 4, to include "any communicable disease caused by a virus, bacterium, or fungus."

After 90 days for public comments, the Bureau begins sorting through the thousands of comments submitted by consumer-products companies, consumer organizations, lobbyists, and others. Nine months of work later, the Bureau publishes its final rule, making numerous changes in response to comments. With respect to the definitions mentioned above, the final rule makes a few changes:

- The final rule defines "label" as described in the notice of proposed rulemaking, except that in response to a comment from the National Retail Federation, the final rule clarifies that the "manufacturer or seller" does not include a retailer of a product or service when a reasonable consumer would not understand the retailer to be responsible for the product or service's label. The Bureau also rejected several comments arguing that it would be inconsistent with the statute to include marketing and literature in the definition of "label," concluding that it best accomplished the purpose of the Act to include the broader definition in the final rule.
- The final rule defines "misleading" to include "any claim that is materially misleading, including any claim that would induce or persuade a consumer to purchase a product or service without meaningfully distinguishing the product or service from competitors, regardless of the literal truth or falsity of the claim." The final rule does not mention any comments that triggered the revised definition.
- The final rule defines "communicable disease" to include "any airborne disease that the Secretary [of Health and Human Services] has declared to be an ongoing pandemic or for which there is evidence of current community spread in the United States." The narrower definition was adopted in response to comments from consumer-product companies arguing that the definition in the notice of proposed rulemaking would bring in too many products aimed at non-airborne diseases like sexually transmitted infections and that the broad definition would therefore conflict with Section 5 of the Act.

Question 1. Public Citizen and the Center for Science in the Public Interest are disappointed. They consider the final rule weak and would like to persuade a court to strike it down so the Bureau can enact a stronger one. They bring a timely lawsuit. What arguments can they make to set aside the rule, what responses can the Bureau make in response, and how should the court rule on those arguments? (Ignore any arguments that are not about the rulemaking.)

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Regardless of your answer to question 1, assume for the rest of the exam that the litigation fails and that the final rule is valid and remains in force.

In late 2024, the Bureau receives complaints from several consumers that they got sick with COVID-19 (which by this point has become an annual winter annoyance, albeit an occasionally deadly one, like a more severe form of flu) while traveling for the holidays, even though they wore expensive portable air purifiers that were supposed to prevent illness. These air purifiers, which are battery powered and rechargeable via USB, are designed to emit a stream of ions into the air around the wearer; the charge of the ions attracts airborne particles, like viruses and bacteria, which then fall to the floor. Or at least that's what the manufacturers claim.

The Bureau investigates and learns that the complaints all come from people who bought their purifiers from Sharper Image, a retailer that sells tech gadgets and toys through a catalog and website. (They used to have mall stores, but they were all closed during the COVID-19 pandemic of 2020–21.) An image of the purifier sold by Sharper Image, from the company's website, is shown above. The Bureau hires a scientist to test the device, who finds that it doesn't work; though it emits ions, it does so in such small quantities and at such slow speeds that they can't really attract a meaningful number of viruses or bacteria.

The Bureau sends Sharper Image a letter informing it that the agency is initiating enforcement proceedings against Sharper Image for violating Section 4 of the Act. The letter informs Sharper Image of the Bureau's scientific findings and explains that because the product is unbranded and does not appear to be sold by anyone but Sharper Image in the United States, Sharper Image is the appropriate "seller" respondent.

The letter also informs Sharper Image that on the basis of the Bureau's scientific findings, the Bureau has entered a preliminary injunctive order prohibiting Sharper Image from selling the purifier, effective immediately, pending a hearing in the matter, which it has scheduled for 60 days later. Finally, the letter directs Sharper Image to submit a written response to the letter within 30 days, which shall be considered during the hearing.

Question 2. Sharper Image immediately files a lawsuit claiming that (a) the Bureau's structure is unconstitutional under the Appointments Clause and (b) the preliminary injunctive order entered by the Bureau is procedurally unlawful. What arguments can Sharper Image make on those subjects, what responses can the Bureau make, and how should the court rule? (Ignore the issue of what remedy the court might order if it agrees with Sharper Image.)

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While the lawsuit in question 2 is slowly working its way through various motions in federal district court, the Bureau conducts the Sharper Image hearing and issues a final order. The final order finds the company in violation of Section 4 and orders it to permanently cease and desist from selling the portable air purifiers. It also fines Sharper Image $3.8 million, $10,000 for each of the 380 purifiers the company sold before the preliminary injunctive order was entered.

The written decision accompanying the Bureau's order rejects, among other arguments, the argument that there was no specific health claim that qualified as false and misleading. The Bureau concludes that the advertisement showed on the previous page qualifies as making a specific health claim because it includes three copies of the now-famous and recognizable image of the SARS-COV-2 virus, the virus that causes COVID-19.

Question 3. After the final order is issued, Sharper Image decides not to appeal to the Secretary of Health and Human Services. Instead, it amends the complaint in its ongoing lawsuit to add a claim seeking to set aside the final order. What arguments can Sharper Image make to set aside the final order, what responses can the Bureau make, and how should the court rule?

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