Administrative Process
Fall 2020
Prof. Ford

Take-Home Final Exam (Makeup)

This take-home final exam is being given … at some point, for eight hours, to be arranged by Dean Berger. It consists of one fact pattern and two 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" and email the file to Dean Berger.

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!

The Pandemic Preparedness Act.

In early 2022, after the COVID-19 pandemic had largely subsided, a team of reporters from the *New York Times* published a lengthy multi-part investigative series on how the United States came to be so vulnerable to a pandemic. The series identified numerous disparate factors, from political polarization to disorganization within the Trump administration, that had contributed to the nation's failure to address the pandemic as quickly as other nations.

Many of the factors identified in the series had a common origin in failures to prepare for future public-health crises. For instance, the series noted that the United States had outsourced much of its manufacturing capacity to foreign nations, rendering it vulnerable to supply shortages. Likewise, the series observed that scientists had long expected one of a few dozen viruses observed in animals to cause a pandemic, including the virus that causes COVID-19, but that Congress had not funded research to develop vaccines for those viruses.

In Senate hearings following the publication of the series, witnesses and senators concluded that many of these preparation failures were the result of an overburdened Centers for Disease Control and Prevention (CDC), the principal federal public-health agency. Because the same agency was responsible both for responding to ongoing public-health crises and for trying to prevent future public-health crises, there was a natural tendency to respond to the current crisis at the expense of planning for the future. This led to failures of preparation, like empty and expired stockpiles of ventilators and personal protective equipment and an inability to quickly ramp up production once more was needed.

After the hearings, Congress passes, and President Biden signs, the Pandemic Preparedness Act. The law creates a new agency, the Pandemic Preparedness Board, that is charged with planning and preparing for future public-health crises. The Act reads, in relevant part:

> **Section 1. Board.** There is established within the Department of Health and Human Services an agency to be known as the Pandemic Preparedness Board. The Board shall be headed by three Board Members consisting of the senior officials of the Centers for Disease Control and Prevention and the Food and Drug Administration, with the third Member chosen by the other two Members.[*]

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[*] The CDC and Food and Drug Administration (FDA) are both federal agencies within the Department of Health and Human Services. The CDC is headed by a Director appointed by the President, without Senate confirmation. The FDA is headed by a Commissioner of Food and Drugs appointed by the President and confirmed by the Senate.

> **Section 2. Duties and powers of the Board.** The Board shall be responsible for planning and preparing for the needs of the United States during future pandemics and public-health crises and for procuring supplies, matériel, and capabilities necessary to meet those needs. The Board shall have the power to make contracts and issue grants as needed to support these duties.
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> **Section 3. Procedure.** The Board may act through appropriate means consistent with the Administrative Procedure Act. Any final decision may be appealed to the Secretary [of Health and Human Services] 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 Board.

Once the law goes into effect, the heads of the CDC and FDA meet and appoint a third Board Member, a Deputy Assistant Secretary who works on procurement and logistics. Because the heads of the CDC and FDA have busy day jobs, they expect the third Board Member to do the bulk of the day-to-day work. She and the Board's staff get started by scouring the Department for existing planning documents and making lists of actions to be taken. They also hold a series of workshops with public-health experts, medical-supply companies, hospital systems, state- and local-government officials, and other stakeholders to discuss potential needs in a future pandemic.

After reviewing its research, the Board and its staff identify three broad sets of needs: (1) replenished federal and local stockpiles of medicines, medical and protective equipment, and other items that would be needed during a pandemic; (2) supply-chain improvements to enable unexpected needs to be filled quickly and to replenish stockpiles during and after a pandemic; and (3) clarified emergency authority to implement public-health measures like quarantines and immunization mandates. The Board then publishes three Notices of Proposed Rulemaking, one corresponding to each of the three needs it had identified: the (proposed) Public-Health Stockpile Rule, Supply-Chain Improvements Rule, and Emergency Public-Health Authority Rule.

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The Public-Health Stockpile Rule. The first proposed rule would give the Board the power to spend money allocated by Congress to procure and stockpile goods that the Board believes will be needed in a pandemic, like medical supplies and equipment, drugs, cleaning supplies, personal protective equipment, and so forth. The draft rule included in the Notice would establish various national and local stockpiles. It also set forth the procedure by which the Board would purchase things to include in the stockpiles:

- The Board would be required, within 90 days of an appropriation by Congress to purchase items for a stockpile, to publish (on the Board's website and the Federal Register) a Notice of Proposed Procurement describing the items and quantities to be procured using the appropriation.
- The public would have 30 days to comment on the Notice of Proposed Procurement. The Board would review comments and publish a final procurement plan, with any changes the Board considered appropriate.
- The Board would then execute the procurement plan by purchasing items on the open market or by publishing solicitations for bids to which potential suppliers could respond. If it chose to proceed by purchasing items on the open market, the Board would be required to make best efforts to find the lowest available price. If it chose to proceed via public solicitation, the Board would be required to accept the lowest qualified bid.

After 90 days for public comments, the Board sorted through the comments it received and published a final Public-Health Stockpile Rule. The final rule tweaked some of the details of the different stockpiles but didn't change any of the language governing the procurement process.

A year after the Rule goes into force, Congress appropriates $8 billion to the Board for use according to the Public-Health Stockpile Rule. The Board then meets to discuss potential uses and concludes that the money should be divided between the national stockpiles of critical drugs ($1.5 billion), medical equipment ($3 billion), personal protective equipment ($1 billion), and sanitation and disinfectant supplies ($500 million). The Board also concludes that $2 billion should be reserved for grants to researchers developing new vaccines and treatments. The Board publishes a Notice of Proposed Procurement describing this plan. After receiving a few dozen comments, mostly from companies lobbying for more money to be allocated to the category containing products sold by each company, the Board publishes the final procurement plan, unchanged from the Notice.

Question 1. Johnson & Johnson, a major manufacturer of drugs and medical supplies, sues the Board, asserting that (a) the Board's structure is unconstitutional under the Appointments Clause and (b) the Board should allocate more money to the stockpiles of drugs and medical equipment. What arguments can Johnson & Johnson make on those subjects, what responses can the Board make, and how should the court rule?

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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.

The Emergency Public-Health Authority Rule. The third proposed rule would give the Board the power to issue "Emergency Public-Health Orders" during a pandemic recognized by the Secretary of Health and Human Services. These orders could be binding on anyone in the United States and could require measures like staying home, wearing masks, quarantining, and so forth. The proposed rule described how such an order would be enacted:

- The Board was permitted to issue an Emergency Public-Health Order upon a majority vote of the Board Members or, if any one Board Member concluded that health conditions or other emergency conditions made it impossible to assemble a majority of the Board to vote, by that one Board Member acting alone. Such an order would be effective immediately or at a time set in the order.
- An Emergency Public-Health Order could last for up to 30 days without renewal by the Board. An order could be renewed for at most three additional 30-day periods before the Board would be required to initiate a notice-and-comment rulemaking to implement the order.

As with the first proposed rule, after 90 days for public comments, the Board sorted through the comments and published a final Emergency Public-Health Authority Rule. The final rule tweaked some details but didn't change any of the language governing the enactment process. The explanation issued as part of the final rule rejected several comments arguing that the Emergency Public-Health Authority Rule was unwise or unlawful on various grounds.

In 2024, a novel flu virus begins spreading, first in South America and quickly around the world. The Department of Health and Human Services declares a pandemic and the Board exercises its authority under the Emergency Public-Health Authority Rule to issue an order requiring all people arriving in the United States to quarantine in a hotel for 14 days upon arrival to prevent the novel flu from spreading in the United States. The Board also orders airlines to contract with hotels to provide quarantine rooms to all passengers and authorizes airlines to charge passengers for these costs.

Question 2. Airlines for America, a trade association, sues the Board, asserting that the Emergency Public-Health Authority Rule and the Emergency Public-Health Order issued pursuant to it should be set aside. What arguments can the plaintiff make on those subjects, what responses can the Board make, and how should the court rule?