Hypotheticals for Introduction to Rulemaking

I. The Food, Drug and Cosmetics Act provides for an elaborate system of testing drugs before the Food and Drug Administration can approve them for sale to the public.

Assume that in response to a public outcry for quicker approval of drugs to combat potential outbreaks of pandemic flu, Congress passed an Pandemic Flu Law that included a rulemaking provision that provides that "the FDA may, by regulation, adopt procedures for expedited approval of pandemic flu drugs."

In accordance with Section 553 of the APA (informal rulemaking provisions), the FDA proposed rules that would greatly streamline the process for approval of pandemic flu drugs.

Before the FDA's rules were finalized, the manufacturers of the pandemic flu drugs that were currently approved by the FDA lobbied Congress, and Congress adopted several amendments to the Pandemic Flu Law. In one of the amendments, Congress changed the rulemaking provision to provide that "After opportunity for a hearing, the FDA may adopt procedures for expedited approval of pandemic flu drugs."

After the amendments to the Pandemic Flu Law were enacted, the FDA began the informal rulemaking procedures again, and, in full compliance with Section 553 of the APA, the FDA promulgated a final rule that provided for an expedited approval process for pandemic flu drugs.

A. You represent an interest group that opposes expedited review of drugs by the FDA. What challenges might you make to the final rule?

B. Representing the FDA, how would you counter the arguments raised by the interest group?

C. Assume that a court concludes that the FDA was not required to comply with 5 U.S.C. sections 556 and 557 when adopting the regulations above. Representing the interest group, how might you argue that the FDA nevertheless had an obligation to provide an opportunity for you and other interested persons to present oral testimony to the agency regarding the regulations? How would the FDA respond?

D. Assume that prior to the enactment of the Pandemic Flu Law, the FDA generally provided interested persons with an opportunity to provide oral testimony on proposed regulations that would provide for expedited review of drugs whenever the regulations were adopted pursuant to a law that

authorized the agency to adopt rules "after opportunity for a hearing." Although that was the agency's practice, FDA did not have any rules that required it to provide persons with an opportunity to provide oral testimony in those instances. Assume that, despite that past practice, the FDA did not provide an opportunity for persons to submit oral testimony when they approved the streamlined approval for pandemic flu drugs. Assume also that the rulemaking above was the agency's first rulemaking under the Pandemic Flu Law. How would that impact the interest group's argument that the FDA was required to provide them an opportunity to present oral testimony before adopting the regulations?

E. Assume, in addition to the facts outlined in "D." above, that before the Pandemic Flu Law was enacted, the FDA had adopted regulations that provided generally that whenever the FDA promulgated rules to approve drugs on an expedited basis, the agency would provide an opportunity for oral testimony? Despite those regulations, after the Pandemic Flu law was passed, the FDA adopted the rules that provided for the expedited approval of pandemic flu drugs using the notice and comment procedures and the agency did not provide interested persons an opportunity to present oral testimony. How would that impact the interest group's argument that the FDA was required to provide them an opportunity to present oral testimony before adopting the regulations?

F. Would the interest group have a stronger argument that formal hearing procedures under the APA were required, or at least an opportunity for presentation of oral testimony was required, if the Pandemic Flu Law required FDA to adopt regulations for the expedited review of pandemic flu drugs "after a public hearing"?