ADMINISTRATIVE LAW
PROFESSOR WELLS

FALL, 1992
DECEMBER 15, 1992

FINAL EXAMINATION

INSTRUCTIONS:

1. This is an essay examination. You should have 10 numbered pages. You are entitled to have with you your casebook, classnotes (including any problems we discussed), AND any briefs and outlines which are substantially the product of student work. Commercial outlines and hornbooks (including Understanding Administrative Law by Fox) are not permitted. If you have any prohibited items, please remove them from the room now or stack them at the front of the room.

2. You are limited to one blue book for each question (writing on only one side of the paper). Please use a separate blue book for each question. Write your examination number on each blue book. State which question you are answering on the cover.

3. Write legibly and avoid irrelevant discussion. Discussion which is not pertinent will not be credited and may detract from your grade.

4. Before you begin, scan your exam to get an idea of what you're up against and how to budget your time.

5. Be sure to answer the question(s) asked. Read the question all the way through before you begin to respond. This should help you save valuable time.

6. It is essential that you use your time wisely. Each question is preceded by a notation as to the amount of credit it will receive. This may be a useful guide in allocating time. Decide how much time to allocate to each question and discipline yourself to stay within a time frame. You may feel that there are many "interesting" aspects of a given problem. However, your task is to complete the exam within the time permitted, writing the best answer possible within the allotted time. Therefore, you may have to make choices (i.e., discuss the most pertinent aspects first).

7. Read carefully and think before you write. Good organization will count in your favor.

8. The examination will be collected promptly at 9:30 p.m.

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I.

(30 Per Cent)

As enacted in 1938, Sec. 701 of the Food and Drug Act contained two grants of authority to the Food and Drug Administration (FDA) to regulate drugs.

Sec. 701(a) provides:

"(a) The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Commissioner."

Sec. 701(e) provides:

"(e)(1) Any action for the issuance, amendment or repeal of any regulation dealing with [specific enumerated categories of drugs] ... shall be initiated (A) by the Commissioner on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Commissioner.

"The Commissioner shall publish notice of such proposed action and shall afford all interested persons an opportunity to present their views thereon orally or in writing. As soon as practicable thereafter, the Commissioner shall act upon such proposal by issuing an order and shall make such order public through publication."

"(e)(2) On or before the 30th day after the date of the issuance of any such order under paragraph (1), any person who is adversely affected may file objections thereto with the Commissioner, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections."

"(e)(3) As soon as practicable after such hearing request, the Commissioner after due notice, shall hold a hearing for the

purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested persons may be heard in person or by representative. As soon as practicable after completion of such hearing, the Commissioner shall by order act upon such objections and make such order public.

"Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based."

Purporting to act under the general rule-making power vested in the Commissioner under the Act, the Commissioner followed the notice-and-comment procedure outlined by the Administrative Procedure Act, 5 U.S.C. § 553(c), in promulgating the regulations which are challenged in this action. First, she published a statement in the Federal Register, giving notice of her proposal to adopt regulations, pursuant to the agency's statutory authority, which would require that Vitamins A and D in dosage units in excess of 10,000 IU and 400 IU, respectively ("higher dosage forms" herein), be restricted to prescription sale and deemed misbranded unless the label of the container in which they were sold or dispensed bore appropriate disclosure and warnings. Vitamins A and D were <u>not</u> among the categories of drugs enumerated in 701(e).

The Commissioner's initial statement advised that, according to medical literature, the ingestion of large dosages of Vitamins A and D over long periods could have serious toxic effects. She stated that these vitamins were available over the counter in dosage forms many times the daily allowance recommended by the Food and Nutrition Board of the National Academy of Sciences. According to the Commissioner's statement, the higher dosage forms were subject to widespread promotion to the public for treatment of a variety of diseases and disorders. The American Academy of Pediatrics had published a statement warning physicians regarding the various forms of toxicity that could result from intake of the large amounts of Vitamin A being recommended by vendors to the public in the press, on radio and on TV. Many types of serious adverse effects from ingestion of excessive amounts of Vitamins A and D were listed, including some that resulted in death. The Commissioner placed on public view an extensive bibliography of the medical literature employed by the FDA in formulating its proposed

regulations.

The Commissioner's statement invited interested persons to file with the FDA within 60 days any written comments they might desire to submit with respect to the proposals, together with memoranda and briefs, all of which would be available for public inspection. Over 2,500 written comments were submitted by a wide cross-section of the public, including consumers, physicians, nurses, pharmacists, pharmaceutical manufacturers, and health food store operators.

The comments fell into three general categories. In Group 1 were those who viewed the proposed regulations as suitable. This group included the American Medical Association, the American Academy of Pediatrics, various consumer groups, and physicians. Group 2 was comprised of those who agreed that vitamins could be toxic, but only at higher levels than those proposed to be regulated by the Commissioner. In this group were the majority of the drug manufacturers and trade associations, plus some consumers. Finally, in Group 3 were those who disagreed with the proposals entirely, taking the view that consumption of desired quantities of such vitamins was an individual right. These comments came mostly from consumers and health food establishments.

In a report published in the Federal Register the Commissioner summarized the comments received by the FDA, concluded that the proposed regulations were in the public interest, and ordered that they become effective in 60 days. In response to contentions that Vitamins A and D were foods rather than drugs, and thus not subject to regulation under section 701, the Commissioner referred to orders which she had published years earlier, concluding that vitamins in daily amounts between the upper and lower limits specified in the regulations (i.e., 1,250 to 8,000 IU of Vitamin A and 200 to 400 IU of Vitamin D) were adequate for all nutritional needs of normal individuals. The Commissioner stated in those orders that vitamins at these levels could be considered as dietary supplements or foods for special dietary use. With respect to the higher level dosages, which were to be dispensed only upon prescription, however, the prior orders stated: "No evidence was submitted in the comments to establish a food or nutritional use of vitamin A or vitamin D at higher levels."

Plaintiffs, manufacturers of vitamins, brought suit in federal district court seeking declaratory and injunctive relief that would prevent enforcement of the proposed regulations. The district

court granted FDA's motion for summary judgment, dismissing the complaint on the merits. It upheld the regulations as promulgated pursuant to the Commissioner's authority under the Act.

On appeal, plaintiff-appellants re-assert the multifaceted attack upon the challenged regulations which they launched unsuccessfully in the district court. First, they contend that the FDA has no authority to issue regulations having the binding effect of law, other than those regulations which must be issued under the adjudicatory hearing procedures provided by § 701(e). Along these lines, they urge that regulations issued under § 701(a), which does not provide for a hearing, at best represent merely administrative interpretations of the substantive law, which according to plaintiff-appellants could only be made through case-by-case adjudication. In short, they argue that the regulations should have been promulgated only after a formal adjudicatory hearing, including presentation of oral evidence, had been provided.

Secondly, appellants assert that, assuming arguendo that the FDA had the power to promulgate binding regulations via notice and comment rulemaking under 701(a), the present ones are deficient because they are unsupported by substantial evidence and the record fails to contain adequate findings and a sufficient explanation of the basis and rationale of the FDA's action to enable a reviewing court to determine whether the FDA acted within the scope of its statutory authority and on the basis of supporting evidence.

They argue that the district court improperly used the "arbitrary, capricious" rather than the "substantial evidence" standard of review, but that even the "arbitrary, capricious" standard could not be met here, in view of the inadequacy of the record, which fails adequately to demonstrate the basis of the Commissioner's action.

(a) Decide the appeal. Explain fully.

(b) Does the result change if the court reviews under the "hard look" doctrine?

II.

(30 Per Cent)

Plaintiff Zoological Supply, Inc., a corporation, is in the business of supplying and distributing wholesale equipment, information, and zoological specimens to zoos, schools, and pet shops for educational and scientific purposes. Hamilton was at all relevant times special agent for the United States Fish and Wildlife Service ("FWS"), a branch of the United States Department of the Interior. Shelin ("Shelin") was at all relevant times an agent for the United States Food and Drug Administration ("FDA").

The FDA and the FWS had been monitoring Plaintiff's alleged trafficking in undersized turtles for nearly 12 years. Handling of undersized turtles had been implicated in studies of salmonellosis. Some studies estimated that 14 per cent of all human cases of salmonellosis were turtle-related. In 1986 and 1988 the Government reminded Plaintiff about the relevant regulations. According to Plaintiff, in the summer of 1988, Hamilton came to Plaintiff's place of business, identified himself as a federal law enforcement officer, Mirandized those present, and demanded to see Plaintiff's business records. No search warrant was presented.

The next relevant action in this case occurred three years later, in December 1991, when a meeting was arranged between Plaintiff's chief executive officer ("CEO"), Hamilton, Shelin and two other FDA agents. At this meeting, the FDA agents asked Plaintiff to cease and desist the sale of undersized turtles. Plaintiff's CEO responded that all the company's sales were for educational purposes and therefore were permitted by the relevant federal statute. Plaintiff's CEO suggested that the FDA and FWS utilize the administrative procedure set forth in its regulations published in the C.F.R. if it wished to challenge the allegedly illegal sales. C.F.R.Sec. 1240.62(c)(i), Title 21, provided that the government may make demand that prohibited turtles be humanely destroyed under supervision of the government. The person upon whom the demand has been made must destroy the turtles within 10 days or appeal the demand to the Director of the FWS. A demand conforming to the regulation must recite with particularity the facts which justify the demand. During the December 1991 meeting, Hamilton allegedly commented to Plaintiff's CEO that he could take some action against Plaintiff. Plaintiff's CEO understood this as some sort of threat.

On or about July 17, 1992, Hamilton obtained an administrative search warrant from a clerk in Magistrate's Court to search and seize property, equipment, and documents from Plaintiff's place of business. The procedure used permitted the issuance of the warrant by a clerk upon the affidavit of an administrative officer, without a hearing before a judicial officer. The FWS seized, among other things, Plaintiff's entire stock of undersized turtles (valued at $50,000 wholesale) and business records.

The next day Hamilton allegedly called Plaintiff's place of business and stated that if Plaintiff signed an abandonment form there would be no further action taken against it. Hamilton allegedly telephoned the following day and again demanded that Plaintiff sign an abandonment form.

Three days later, on July 20, 1992, a representative of Plaintiff contacted Hamilton by phone. Hamilton allegedly said that if Plaintiff did not sign an abandonment form, there would be criminal charges filed against it. Hamilton also said that the seized turtles were dying and asked Plaintiff for information on how to care for them.

Subsequently, Plaintiff obtained a copy of the search warrant affidavit and found that it contained allegedly false information. Specifically, Hamilton omitted four exceptions to the rule against the sale of undersized turtles, misrepresented that Plaintiff supplied turtles to a pet store in Ohio, and misrepresented that Plaintiff was uncooperative and refused to provide distribution lists.

According to Plaintiff, Hamilton instituted a series of actions designed to harass Plaintiff. Hamilton began subpoenaing Plaintiff's customers to appear before a grand jury. Plaintiff's customers also allegedly complained to Plaintiff that Hamilton and others pressured them to cease their purchases from Plaintiff. Further, Hamilton allegedly stated to customers that he was going to put Plaintiff out of business, and allegedly told Plaintiff's customers that Plaintiff was selling illegal turtles.

Plaintiff subsequently sought return of the turtles and other seized property. Defendants refused to comply with this request and stated that the turtles had been transported to a FWS facility in Louisiana. Plaintiff was unable to learn of the disposition of the turtles in Louisiana, although it was rumored that the turtles may have been mistakenly released into the wild and that some may

have died during the seizure period.

Hamilton and others sought to have Plaintiff indicted before two separate grand juries. Neither grand jury returned an indictment.

Plaintiff seeks your counsel. Plaintiff asks you to represent the corporation in retrieving the turtles and pursuing any other legal rights it might have. Please advise Plaintiff on any claims it may assert and the likely resolution of such claims. (For this question, you may assume that there are no problems relating to availability or timing of judicial review).

III.

(40 Per Cent)

Congress passed The Immigration Reform and Control Act of 1986 ("IRCA"), Pub.L. 99-603, to create a comprehensive program to regulate immigration to the United States. One of the IRCA's main purposes is to grant legalization to certain groups of illegal aliens with longstanding residence in the United States. The legislative history indicated that Congress believed that the legalization program should be implemented in a "liberal and generous fashion." The House Judiciary Committee was concerned that "unnecessarily rigid demands for proof of eligibility could seriously impede the success of the legalization effort."

To achieve the purposes of Congress, IRCA provides that persons who have lived continuously and unlawfully in the United States since January 1, 1982 may become lawful permanent residents if they satisfy certain conditions. IRCA requires nonimmigrant aliens -- aliens who are in the United States for a specified purpose and for limited time -- to show that they lived "continuously and unlawfully" in the United States, and were "known to the government," as of January 1, 1982, in order to qualify for legalization.

The Immigration and Naturalization Service ("INS") has statutory authority to promulgate regulations establishing criteria and procedures for the legalization process and to adjudicate individual cases arising under the Act, subject to judicial review as provided in the Administrative Procedure Act. However, INS adjudicators are not empowered to invalidate agency regulations. The only opportunity for an alien to challenge INS regulations is to surrender for deportation and then appeal the deportation order in federal court.

In 1988, the INS promulgated regulations interpreting the statutory requirements of "continuous unlawful residence" and "known to the government."

The category of illegal aliens at issue in this case includes nonimmigrants who failed to comply with the registration requirements of section 265 of the Immigration and Naturalization Act ("INA"), a prior related statute. Under section 265, nonimmigrants were required to register with INS by January 30 of each year and to notify INS of their address at the end of each three-month period. The INS promulgated regulations, published in the C.F.R., which stated that nonimmigrants who had failed to meet the registration requirement could <u>not</u> satisfy the "known to the

government" requirement within the meaning of IRCA legalization process.

Several individuals and organizations filed suit in federal district court challenging INS policy and regulations. The plaintiffs included five individual nonimmigrants and seven organizations that assist nonimmigrants throughout the legalization process. The individual plaintiffs are nonimmigrants who are threatened with deportation as illegal aliens. The organizational plaintiffs have asserted that the INS policy has caused and will continue to cause harm to the organizations by draining organizational resources and impairing their ability to assist and counsel nonimmigrants. Their challenge to INS policy and regulations focused on the agency's interpretation of the "known to the government" requirement.

The INS regulations are clear on their face that section 265 nonimmigrants will be denied legalization under IRCA. As written the regulations will not allow applicants to use their previous noncompliance with section 265 as a means of proving that their unlawful status was "known to the government under IRCA." The record shows that before January 1, 1982, the INS reviewed agency records to determine whether nonimmigrants had complied with the reporting requirements of section 265. The absence of the required 265 report identified those who were in violation of the registration requirement.

The INS argues that its interpretation of "known to the government" should be upheld. At the same time, the INS argues that its "law" in this area is unsettled because it is in the process of developing a new policy through case by case adjudication in light of new directives from the President. It is unlikely that the new policy will result in greater flexibility in the legalization process. In fact, INS legalization officers have informed both groups of plaintiffs, the organizational plaintiffs and the individual nonimmigrants, that section 265 applicants would be denied.

Plaintiffs argued before the federal district court that noncompliance with section 265 should satisfy some of the statutory requirements for legalization under IRCA. In particular, plaintiffs urged that failure to comply with section 265 was sufficient to show that these nonimmigrants were unlawful residents of the U.S. and that their unlawful status was "known to the government" within the meaning of IRCA. Accordingly, plaintiffs argued that INS policy was invalid because it did not permit this group of nonimmigrants to satisfy IRCA legalization requirements by showing that they failed to comply with the registration and notice

requirements of section 265. Plaintiffs challenged those regulations in federal district court on both statutory and constitutional grounds.

The contentions raised by the INS in this appeal were all argued by the agency in the district court. The district court rejected all of the agency's contentions. The court found that the agency had a set policy regarding section 265 nonimmigrants and further that the INS interpretation of "known to the government" was erroneous. The district court further concluded that INS policy regarding section 265 nonimmigrants was inconsistent with congressional intent. It granted both declaratory and injunctive relief in favor of plaintiffs.

On appeal, the agency maintains that its policies and regulations are valid because its interpretation of the "known to the government" requirement was valid in relation to section 265 nonimmigrants and, therefore, that the district court exceeded its authority to grant relief to the plaintiffs under the applicable standard of review. As an alternative position, the INS asserts that the district court erred in failing to stay its hand while the INS was developing a "new" policy through case by case adjudication. In other words, the agency's alternative argument is that it, in effect, had no settled policy regarding the section 265 nonimmigrants and that, consequently, the plaintiffs' contentions regarding section 265 nonimmigrants were not ripe for judicial review. Specifically, the INS contended that its interpretation of the statutory requirement of "known to the government" was still too unsettled to form a basis for judicial review. In another prong of its attack, the INS has also asserted that the plaintiffs lacked standing and had failed to exhaust administrative remedies.

Decide the appeal. Explain fully.