

**FINAL EXAMINATION
ADMINISTRATIVE LAW
PROFESSOR POWER**

Time: Three Hours
Closed Book

INSTRUCTIONS

This is a three-hour, closed book examination. It consists of two 90-minute essay questions. Each will be weighed equally. Each question has two sub-parts, however, and you should follow the time recommendations for each sub-part.

The examination contains 6 pages. Be certain that you have the entire examination. The questions are on pages 2 to 6. Section 553, 554, 556, 557 and 706 of the Administrative Procedure Act are on pages 7 to 13. Do not assume that this makes them relevant in whole or in part, or that they are the only relevant statutory provisions.

Please write your examination number on this examination in the upper right hand corner of this page. Also, write your number on each exam book you use. If you use more than one book, write the total on the first book (e.g., book 1/3).

It is essential that your writing be legible. You will not be given credit for illegible answers. **Please write on only one side of each page.** If your handwriting makes it necessary, write on every other line. If you have any doubt about the clarity of your handwriting, this means you.

Do not play the trombone during the examination.

If you find it necessary to make any assumption as to law or fact in writing your answer, please state the assumption and explain why you are making it.

I. (90 minutes)

The Department of Real Estate Control (DREC), a previously unknown federal agency, was recently created to oversee real estate brokers and salespersons. The statute establishing the Department provides in pertinent part as follows:

Preamble: In order to achieve confidence in the fairness of real estate transactions, to encourage more sales of real estate, and to improve the caliber of real estate brokers and salespersons;

I.) There shall be a Department of Real Estate Control in the Executive Branch, headed by a Secretary.

II.) The Department of Real Estate Control may from time to time adopt reasonable rules and regulations to aid it in its mission.

III.) The Department of Real Estate Control shall issue brokers or sales licenses only to individuals who prove themselves fit by ability, experience and moral character. No one may broker or otherwise represent a buyer or seller of real estate without first obtaining a license.

A. (45 minutes) Soon after being sworn into office, the first Secretary of Real Estate, Tara Blackacre, was visited by Dewey Cheatum, chair of the American Bar Association's Section of Real Estate. Cheatum was concerned that someone might read the Act to apply to attorneys representing parties to real estate transactions, and not just to the brokers or salespersons who bring the parties together. Cheatum pointed out that attorneys rarely participate in the early stages of a real estate transaction (listings, showings, general agreement on price), but instead come in to draft and negotiate contracts, mortgage documents, and deeds after the basic deal has been made. Cheatum suggested to Blackacre that the apparent inclusion of attorneys should be remedied as soon as possible.

You are the General Counsel of the DREC. Secretary Blackacre wants to know whether the Department can exempt attorneys from the license requirement, or grant all attorneys a license, or officially characterize the Act as not applicable to attorneys, or, as Blackacre put it, "do something to make it easy for attorneys to qualify." Give Blackacre your best advice as to what can be done and how to do it. Give as many ethical and legal options as you can, as Blackacre would like to choose among several alternatives.

B. (45 minutes) Assume that the attorney issue has been resolved and the Department has been chugging along for a couple of years. As was expected, the Department was engulfed in applications for licenses and muddled along as well as it could. One day, Secretary Blackacre decided the Department could cut down on the volume of paperwork by being more precise about qualifications. Accordingly, her assistants studied the Department's treatment of

applications and determined that it rarely granted licenses to persons with less than two years of experience, almost always concluding that such persons lacked the necessary skills or ability. The Department therefore proposed and eventually adopted a rule that established two years of experience as a minimum requirement for a license.

You are now an attorney in private practice (the revolving door between government and Washington law firms turns very quickly). Caldwell Banker visits you. Banker is one of the few persons who received a license without two years of experience. He just received a registered letter from the DREC that reads in part as follows:

“On information and belief, the Enforcement Division of the DREC has concluded that you are no longer eligible for a broker’s license. Please surrender your license within 10 days of receiving this letter, or, if you choose to contest this determination, show up at DREC headquarters, Room 754, to make your presentation before the Office of Hearings and Appeals.”

Banker wants to know if the Department has the authority to adopt this rule, the legal sufficiency of the letter he received, and the procedures DREC would have to follow to take away or decline to renew his license. **ASSUME THAT IF AUTHORIZED BY STATUTE, THE DEPARTMENT’S RULE WAS VALIDLY ADOPTED.**

II. (90 minutes)

It is July, 1993. Some scientists believe they have discovered the cure for the common cold. The scientists form a company called the Cold Cure Company, or “CCC” for short, to market the product, which they call Coldcure. Coldcure is a compound of chemicals combined in a secret process. Curiously, all of the ingredients are also found in chicken soup. Nonetheless, Coldcure is classified as a drug under the Food, Drug and Cosmetic Act. That Act provides in pertinent part:

Section 355(a). No person shall introduce or deliver for introduction into commerce any new drug, unless an approval of an application filed pursuant to subsection (b) of this section is effective with respect to such drug.

(b). Any person may file with the Commissioner of the Food and Drug Administration an application with respect to any drug subject to the provisions of subsection (a).

(c). Within 180 days after the filing of an application under this subsection, the Commissioner shall either -

(1) approve the application if the Commissioner finds that none of the grounds for denying approval specified in subsection (d) of this section applies; or

(2) give the applicant notice of an opportunity to present evidence and argument under subsection (d) on the question of whether such application should be approved. If the applicant agrees, a transcript should be made of the proceeding and all documents relating to the matter should be kept with the transcript and available to the public.

(d). If the Commissioner finds, after conducting an appropriate factual inquiry, that (1) the results of tests show that such drug is unsafe for human use under the conditions prescribed for use, or (2) evaluated on the basis of any information before the Commissioner, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions prescribed for use, he or she shall issue an order refusing to approve the application. As used in this subsection, the term “substantial evidence” means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the safety and effectiveness of the drug involved.

The directors of CCC want to market Coldcure as soon as possible and promptly file an application under Section 355(b). In response to a growing public clamor, FDA Commissioner David Kessler schedules the matter for a proceeding before Administrative Law Judge Ah Chu. A number of entities submit evidence at the proceeding. Central to the decisions eventually reached by ALJ Chu and Commissioner Kessler are the following:

1. Testimony by Dr. Beverly Crusher, a consultant to the FDA. She testified to the results of tests conducted under her supervision. Those tests, using the accepted “double blind” method of drug testing, compared the experiences of patients who received Coldcure to the experiences of patients who received a placebo. 40% of the users of each product reported an improvement in their symptoms, which is typical of people who erroneously believe they are receiving medicine. Crusher accordingly concluded that there was no meaningful distinction between the use of Coldcure and the use of the placebo.

2. Testimony by Dr. Leonard McCoy, a viral specialist with the National Institute of Health. Dr. McCoy testified that his review of the tests conducted by CCC and his own preliminary observations indicated that Coldcure was unlikely to do any harm. That is, each of the tests to date indicated that all of the chemicals in the compound were metabolized and left the body within several hours after digestion. Upon questioning by ALJ Chu, McCoy admitted that no long term studies had been conducted, but noted that “if everything leaves the body, it is very unlikely to have any harmful long-term effect.”

3. Dr. Julian Bashir, a pharmacologist employed by the FDA, testified concerning his evaluation of animal studies CCC submitted as part of the new drug application. Dr. Bashir testified that the animal studies indicated that cats and dogs with colds seemed to improve with Coldcure and none of them developed adverse side effects.

4. Dr. Catherine Pulaski, head chemist with the Association of Major Pharmaceutical Manufacturers, testified that in her opinion, there was insufficient data to evaluate properly the safety or effectiveness of the drug. She pointed out that the harmful side effects of many new drugs are not apparent until after several years of use and that the apparently favorable results of Coldcure on cats and dogs were not clearly duplicated when monkeys, which are genetically much closer to humans, were tested. She also pointed out that in every new drug application proceeding of recent years, the FDA had concluded that several years of testing were necessary before approval.

At the hearing, attorneys for the AMPA attempted to cross-examine Crusher, McCoy and Bashir, but were denied the opportunity by ALJ Chu, who said “we appreciate your evidence and argument, but I will handle all questioning of witnesses.”

A.) (20 Minutes) Assume that Administrative Law Judge Chu issues an initial decision granting the application. The AMPA immediately files suit in federal court to set aside the decision. The FDA and CCC move to dismiss AMPA’s suit on all arguably applicable grounds. You are the

judge. Draft an opinion **granting** the motion to dismiss.

B.) (70 Minutes) After you dismiss the case, the matter proceeds within the FDA. Commissioner Kessler announces that he will review the record and decide whether to grant the application. Three weeks later, he issues a document headed “Statement and Order.” It states that he studied the transcript of the hearing before ALJ Chu and all other items in the record, and that he adopts Chu’s decision as his own. The document concludes:

“Accordingly, I find that it is more likely than not that Coldcure is effective and safe, and therefore approve its sale in commerce in the United States.”

As soon as it learns of Commissioner Kessler’s decision, the AMPA files another suit in your court, arguing that the decision should be set aside under the appropriate provisions of APA section 706(2). The FDA and CCC defend the decision on the merits. Write an opinion either upholding or setting aside the Commissioner’s decision. If you wish to weasel out in part, you may pretend to be a 3-judge court and include a dissenting opinion.