Professor Larry A. Bakken
Law/Grad Bldg. – Room 220E
Office: 651-523-2189
Home: 763-521-6011
E-mail: lbakken@hamline.edu

Office Hours:
Mon. Wed. Fri.: 9:00 a.m.-10:00 a.m.
Saturday: 11:30 a.m.- 12:15 p.m.
other times by appointment
Students are welcome

Syllabus
ADMINISTRATIVE LAW
Fall 2010 – Room LAW 04
8:15am-11:15 a.m. Saturday

REQUIRED TEXT: **Administrative Law: 2nd ed.**
Roger Healy, Krotoszynski Aspen Pub, 2008,
ISBN 13-978-0-7355-7142-6

RECOMMENDED READING: **Administrative Law and Process in a Nutshell**
Gellhorn & Levin West 6thd ed. 2006,
ISBN-0-314-14436-6

WESTLAW TWEN SITE: Register before first day of class.

PURPOSE: Administrative Law incorporates public policy, economic social values, politics, and basic democratic principles into an understanding of government decision making. Administrative law includes regulatory compliance and enforcement of legislation, rules/regulations and adjudications. Administrative Law also engages the legislature, the chief executive, government agencies and the judiciary. This course attempts to make students aware of current developments, and to inform students about the law of public administration and its impact on the interaction of individual citizens with government bureaucracy. In addition student attention will be directed to the ongoing constitutional dialogue that occurs in regard to agency policy, agency rulemaking and adjudication. Finally students will develop an understanding and appreciation for administrative powers, procedures and practices.

COVERAGE: Administrative Law will mean different things to different people. Practicing lawyers, judges, bureaucrats, students and citizens have different perspectives and points of view about government regulations, regulatory compliance, judicial oversight and legislative directives. One's point of view, personal values and political orientation will influence how one responds to issues addressed by agencies and appellate courts. Administrative Law requires those studying this area of law to consider the particularities of the organic (enabling) statute, the rules and procedures of the agency; the historical, political economic and social factors; judicial decisions, agency procedures and constitutional standards. Specific attention will be given to the history and development of administrative regulations and the law associated with government agencies especially federal agencies. Special time and energy will be devoted to the Administrative Procedure Act which establishes standards for agency procedural requirements, rulemaking, adjudication and requirements for public participation in agency decision making. Attention and time will also be allocated to the Freedom of Information Act, The Open Meeting Act, Negotiated Rulemaking, The Role of Administrative Law Judges the Privacy Act, The Advisory Committee Act, and The ADR Act and Administrative "Due Process". Time will also be devoted to practice aspects of Administrative Law.

CLASS FORMAT: Lectures, group participation, questions/answers, class discussion, case studies and study of appropriate statutes and case law. Includes reading assignments, preparation of an agency comment, optional research paper and a final exam.

OBJECTIVES: Introduce students to the regulatory role of agencies and their legal and political limits; provide a brief history and background for understanding the development of administrative law, quasi- legislative and quasi-judicial aspects of agency action; and the importance of informal aspects of administrative law. Provide students with a basic understanding of federal legislation important to administrative practices. Students should, when the class is complete be familiar with the classic cases of administrative law, the changing emphasis regarding standards within administrative law and recent developments in administrative law. Students will learn the importance of procedural questions and how procedure differs in rulemaking and adjudication, formal and informal actions and in how courts review administrative action. Finally students will learn about the powers of the executive and Congress and how they influence agency actions.

FINAL EXAMINATION AND GRADING POLICY: Three-hour final examination. The exam accounts for two-thirds (2/3) of the final grade. The instructor reserves the right to increase the final exam grade by one half grade for any student making significant positive and regular contribution to class discussion. One third (1/3) of the final grade will be based upon a written assignment (comment).

COMMENT-WRITTEN ASSIGNMENT: You have been approached by a representative of Lose Weight Now be Healthy Tomorrow (LWBHT) a non-profit organization. **LWBHT** believes the Food and Drug Administration should approve the Qnexa weight loss drug from Vivus Inc. The only information you have been given are the attached newspaper articles. You are told there should be other information available from the company and the FDA. It is suggested you can find more information online. Make the most compelling argument possible in support of LWBHT. (Additional information will be available later.)

The assignment shall be six to seven (6-7) pages, typed and double-spaced pages. The text should be 12-point font. Margins should be 1" on the right side, top, bottom, and left margins should be 1 ¼". **The Comment must be submitted to TWEN by 12 Midnight Nov. 20, 2010.**

OPTIONAL: Students may submit a research paper for a portion of their final grade. If the paper is C+ quality or better, the final course grad**e will be raised one-half grade. The topic of the paper and a brief outline (1 page) must be approved by the instructor and submitted to him in class by November 11, 2010**. The paper should be a typed, double-spaced, and 18-20 pages in length. Text should be in a 12-point font Margins should be 1" on the right side and top; bottom, and left margins should be 1¼". The paper should include a table of contents, footnotes, bibliography and a separate two page executive summary. **The extra credit paper must be submitted to TWEN by 12:00 Midnight November 20, 2010.** The final copy will <u>not</u> be returned.

ATTENDANCE: Students are expected to attend class and be prepared each day. According to school policy, students may miss six hours of class. When students miss the seventh hour of class a ten-page paper must be submitted to the instructor. If an eighth hour of class is missed, a second ten-page typed paper will be turned in. On the ninth hour missed, the name of the student will be submitted to the Dean's office and the student will be dropped from the class. Remember each session is three hours. This policy becomes operational after you miss the two days of classes.

COMPUTER POLICY - You may use laptop computers or other electronic devices in class to take notes and access course related materials. You should not use your laptop or electronic devices for other purposes.

In addition to the usual courtesies due to your classmates, refrain from text-messaging and email, using cell phones, pagers, or any other communication device. Refrain also from displaying wallpaper, screen savers, or other material on your computer screen that can reasonably be expected to distract your classmates.

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FDA Panel Rejects Weight-Loss Drug

By Jennifer Corbett Dooren

WASHINGTON—A federal advisory panel Thursday narrowly rejected **Vivus** Inc.'s experimental weight-loss drug Qnexa on concerns potential safety issues could be magnified if it were used by millions of patients.

The Food and Drug Administration's advisory panel of medical experts voted 10-to-6 against recommending approval for Qnexa in obese and certain overweight patients who also have another health problem such as diabetes or high blood pressure.

The vote was initially 9-to-7 against, but one panel member changed his vote as the committee discussed the pros and cons.

The FDA usually follows its panel recommendations but isn't required to, and it often considers close votes a split decision.

Qnexa combines low doses of two older drugs: the stimulant phentermine, which cuts appetite, and topiramate, which increases the sense of feeling full.

The review of Qnexa by the FDA's endocrinologic and metabolic drugs advisory committee was being carefully watched by other companies with obesity drugs in development. **Arena Pharmaceuticals** Inc.'s lorcaserin will face an FDA panel in September, and **Orexigen Therapeutics** Inc.'s Contrave is tentatively scheduled for a December panel review. The three drugs use different methods of damping appetite.

Arena shares were up 12% in after-hours trading Thursday, while Orexigen's stock was down 10%. Trading in Vivus shares was halted Thursday.

The FDA said Qnexa resulted in "significant" weight loss, but the agency raised questions about the drug's long-term side effects, including birth defects, depression and an unknown impact on the heart. Some patients in clinical studies had an increase in heart rate.

In a statement, Vivus Chief Executive Leland Wilson said the company was disappointed by the panel's decision but said it would work with the FDA in advance of an Oct. 28 deadline to rule on the drug. Additional clinical data is expected this quarter.

F.D.A. Panel Votes Against Obesity Drug

By ANDREW POLLACK

A federal advisory committee voted narrowly against endorsing a drug vying to become the first new prescription medicine for obesity in more than a decade, signaling heightened concerns for possible health risks associated with a new generation of diet pills.

The advisory committee to the Food and Drug Administration voted 10 to 6 that the safety concerns, like increased heart rate, possible birth defects and psychiatric problems, overrode the potential benefits of the drug, called Qnexa and developed by Vivus.

The meeting was closely watched by both the medical community and Wall Street as a sign of how the F.D.A. might handle new obesity drugs. Typically, the agency has paid extraordinary attention to safety because weight-loss drugs have a history of safety problems and because the medicines are likely to be used by millions of people for long periods of time.

The committee vote suggests that drug safety will continue to be paramount.

"No one wants to conduct a large public health experiment on the population," one panel member, Elaine H. Morrato of the University of Colorado, Denver, said.

The F.D.A. is scheduled to decide by late October whether to approve Qnexa. It usually abides by the advice of its advisory committees. But a split vote like this one is often viewed by the agency as less definitive. Indeed, several panel members said they could just as easily have voted the other way.

The outcome of the meeting could portend

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In 10-6 Vote, F.D.A. Panel Rejects Obesity Drug From Vivus Over Safe

From First Business Page

a more difficult time for two other new obesity drugs that will face advisory committee hearings this year — lorcaserin from Arena Pharmaceuticals and Contrave from Orexigen Therapeutics.

The F.D.A. and most panel members did not question the effectiveness of Qnexa. Results from clinical trials suggested that in reducing weight, Qnexa was superior to the currently approved drugs and to the other two possible new ones.

Those getting the highest dose of Qnexa lost an average of 10.6 percent of their weight after one year, compared to 1.7 percent for those on a placebo.

The F.D.A. had five safety concerns that the panel spent most of the day addressing: possible psychiatric problems like depression and suicidal thinking, impaired memory and concentration, acid buildup in bodily fluids that could increase the risk of kidney stones, an increase in heart rate that could portend cardiac problems and possible birth defects.

Qnexa is a combination of two already approved drugs: phentermine, the part of the fen-phen combination that remained on the market after fen-phen was withdrawn in 1997 for causing heart valve problems, and topiramate, an epilepsy and migraine drug sold as Topamax by Johnson & Johnson. Phentermine, a stimulant, is responsible for the faster heartbeat, and topiramate causes the other side effects.

Leland F. Wilson, the chief executive of Vivus, said the company was disappointed with the vote but not deterred from trying to win approval. "The advisory committee vote is a recommendation, not a final step," he said in a brief conference call.

Trading in Vivus, based in Mountain View, Calif., was halted on Thursday during the panel's meeting, but shares plummeted 56 percent, to $5.27, in early after-hours trading. Shares of both Orexigen and Arena fell late in the day after the committee vote.

In after-hours trading, however, Arena was up somewhat. That could be because investors see its drug as having a better safety profile than Qnexa, although it is less effective in reducing weight.

About one-third of American adults are obese and another third overweight, so a successful diet drug could garner sales of billions of dollars a year.

Yet there have been few, if any, successful obesity drugs. The two existing drugs approved for long-term use — Meridia from Abbott Laboratories and Xenical from Roche — have modest sales, in part because of side effects and limited efficacy. Three years ago, the F.D.A. declined to approve rimonabant from Sanofi-Aventis because of concerns about suicide risk and depression.

Vivus argued on Thursday that obesity itself was a health risk, associated with a higher risk of diabetes, heart disease and other problems. "Obesity treatment can improve health and save health care dollars," Dr. Louis J. Aronne, an obesity expert at Weill Cornell Medical College and a consultant to Vivus, told the committee. "Weight loss now appears to be like a gift that keeps on giving."

A move that could bode poorly for two other diet pills.

In the trial, Qnexa improved blood pressure, blood sugar and cholesterol levels. But Dr. Mary

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