

Compliance Issues in the Life Sciences: Advertising, Promotion & Transparency

HLTH 7590

Course Description

This course provides an overview of the laws, regulations, guidances and enforcement actions related to the advertising and promotion of prescription drugs and medical devices, including direct-to-consumer advertising, scientific and educational activities and off-label promotion, the drug and device industry's approach to self-regulation, the FDA's evolving approach to the use of social media tools for drug and device marketing and patient relations, First Amendment protections applicable to advertising and promotion, and transparency and disclosure requirements.

Readings

All readings for this course are available in a [custom-made textbook, which is available for purchase through XanEdu.](#)

Weekly Schedule

Week	Topic
1	Overview and DTC Ads
2	Life Science Companies and the First Amendment
3-4	Scientific and Educational Activities
5-6	Social Media and Patient Relations
7	Transparency and Disclosure
8	Recent Developments

Course Outcomes

Upon completion of the course, students will be able to:

- CO 1. Identify and interpret key sources of law applicable to drug and device advertising and promotion, and explain what companies must do to comply with these requirements.
- CO 2. Assess the industry's approach to self-regulation with respect to (1) direct-to-consumer advertising and (2) educational and scientific exchange between manufacturers and health care professionals.
- CO 3. Explain the FDA's new social media guidances and evaluate their impact on drug and device manufacturers' use of Internet platforms for advertising, promotion, and patient relations.
- CO 4. Summarize the transparency and disclosure requirements applicable to drug and device manufacturers and assess their impact on companies' relationships with health care providers.
- CO 5. Recognize the First Amendment arguments that have been raised against laws and regulations related to advertising and promotion.
- CO 6. Analyze real-world situations related to drug and device advertising and promotion, in order to spot legal issues and formulate options.
- CO 7. Develop strategies for avoiding government enforcement action by designing policies and practices that reflect legal requirements.
- CO 8. Recognize situations in which professional legal advice is necessary and communicate effectively with legal counsel.

Overview of Course Activities

Activity #1: Tutorial Questions

The Tutorial Questions are weekly assignments designed to ensure that you have an accurate understanding of the key points in the readings. Answers to these questions can be any length. Your goal should be to accurately state the relevant points of law as concisely as possible. Your professor will provide feedback and guidance on your responses.

Answers are due by 11:59PM on Wednesday.

Tutorial Questions for week 1 are available with the [first week's assignments](#). Tutorial Questions for the remaining weeks of the course are available on the Blackboard course site.

Activity #2: Discussion Questions

A "threaded discussion" is a discussion forum that allows students to respond to questions posted by the professor (original responses), which can then be read by other users who add their own comments in response (secondary postings). Unlike chat rooms and other "real-time" interaction forums, threaded discussions do not require different users to be logged on at the same time.

Discussion questions are assigned each week. **Original responses to these questions must be posted by Thursday at 11:59PM.** Original responses must be at least **250 words** and must incorporate concepts from the lectures and assigned readings.

Secondary Responses/Postings: Each student must post **two or more** secondary responses to other students' postings **for each discussion question**. Secondary responses are due by **11:59PM on the Monday following the week in which the questions were assigned**. They must be a minimum of **150 words** and, like original responses, should incorporate concepts from the lectures and assigned readings. Students are encouraged to embark on interactive discussions that go beyond the minimum number of secondary postings.

Although the discussion board is expected to be student-driven, professors will be participating in the discussions as well.

Discussion Questions for week 1 are available with the [first week's assignments](#). Discussion Questions for the remaining weeks of the course are available on the Blackboard course site.

Activity #3 – The Truth in Medical Advertising Act

This activity is due on Saturday of Week 2. Further information is available on the Blackboard course site.

Activity #4 – Recommendations on Scientific and Educational Activities

This activity is due on Saturday of Week 4. Further information is available on the Blackboard course site.

Activity #5 – Guidance for Marketing Team on Use of Social Media

This activity is due on Saturday of Week 6. Further information is available on the Blackboard course site.

Activity #6 – Capstone Project

This activity is due on Saturday of Week 8. Further information is available on the Blackboard course site.

Grading

ACTIVITIES	% OF FINAL GRADE
Activity #1: Tutorial Questions	25%
Activity #2: Discussion Questions	25%
Activity #3: The Truth in Medical Advertising Act	12.5%
Activity #4: Recommendations on Scientific and Educational Activities	12.5%
Activity #5: Guidance for Marketing Team on Use of Social Media	12.5%
Activity #6: Capstone Project	12.5%

Responses to the Tutorial Questions and Discussion Questions will be graded each week in which they are assigned. At the end of the course, the lowest grade you receive for the Tutorial Questions and for the Discussion Questions will be dropped and will not be counted towards your final grade for the course. The purpose of this policy is to accommodate unanticipated professional or personal scheduling conflicts that may arise during the course.

IMPORTANT: You are required to post a *minimum* of one 250-word main post plus two 150-word secondary posts to each weekly discussion thread/topic. Your weekly discussion board grade will be based upon the quantity and overall quality of your postings.

Late Activities: For purposes of grading, activities and assignments that are submitted late will be treated as not having been submitted at all. The professor may make exceptions to this policy for true emergencies, such as serious illness. Requests for exceptions should be made in advance of the deadline, if possible. The professor's decision to grant or deny a request for an exception is final and unreviewable.

The following grade scale will be used to calculate final grades. The following is an explanation of how points equate to grades, based on a 4.33-point scale:

Grade	Quantitative	Qualitative	Definition
A+	4.33	Excellent	Superior understanding of the content and method of the course, extraordinary ability to recognize relationships between concepts, initiative in doing work in which quality consistently surpasses that required.
A	4.00		
A-	3.67		
B+	3.33	Good	Good understanding of the content and method of the course, demonstrated ability to recognize relationships between concepts, substantial achievement of course objectives and fulfillment of course requirements.
B	3.00		
B-	2.67	Fair	Rudimentary understanding of the content and method of the course, limited recognition of relationships between concepts, basic but incomplete achievement of course objectives and requirements.
C+	2.33		
C	2.00		
C-	1.67	Unsatisfactory	Little understanding of the content and method of the course, inability to demonstrate minimum recognition of relationships between concepts, unsatisfactory achievement of course objectives and requirements.
D+	1.33		
D	1.00		
F	0.00	Failure	Lack of understanding of the content and method of the course, failure to achieve objectives and/or complete requirements of the course.

Grades are based strictly on individual performance, not on any external factors (e.g., tuition reimbursement policies at your place of employment). Any questions about grades must be made in writing.