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Course Description
Drug utilization research forms a core backbone of the field of pharmacoepidemiology. This is because the determinants of the utilization of prescription drugs are complex and multifactorial, and understanding how, why, when and where drugs are used is crucial to inform both regulatory and payment policy as well as clinical practice. This course will begin with an overview of drug classification systems as well as a review of data sources used for drug utilization research, ranging from primary data collection using surveys and audits of patients and providers to secondary data from administrative claims, electronic health information and other sources. We will review methods of investigating drug utilization and evaluating interventions to modify utilization, such as time-series designs and segmented regression analyses. We will then consider varied patient, provider, practice and system-level determinants of prescription drug utilization, including their impact on costs and quality of care. Particular emphasis will be devoted to the impact of drug formularies, marketing and promotion, health insurance, and emerging evidence of benefits and harms. Core topical areas such as adherence and value-based insurance designs, as well as current challenges and opportunities regarding topically important areas such as biosimilars and the opioid epidemic, will also be covered.
Course Objectives
This course is designed to provide participants with a foundation for understanding one core domain of pharmacoepidemiology - drug utilization. At the conclusion of this course students should be able to:

1. **Apply** knowledge to a critical discourse demonstrating intermediate/advanced knowledge of the determinants of drug utilization, including the effect of marketing and promotion, pharmaceutical regulation, and payment policies.

2. Critically **evaluate** studies that examine drug utilization through a firm understanding of analytic approaches of such studies as well as the numerous determinants and predictors of utilization.

3. **Create** rigorous evaluations of drug utilization by employing knowledge of drug taxonomies, data sources, data interpretation, and implications for public policy and clinical care.

Course Organization

*Required Textbook:* None

*Recommended Textbook:*

*Readings:*
The required readings will be available on the course website. Additional recommended readings are provided for students who are particularly interested in a topic and who seek additional enrichment. All readings can be downloaded and printed out from the course’s E-reserve website.

*Lectures:*
This course consists of a series of lecture sessions as well as interspersed small group and independent activities. The class will meet every Tuesday and Thursday during the 3rd Term at 8:30 AM in W4007. Students are expected to attend ALL classes and attendance will be taken at the discretion of the instructor or teaching assistant. Select guest speakers will be incorporated to provide information and expertise in a particular field.

*Participation:*
Students are expected to attend every lecture, complete assigned readings and actively participate in class discussions in class and on the discussion forum. We will begin many classes with the opportunity to ask questions about the pre-assigned readings, which will help to set the stage for and prioritize in-class discussions. Students are also expected to follow media coverage of relevant topics in pharmaceutical utilization during the course (e.g., the opioid epidemic, changes in relevant FDA regulations). These issues will be used regularly to illustrate class concepts. Class participation will be based in part on your understanding and critical assessment of didactic material, class readings and topically important areas of pharmaceutical utilization. The structure of this class is primarily seminar-style. Thus, active participation in instructor-led class discussions by all students is critical to creating an engaging environment in which all of us can learn. Additionally, students will be expected to participate in regular in-class workshops and activities.
Pharmacoepidemiology: Drug Utilization
2018 – 2019 Syllabus

Assignments & Grading:
Students are expected to complete all required readings. These readings have been kept to a minimum and focus on areas highly relevant to the class content. Readings are listed on the syllabus for the date they are due. Additionally, there will be weekly activities that will not be possible to do well without completing the reading.

Final grades will be determined based on the following:
- Class Participation – 20%
  - This includes attendance, CoursePlus communication and in class participation.
- Weekly exercises – 60%
  - This includes preparation, participation and performance during weekly activities that will take place during many weeks of the course. Each activity will count for between 5-15% of your final grade. Additional information will be provided for each activity during the course, although they are broadly outlined below.
  - Week 1: Drug Utilization in the News (5%)
  - Week 2: Identification of Drug Utilization Studies (5%)
  - Week 3: Critical Evaluation of a Scientific Manuscript (10%)
  - Week 4: Designing a Drug Utilization Study (15%)
  - Week 5: Short Question Generation (5%)/Evaluation of a Peer’s Drug Utilization Study (5%)
  - Week 6: Short Question Knowledge Assessments (15%)
  - Week 7: No assignment
  - Week 8: No assignment
- Final Hearing – 20%
  - We will hold a mock congressional hearing addressing a topically important area of drug utilization. Prior years have examined the use of exogenous testosterone to treat male hypogonadism, utilization and policies governing biosimilars and the opioid epidemic. I have not selected a topic for this year yet but will do so several weeks prior to the Final Hearing. For this hearing, you will be assigned to represent a major stakeholder vested in this issue, such as the FDA, drug manufacturers, patient advocates or payers. You will need to investigate your stakeholder’s position on the issue and be able to represent their perspective.

Academic Integrity:
Students are to adhere to the following Policies and Procedures of the School regarding academic ethics: "Students enrolled in the Bloomberg School of Public Health assume an obligation to conduct themselves in a manner appropriate to The Johns Hopkins University’s mission as an institution of higher education. A student is obligated to refrain from acts which he or she knows, or under the circumstances has reason to know, impair the academic integrity of the University. Violations of academic integrity include, but are not limited to: cheating; plagiarism; knowingly furnishing false information to any agent of the University for inclusion in the academic record."
### Session Topics

<table>
<thead>
<tr>
<th>Week</th>
<th>Tuesday</th>
<th>Thursday</th>
<th>Assignments/Weekly Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>(Overview:) Drug Utilization Research January 22</td>
<td>Life-cycle, Taxonomies, Data January 24</td>
<td>Posting a News Article with Commentary</td>
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<tr>
<td>2</td>
<td>Managed Care and Medication Management (Pinto) January 29</td>
<td>Methods January 31</td>
<td>Identification of Drug Utilization Study</td>
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<td>3</td>
<td>Quality and Appropriateness February 5</td>
<td>Food and Drug Administration February 7</td>
<td>Critical Evaluation of a Scientific Manuscript</td>
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<td>4</td>
<td>Emerging Benefits and Risks February 12</td>
<td>Adherence (Riekert) February 14</td>
<td>Designing a Drug Utilization Study</td>
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<td>5</td>
<td>Marketing and Promotion February 19</td>
<td>Off-label Use February 21</td>
<td>Short Question Generation Evaluation of Peer Utilization Study</td>
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<td>6</td>
<td>Psychiatric Drugs (Mojtabai) February 26</td>
<td>Generic Drugs (Greene) February 28</td>
<td>Short Answer Knowledge Assessment</td>
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<td>7</td>
<td>Prescription Opioids March 5</td>
<td>Hearing: working groups March 7</td>
<td>No assignment</td>
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<tr>
<td>8</td>
<td>Hearing: working groups March 12</td>
<td>Final Hearing March 14</td>
<td>No assignment</td>
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READINGS

Class 1 – Introduction to Drug Utilization

Required


Recommended


Class 2 – Life cycles, Taxonomies, Data

Required


type of more flexible product approval would serve.

Recommended
   The Director of the FDA’s Center for Drug Evaluation and Research (CDER) provides an accompanying editorial to the article about adaptive licensing; this piece provides some perspectives from the FDA.

   This accessible piece introduces a framework for one approach to adaptive licensing.

Class 3 – Managed Care and Medication Management (Pinto)
Required
   This report provides a helpful overview of the origins of PBMs as an industry, their performance, roles they can play in Medicare and challenges that lie ahead.

2. Effect of 6 Managed Care Pharmacy Tools: A Review Of The Literature. Journal Of Managed Care Pharmacy Supplement, July 2010, Vo.l 16, No 6-a
   This article discusses tools that are commonly used to manage pharmacy benefits.

   This is an excellent report that covers the flow of medicines from manufacturers to end consumers, as well as the flow of money and key financial relationships between relevant entities.

   The authors evaluate prior analyses that quantify how drug management programs impact health plans and patients.

Recommended
   This is a widely cited study that examines the effect of prescription cost-sharing on drug and non-drug utilization and health.

   This is another widely cited study that characterizes how pharmacy benefits impact the use of medicines by those with chronic disease.

Class 4 – Methods in Drug Utilization
Required
Pharmacoepidemiology: Drug Utilization
2018 – 2019 Syllabus

This report introduces one of the most commonly used methods in drug utilization research – interrupted time series designs.

This report also discusses interrupted time series designs.

Class 5 – Quality and Appropriateness
Required
This is a relatively recent and rigorously performed evaluation of the quality of medication use in the United States.

This article provides an excellent review of measures that can be used to assess medication appropriateness in the elderly.

This is an update to a classic article and method of assessing medication appropriateness in the elderly using explicit criteria.

Recommended
This is a classic example of an implicit medication appropriateness tool, the “Medication Appropriateness Index”.

This investigation used the National Ambulatory Medical Care Survey (NAMCS) to creatively assess the quality of medication use in the United States using cross-sectional rather than longitudinal data.
Class 6 – Food and Drug Administration

Required
   This systematic review considers the totality of evidence regarding the impact of FDA regulatory communications regarding prescription drugs.

   This commentary provides the perspective of a UK regulator regarding regulatory risk management and communication.

Recommended
   This report is included in the systematic review above and serves as one example of a study demonstrating the challenges of FDA risk communication.

   This report is also included in the systematic review above and also serves as another example of a study demonstrating the challenges of FDA risk communication.

Class 7 – Evidence of Emerging Benefits & Risks

Required
   This report is a rare one that attempts to informally synthesize information regarding what factors influence the impact of new evidence on physician prescribing.

   This commentary raises provocative questions regarding how to manage drug risk information in the era of “big data”.

Recommended
   This is a nice example of the potential unintended consequences of well-intended drug risk communications.

Pharmacoepidemiology: Drug Utilization
2018 – 2019 Syllabus

This widely cited study documents large changes in the use of post-menopausal hormone therapy based on emerging evidence of potential risks.


Class 8 – Medication Adherence (Riekert)
Required

1. Steiner JF. Rethinking adherence. Annals of Internal Medicine. 2012;157:580-585. This brief commentary addresses the inclusion of adherence quality measures by the Centers for Medicare and Medicaid Services (CMS), and considers how clinicians, organizational leaders and policy-makers will need to respond to address perennial challenges in adherence.


Recommended

3. Haynes RB, Ackloo E, Sahota N, McDonald HP, Yao X. Interventions for enhancing medication adherence. Cochrane Collaboration. 2008;4. This is a rigorous systematic review that examines the effectiveness of interventions for enhancing medication adherence.

4. Ratanawongsa N, Karter AJ, et al. Communication and medication refill adherence. JAMA Intern Med. 2013;173:210-218. This study identified that poor communication ratings of clinicians were independently associated with objective measured inadequate cardiometabolic medication refill adherence. Causation or correlation?

Class 9 - Marketing and Promotion
Required

1. Wazana A. Physicians and the pharmaceutical industry: is a gift ever just a gift? JAMA. 2000;283:373-380. This is a classic systematic review regarding the effect of physician interaction with the pharmaceutical industry.

   *This is an eloquent and well-done study using standardized patients to assess the effect of patient request on medication receipt.*

**Recommended**

   *The authors, behavioral economists, consider a variety of factors that should give pause to those supporting physician interaction with the pharmaceutical industry.*

   *This commentary considers the effect of new social media tools such a Facebook and Twitter on the regulation and conduct of pharmaceutical marketing and promotion in the digital age.*

   *This provides editorial comment on the 2019 Schwartz and Woloshin paper that is required reading.*

   *The author reviews evidence of the effect of direct-to-consumer advertising (DTCA) on a variety of outcomes.*

**Class 10 – Off-Label Use of Prescription Drugs**

**Required**

   *This study examines the frequency of off-label drug use and the degree of scientific evidence supporting this practice.*

   *This report examines off-label utilization and policy in an important, vulnerable population - children.*

   *This survey of 600 primary care physicians and 600 psychiatrists examines physician’s knowledge of the FDA-approved indications of commonly prescribed drugs.*
Recommended
   *The authors use three key factors to develop a list of drugs for which future research regarding off-label use is warranted.*

   *This study evaluates patterns of antipsychotic use and off-label prescribing.*

   *The author outlines a two-step process for controlling the use of off-label drugs.*

**Class 11 – Pharmacoepidemiology of Psychiatric Drugs (Mojtabai)**

Required
   *This provides a brief introduction to Pharmacoepidemiology of psychiatric medications and the overarching concepts of psychopharmacoepidemiology*

   *This study examines trends in psychotropic medication use among noninstitutionalized US adults.*

Recommended
   *The authors seek to demonstrate selection bias may be present in RCTs where treatment effect varies across individuals.*

   *This study compares psychotropic medication treatment patterns between youth in the US and Western Europe and possible explanations for these differences.*

**Class 12 – Generic Drug Utilization**

Required
   *The authors examine adherence rates in patients enrolled in 3-tier pharmacy benefit plans and receiving generic of preferred brand-name agents.*
This study estimates the cost savings and reductions in direct spending associated with the FDA’s lower-cost approval pathway requirements for biosimilars.

This article provides perspective on the history of bioequivalence as well as the concept of “bioequivalence” as a joint regulatory and scientific creation.

Recommended
This article reviews the history of trade dress, including its legal basis as well as the public health implications of variations in pill appearance.

The author discusses the unique issue of substitution of brand-name AED with generic AEDs and seizure risk.

This article from 1979 outlines the relevant real world issues at the time of its publish.

This New York Times article draws light on Generic drug companies and the scientific, legal and regulatory process by which they market generics.

The authors examine whether nonadherence and nonpersistent use of generic drugs is associated with varying color or shape between generics.

Class 13 – Prescription Opioid Epidemic
Required
This study examines the association between maximum prescribed daily dose and dosing schedule with risk of opioid overdose death.

This review offers a critical look at studies supporting the notion that opioid addiction is rare during chronic opioid therapy.
Recommended


This review provides the scope and background of this epidemic as well as a framework for interventions to address the epidemic.


The authors discuss the effectiveness and risks of long-term opioid therapy as well as safer prescribing including how to balance benefits and risks.


This is a well designed study that adds to growing literature that early opioid prescribing patterns are associated with long term use.


This monograph provides comprehensive, concrete, evidence-based solutions to reverse the opioid epidemic.

Activity #1. Identification of Drug Utilization Studies.

Over the course of the term you will be expected to be able to correctly identify a drug utilization study. In order to ensure that you are aware of what constitutes a drug utilization study and what does not, you will be provided with 20 titles of studies and asked to identify whether or not they fall under the realm of drug utilization.

This will be provided in the form of a quiz on CoursePlus. The quiz may be taken as many times as necessary until the deadline. Please mark whether each study is or is not a utilization study. If a study has drug utilization components, mark it as a utilization study. For example, a study entitled “Safety and use of Atorvastatin” will be considered a utilization study, although it also addresses safety.

Quiz will open Tuesday, January 24th
Quiz will close Friday, February 1st at Midnight
Worth 5% of your total grade.
Activity #2. Drug Utilization in the News.

You will need to find one news article that addresses drug utilization. You will be expected to post this article on the appropriate Discussion Forum thread along with a one to two paragraph discussion of its relevance to drug utilization.

While many articles will be geared toward safety and/or effectiveness, it will be important for you to think about how these reports may impact utilization. For example, in 2012 there were numerous news stories related to the safety of epidural steroid injections connected with fungal meningitis. While these articles did not directly discuss utilization patterns, the use of steroid injections and meningitis treatments were most likely impacted by these reports. As a second example, there have been recent reports linking a commonly used class of antibiotics to increased cardiovascular risk. Such emerging scientific information might have an important impact on a variety of stakeholders (e.g., payers, regulators, health systems, professional societies) that ultimately cause changes in how this therapeutic class is used. Thinking creatively and critically about the intended and unintended consequences of news and media is an important part of understanding drug utilization. While only one article is required, we encourage you to constantly be on the lookout for this kind of news and to share it with the class via the discussion forum.

Discussion Forum posting due Monday, January 28th by Midnight
Worth 5% of your total grade.
Activity #3. Critical evaluation of a Scientific Manuscript.

Please search via PubMed for a drug utilization study that examines a clinical or policy question of importance that is also of interest to you. If you are wondering “Is this a drug utilization study?”, (re)review the course material from Class #1 and ‘Identification of Drug Utilization Studies’ activity #1. The manuscript may reflect either a descriptive or analytic study – either is fine. Be sure that you have selected a drug utilization study and contact me if you have any questions.

Answer the following:

Please very briefly summarize:

- Article citation (title, authors, journal)
- Hypothesis or Specific Aim
- Source(s) of data and types of information extracted from the data
- Primary outcome
- Main findings and major implications
- Unanswered questions

Then spend approximately half of your overall effort considering the limitations of the manuscript, and how these might have been better addressed. Consider things such as the appropriateness of the data sources and analytic approach, common threats to internal validity, and how generalizable and actionable the findings are.

Due **Sunday, February 3rd** by Midnight - submit via Dropbox

Worth 10% of your total grade.
Activity #4. Designing a Drug Utilization Study.

Select a clinical topic that is of interest to you regarding a prescription drug or therapeutic class. Develop a one-to-two page research proposal that examines some facet of drug utilization relevant to the topic proposed. Although additional elements of the proposal can be provided, be sure at a minimum to discuss the following:

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>Background</td>
<td>What is the general context for the study? What are the gaps in the current knowledge or practice in the field of study? (2 sentences)</td>
</tr>
<tr>
<td>Objectives</td>
<td>What do you, as the researcher, plan to do and expect to achieve? (2 sentences)</td>
</tr>
<tr>
<td>Study design</td>
<td>What data sources are to be used? What population is to be studied? How will the outcome be defined? What statistical approach will be undertaken? If an analytic design is proposed, what methods will be used to strengthen causal inference? For example, briefly state the dependent (or response) variables, the independent (treatment or explanatory) variables, and the factors that may need to be measured or accounted for because they might otherwise confound the analyses. (several sentences)</td>
</tr>
<tr>
<td>Limitations</td>
<td>What are key limitations? How can the threat of these be minimized? (a few sentences)</td>
</tr>
<tr>
<td>Importance</td>
<td>Why is this important? What will the implications be for one or more core stakeholders, including patients, providers, researchers and policy-makers? (a few sentences)</td>
</tr>
</tbody>
</table>

Your paper will be anonymized, evaluated and graded by one of your peers. To have a better understanding of how your paper will be evaluated, please refer to the rubric provided in the activity #5 “Evaluation of a Peer’s Drug Utilization Study”.

Due **Sunday, February 17th** by Midnight – submit via Dropbox
Worth 15% of your total grade

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1 One source of information for topically important examples is the news, of course there are many other sources for potentially interesting topics as well, such as Pub Med, National Institutes of Health (NIH) Request for Proposals, and FDA.gov, to name a few.
Activity #5. Short Question Generation

We would like for you to propose at least three open-ended questions that are relevant to course material covered thus far. Please pose questions that you believe serve as a valuable basis for further discussion. Although the ability to formulate such questions is important in its own right, we will also select a subset of these questions for Activity #7, “Short Question Knowledge Assessment”. Please submit these to the appropriate Discussion Forum thread by **Friday, February 22nd** at **Midnight**. In addition, please review questions that your peers have posted and indicate those that you believe are interesting or worth delving into by using the "Agree With" button; this will be counted as part of your attendance and participation grade. Examples of questions that have been posed in the past include:

- Some PBM’s formulary requirements, such as prior authorization, are time consuming for physicians and discourage their compliance. In addition, it is often difficult for physicians to figure out what products are on what formulary tiers. Are there any means to minimize such barriers since physicians are busy and want to ensure their patients get the most effective medication(s)?
- How do data sources from office-based audits differ from administrative claims? Name a potential study design where one would be more advantageous than the other and why.
- Assuming that poor adherence is a multifactorial issue that should be identified and resolved by multidisciplinary collaborations, what are the expected roles and responsibilities of each healthcare stakeholder (patients, providers, manufactures, regulators and payers) to improve and manage patients’ adherence?
- Why aren’t Quality Indicators the only standard for quality and appropriateness? When might they be more detrimental than helpful?

Chosen questions and instructions for Activity #7 (due **Sunday, March 10th** at **midnight**) will be uploaded to the online library promptly.

**Due Friday, February 24th by Midnight** – submit via Discussion Forum post

Worth **5% of your participation grade**
Activity #6. Evaluation of Peer’s Drug Utilization Study

You will be assigned to evaluate one of your peers’ drug utilization studies. Please use the rubric below to score your peer out of 21 points, choosing one box per row and commenting on your choice.

<table>
<thead>
<tr>
<th></th>
<th>Excellent (3 points)</th>
<th>Average (2 points)</th>
<th>Poor (1 point)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Background</strong></td>
<td>Essential context is described and gaps identified.</td>
<td>Most context is described and gaps identified.</td>
<td>Context is either insignificant or nonexistent. Gaps are not identified.</td>
</tr>
<tr>
<td><strong>Objectives</strong></td>
<td>Objective is clear and achievable.</td>
<td>Objective is only somewhat clear or impractical.</td>
<td>Objective is unclear and impossible.</td>
</tr>
<tr>
<td><strong>Study design</strong></td>
<td>Data sources, population, outcome and methods are clearly defined. Study design is as free of bias as possible.</td>
<td>Design is good. Most fields are defined.</td>
<td>Design is not present and fields are not defined.</td>
</tr>
<tr>
<td><strong>Drug utilization</strong></td>
<td>The study is a drug utilization study</td>
<td>The study has characteristics of a drug utilization study but focuses on aspects that are not drug utilization.</td>
<td>The study is not a drug utilization study.</td>
</tr>
<tr>
<td><strong>Limitations</strong></td>
<td>Key limitations are stated and their threats minimized.</td>
<td>Majority of limitations are stated and threat completely or mostly minimized.</td>
<td>Limitations are not stated and no means to minimize threat identified.</td>
</tr>
<tr>
<td><strong>Importance</strong></td>
<td>Importance is high and noted. Relevance to important stakeholders is identified.</td>
<td>Importance is somewhat high and noted. Importance and relevance to stakeholders only obliquely discussed.</td>
<td>Importance is low or not noted. Stakeholders are incorrect or not at all identified.</td>
</tr>
<tr>
<td><strong>Communication &amp; Organization</strong></td>
<td>Study is within page limit. Writing is very cogent and concise.</td>
<td>Study is within or close to page limit. Writing is moderately cogent and concise.</td>
<td>Study is far beyond or below page limit. Writing is not at all cogent or concise.</td>
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Due **Sunday, February 24th by Midnight** – submit via Dropbox.
Worth 5% of your total grade
Activity #7, Short Question Knowledge Assessment

Ten questions will be chosen from those posted to the Discussion Forum in Activity #5. Students will be required to respond to 8. A half-page, single-spaced, should suffice per answer. Outside references are not required but may be used (sparingly).

Please note that this activity is 15% of your grade and may take longer than others. We have provided you with two weeks to complete the Knowledge Assessment and hope you can use this time to your advantage.

Due Sunday, March 10th by Midnight
Worth 15% of your total grade.
Final Course Evaluation: Congressional Hearing

We will hold a mock congressional hearing addressing a topically important area of drug utilization. I have not selected a topic for this year yet but will do so several weeks prior to the Final Hearing. For this hearing, you will be assigned to represent a major stakeholder vested in this issue, such as the FDA, drug manufacturers, patient advocates or payers. You will need to investigate your stakeholder’s position on the issue and be able to represent their perspective. What follows is an example of the instructions that were used to accompany a hearing on exogenous testosterone.

Hearing on Use of Exogenous Testosterone

This hearing is for information gathering regarding the use of exogenous testosterone for the treatment of hypogonadism in middle-aged and elderly men. In other words, the assembled Congressmen and Congresswomen would like to better understand questions such as:

1. How is testosterone being used among the population?
2. What has contributed to changes in the use of testosterone over time?
3. To what degree has the utilization been consistent with high quality clinical practice?
4. What clinical, regulatory or payment strategies have been used, or could be used, to modify the use of these products so as to maximize their risk/benefit balance?
5. How effective do we believe these strategies will be?
6. Are there other therapeutic settings where similar challenges have been faced?
7. What lessons can we learn from those alternative settings?

The most important component of your preparation is your mastery and framing of the pharmacoepidemiologic literature regarding these topics. For this hearing, you will be assigned to represent one of four major stakeholders vested in these issues: pharmaceutical manufacturers, payers, patient advocates and the Food and Drug Administration.

You will need to investigate your stakeholder’s position on the issues and be able to represent their perspective. As you develop your proposal, keep in mind the real-world complexities of the problems being examined and the practical constraints that prevent a “magic bullet” solution. Some research into your specific stakeholder beyond the content covered in class is expected, though the material presented throughout the course provides background to understand many stakeholders’ perspectives. The highest quality proposals will be well researched, focused, cogent, data-driven, and present a creative yet realistic view regarding the impact that a specific stakeholder can have. Thus, successful preparation includes both content expertise (e.g., What do we know about the association between marketing and promotion of a product such as this and its utilization?) as well as an understanding of the stakeholders themselves (e.g., How to payers think about an issue such as quality of pharmacologic care for hypogonadism?).

(see next page for additional information)
Final Course Evaluation: Congressional Hearing (continued)

You will be assigned to 4-5 person stakeholder group 2 weeks before the hearing. Your group should prepare a congressional testimony addressing the above concerns to present to a panel of Congressmen and Congresswomen. Class time will be provided for group work and it is expected that groups will meet at least twice before the hearing.

The hearing will occur during our final class. Groups will have 10 to 15 minutes to present their testimony and answer questions. Like a Congressional Hearing on Capitol Hill, slides will not be used.

Groups will be graded by the Congressional Members on the basis of quality of evidence, mastery of content, presentation and communication skills, and creativity.

Worth 20% of your total grade