BIOD-766:  
Development of Vaccines and Therapeutics  

Spring 2020  
3.0 Credits  

Schar School of Policy and Government  
George Mason University

Professor Robert V. House  
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Office Hours: Virtual office hours by appointment or teleconference

Course Description

The world faces an ongoing threat from microbiological, chemical and radiological agents in the form of terrorist weapons, pandemics (particularly influenza), emerging/re-emerging diseases and asymmetric warfare. Characteristics such as high pathogenicity/toxicity and lack of appropriate animal models, as well as lack of a viable commercial market, make it difficult to develop effective medical countermeasures (MCM) for these agents. This course will explore how the US Government is developing MCM against these threats. We will explore the various threat agents, the context of regulatory considerations, and the specifics of how MCMs are developed.

Course Objectives:
1. Familiarity with USG roles and responsibilities for developing MCM, and the role that industry plays  
2. Understanding of the development process for MCM, from discovery through regulatory approval  
3. Understanding of the differences between prophylactic and therapeutic MCM, how they’re developed and how they might be used  
4. Understanding of the basic biology and pathology of select CBRN threats as they relate to MCM development and response

Readings
All readings will be available via Blackboard. Additional readings may be assigned during the semester without prior notice. There is no textbook for this course (until I write one).

Course Format and Process
We will be able to interact several different ways this semester. First, feel free to post questions to the Question and Answer section of the Discussion Board which will serve as my virtual office hours. Second, for communications that you want to be confidential or are directly related to your research proposal or research paper that would not be relevant to the rest of the class, please email me with your question. I can respond via email or we can set up a time to talk by phone. I will try to respond to all emails within 24 hours.

Assignments and Evaluation

Attendance and Participation (50%)  
Attendance at all classes is required. Class structure will be based on instructor presentations and class discussion. The reading load for this course is heavy. Students are required to read the assigned readings before each class, be prepared to discuss the reading, and actively participate in discussions. Student participation in class discussions will have a major impact on final course grades.
Students must have a firm understanding of basic biology and be comfortable with scientific nomenclature. Students will be required to share their thoughts and insights with the class. Students with direct professional and related knowledge of these subjects are especially encouraged to participate actively and help lead class discussions.

**Research Proposal and Paper (50%)**

The major writing assignment for this course is a research paper of approximately 4,000 words (16 double-spaced pages) on an approved topic. The paper must be about an issue related to MCM development or deployment. Examples might include incentives for developing MCMs (such as Priority Review Vouchers), approaches to prevent or treat recalcitrant diseases, novel mechanisms for addressing unknown threats, or strategies to address multiple threats simultaneously. These are examples only and students are strongly encouraged to demonstrate creativity in their choice of topic.

A 2-page research proposal describing the topic of your paper and how you plan on conducting your research is due by midnight EST on March 4, 2020. The research proposal should be uploaded to Blackboard as a Word file labeled as Last Name_First Name_Proposal. The paper should include a clear statement of your research question or topic, how you will conduct your research, and a short bibliography of sources you plan on using. The assigned and suggested readings will provide a foundation for your bibliography, but you are expected to find additional sources. Scholarly and academic books and journal articles and reports by reputable think tanks are preferred although for more recent events media reports are acceptable. Reports and studies published online are acceptable but web sites that simply aggregate information from other sources are not; papers citing Wikipedia will disqualify the paper. You are strongly encouraged to make an appointment with me prior to submitting the proposal to discuss the proposed research over the phone or via email. Please email me at rhouse@gmu.edu or drvhouse@gmail.com to make the necessary arrangements. If you have difficulty choosing a topic, you may elect to have me assign a topic.

The research paper is due at midnight EST on May 6, 2020. The paper should be submitted as a Word file via Blackboard labeled as Last Name_First Name_Research Paper. The paper should be double-spaced with 12-point font, 1-inch margins, numbered pages, and use the Chicago Manual of Style for footnotes. The deadline for the research paper is strict and extensions will not be permitted in the absence of a genuine emergency or documented illness. A late paper will be penalized a full letter grade (for example, from A to B) for every 24-hour period (or fraction thereof) that it is late.

Please note that this is a graduate-level course taught in English. As such, the research paper is expected to be written at a professional level. In addition to content, the paper will be evaluated for structure, grammar, spelling and logical flow.

**Workload**

The reading load for this course is heavy. I appreciate that many students work demanding jobs and that it may be difficult to complete all the reading for each week. The goal for the weekly workload for the course is 8 to 10 hours. That means you should plan to be reading somewhere between 6 and 8 hours each week.

**Blackboard**

Access to MyMason and GMU email are required to participate successfully in this course. Please make sure to update your computer and prepare yourself to begin using the online format BEFORE the first day of class. Check the IT Support Center website. Navigate to the Student Support page for help and information about Blackboard. In the menu bar to the left you will find all the tools you need to become familiar with for this course. Take time to learn each tool. Make sure you run a system check a few days before class. Become familiar with the attributes of Blackboard and online learning.

To login into the course:

2. Login using your NETID and password.

3. Click on the ‘Courses” tab.

4. Click on BIOD-766 (Spring 2020)

Technical Help
If you have difficulty with accessing Blackboard, please contact the ITU Support Center at 703.993.8870 or support@gmu.edu. If you have trouble with using the features in Blackboard, email courses@gmu.edu
University Policies & Information

**Academic Integrity**
Students must be responsible for their own work, and students and faculty must take on the responsibility of dealing explicitly with violations. The tenet must be a foundation of our university culture. [See http://academicintegrity.gmu.edu/distance].

**Honor Code**
Students must adhere to the guidelines of the George Mason University Honor Code [See http://oai.gmu.edu/the-mason-honor-code-2/].

Student members of the George Mason University community pledge not to cheat, plagiarize, steal, or lie in matters related to academic work.

**MasonLive/Email**
Students are responsible for the content of university communications sent to their George Mason University email account and are required to activate their account and check it regularly. All communication from the university, college, school, and program will be sent to students solely through their Mason email account. [See https://masonlivelogin.gmu.edu].

**Patriot Pass**
Once you sign up for your Patriot Pass, your passwords will be synchronized, and you will use your Patriot Pass username and password to log in to the following systems: Blackboard, University Libraries, MasonLive, myMason, Patriot Web, Virtual Computing Lab, and WEMS. [See https://password.gmu.edu].

**Responsible Use of Computing**
Students must follow the university policy for Responsible Use of Computing. [See http://universitypolicy.gmu.edu/university-policies/computing/].

**Students with Disabilities**
Students with disabilities who seek accommodations in a course must be registered with the George Mason University Office of Disability Services (ODS) and inform their instructor, in writing, at the beginning of the semester [See http://ods.gmu.edu].

**University Libraries**
University Libraries provides resources for distance students. [See http://library.gmu.edu/distance].

**Writing Center**
The George Mason University Writing Center staff provides a variety of resources and services (e.g., tutoring, workshops, writing guides, handbooks) intended to support students as they work to construct and share knowledge through writing. [See http://writingcenter.gmu.edu]. You can now sign up for an Online Writing Lab (OWL) session just like you sign up for a face-to-face session in the Writing Center, which means YOU set the date and time of the appointment! Learn more about the Online Writing Lab (OWL).

**Counseling and Psychological Services**
The George Mason University Counseling and Psychological Services (CAPS) staff consists of professional counseling and clinical psychologists, social workers, and counselors who offer a wide range of services (e.g., individual and group counseling, workshops and outreach programs) to enhance students' personal experience and academic performance [See http://caps.gmu.edu].
Family Educational Rights and Privacy Act (FERPA)
The Family Educational Rights and Privacy Act of 1974 (FERPA), also known as the "Buckley Amendment," is a federal law that gives protection to student educational records and provides students with certain rights. [See http://registrar.gmu.edu/privacy].

Other Considerations
If there are any issues related to religious holidays, please inform the instructor the first week of class. [See http://ulife.gmu.edu/calendar/religious-holiday-calendar/]
<table>
<thead>
<tr>
<th>Lecture</th>
<th>Topic</th>
<th>Date</th>
<th>Description</th>
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<tbody>
<tr>
<td>1</td>
<td>Introduction to Medical Countermeasures</td>
<td>1/22/20</td>
<td>This introductory lecture will begin with a class introduction and statement of purpose for the course, including expectations and pertinent course milestones. From here we will move into definitions of what medical countermeasures (MCM) are – and are not – and how they fit into the overall concepts of preparedness and CBRN logistics. A brief history of MCM development will be included.</td>
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<td>2</td>
<td>The regulatory framework for developing MCMs</td>
<td>1/29/20</td>
<td>All medical products licensed in the US must be safe and effective, in that order. In this lecture we will discuss the history of US drug regulations and how they relate to MCM development. The various strategies used to gain regulatory approval, and their relative merits, will be covered.</td>
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<td>3</td>
<td>Animal testing for safety and efficacy</td>
<td>2/5/20</td>
<td>Unless/until technology finds a replacement, nearly all medical products rely at some point on testing in animals before they can be tested in humans. This lecture will cover the basics of animal research (including a discussion on ethics) and then present the basics of testing for safety and efficacy. The FDA Animal Rule and its relevance to MCM licensure will feature heavily in this discussion.</td>
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<tr>
<td>4</td>
<td>Clinical testing for safety and efficacy</td>
<td>2/12/20</td>
<td>Before widescale use in human, MCM must be proven to be safe and effective in human studies. This lecture will cover the basics of how human trials are designed and implemented. The various phases will be compared, and alternative mechanisms of human use outside of product licensure will be described.</td>
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<td>5</td>
<td>Vaccines as MCMs: An introduction to vaccine theory and practice</td>
<td>2/19/20</td>
<td>Vaccines are a powerful tool in prevention of infectious disease and have arguably prevented more deaths than any human medical intervention. This lecture will cover the basic immunologic mechanisms whereby vaccines work, then move into a description of the various types of vaccines, comparing/contrasting them.</td>
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<td>6</td>
<td>Antibodies as MCM</td>
<td>2/26/20</td>
<td>For immunological defense, antibodies (immunoglobulins) are one of the most important mediators. This lecture will discuss the structure and biology of antibodies and how they are important in biodefense. Both polyclonal and monoclonal antibodies will be discussed, and relative advantages/disadvantages will be covered.</td>
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<td>7</td>
<td>Manufacture of biological MCM</td>
<td>3/4/20</td>
<td>This lecture will cover the fundamentals of how biological MCM are manufactured, from early discovery through “commercial” scale manufacture. Students will become familiar with the concepts of Current Good Manufacturing Practice guidelines and as well “the process is the product”.</td>
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<td>8</td>
<td>Development of MCM against bacterial threats</td>
<td>3/18/20</td>
<td>In addition to their potential use as agents of warfare or terrorism, bacteria represent a constant microbial threat to humans via natural sources. Using a selection of diverse bacterial agents, this lecture will focus on similarities and differences in how MCM are developed. Important concepts will include naturally occurring and engineered mechanisms whereby bacterial can evade MCM and how this might be addressed.</td>
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<td>9</td>
<td>Development of MCM against viral threats</td>
<td>3/25/20</td>
<td>Viruses have evolved in parallel with every form of life on earth and are arguably the most dangerous microbial threats. This lecture will review the basics of virology and then focus on a selection of viruses of concern to understand how MCM can address the threat of offensive and naturally occurring viral infections.</td>
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<td>10</td>
<td>Influenza: Pandemic and otherwise</td>
<td>4/1/20</td>
<td>More than any other microbial agent, influenza remains one of mankind’s greatest threats. This lecture will go into detail on the structure and function of the influenza virus and the disease, focusing on how the virus can evade the immune response.</td>
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<td>11</td>
<td>Development of MCM against chemical threats</td>
<td>4/8/20</td>
<td>“Better dying through chemistry”. This lecture will describe the various chemical threat classes (such as neurotoxins, metabolic toxins, blister agents, etc.) We will explore how each category of chemical threat affects the body and how existing and developmental MCM address these various forms of toxicity.</td>
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<td>12</td>
<td>Development of MCM against radiological threats</td>
<td>4/15/20</td>
<td>In the unlikely event that we don’t all die in a nuclear exchange of any size, what MCM might be available? This lecture will review the basic forms of radiation, describe in detail Acute Radiation Syndrome, and cover existing and developmental MCM to treat ARS and other radiation-related sequelae.</td>
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<td>The Enemy Within?</td>
<td>4/22/20</td>
<td>What if, instead of external threats, an adversary could turn the body against itself? This lecture will explore various actual and potential situations in which this could be realized, and the unique challenges associated with this situation.</td>
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<td>14</td>
<td>A Look Ahead</td>
<td>4/29/20</td>
<td>In this final lecture of the course we will dust off the crystal ball and try to predict near- and intermediate-range changes in MCM development and implementation. The Black Swan will make an appearance.</td>
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<td></td>
<td>Research Paper Due</td>
<td>5/6/20</td>
<td>Final research paper due by midnight.</td>
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