Medical Devices and PPE during COVID-19

Michael S. Sinha, MD, JD, MPH
Adjunct, Department of Health Sciences, California State University, East Bay
Research Fellow, Harvard-MIT Center for Regulatory Science
Affiliated Researcher, Program On Regulation, Therapeutics, And Law (PORTAL)
Teaching Faculty, Harvard Medical School Center for Bioethics
Adjunct, Northeastern University School of Law
Visiting Scholar, NUSL Center for Health Policy and Law

CHECK THE SYLLABUS!!!!
http://bit.ly/PharmaPolicy

#PharmaPolicy on Twitter

• Engage with course materials and current topics in drug law and policy by joining the conversation on Twitter!
• Counts toward participation!
• Be sure to tag the following in your tweets:
  • @DrSinhaEsq
  • #PharmaPolicy
• Optional additional tags: @US_FDA, #FDA, #COALaw, #DrugLaw, #Opioids, #MedTwitter, #LawTwitter, #HealthPolicyTwitter
• Student tweets will be highlighted at the beginning of each class
• If you want help getting started on Twitter, schedule time during office hours

Course Expectations

Midterm Assignment:
—800 word op-ed on a topic of your choosing.
—The topic must relate to the course or course materials.
—Op-ed due on March 26th

PLEASE CLEAR YOUR TOPIC WITH ME ASAP IF YOU HAVEN’T DONE SO ALREADY!!!

Science Communication

• The use of appropriate skills, media, activities, and dialogue to produce one or more of the following personal responses to science (the AEIOU vowel analogy):
  • Awareness
  • Enjoyment
  • Interest
  • Opinion-forming
  • Understanding
• Important skill for every health sciences graduate to have
• Writing is only one method of science communication

Op-eds: Audience

• Op-ed: OPINION EDITORIAL
• Audience varies depending on the publication venue:
  • JAMA, NEJM (medical professionals)
  • STAT News (scientific community)
  • Newspaper (general public)
• Imagine you are writing an article for your hometown newspaper:
  • What do you want them to understand about the topic?
  • Can you explain it in language they can understand?
  • Use your own words, don’t quote others
  • You don’t need to say “I believe that...” or “I feel that...”
Course Expectations

Presentation:
— You will give a short presentation based on your op-ed
— Length will be determined by number of students in class
  (most likely 3-5 minutes)
— More details to come

Course Expectations

Final Exam:
— This will be a take-home exam consisting of a 2-page formatted policy memo
— On May 6th, I will give you instructions
— The policy memo will be due in one week (May 13th)
— More information to come

Question Sets for Videos:

Grade updates coming this week!
Next week: review of difficult questions

Have you (or has anyone in your family) had personal experiences with high drug prices?

I am a week out from the 2\textsuperscript{nd} dose of the COVID-19 vaccine. AMA