The FDA and Clinical Trials: Application to COVID-19

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#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, #FDAlaw, #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

http://bit.ly/PharmaPolicy
"As of last week, only 55 people were vaccinated in low-income countries," says Nile Kandari, a Washington-based economic policy and corporate accountability lobbyist at People’s Vaccine Alliance, an international coalition of organizations campaigning for the production of a freely available COVID-19 vaccine for all. Members include Oxford, UNAIDS and Amnesty International. These low-55 individual is a very tiny fraction of the 2.5 billion people that make up the total population of all low-income countries.

Course Expectations

Midterm Assignment:
— 800 word op-ed on a topic of your choosing.
— The topic must relate to the course or course materials.
— Pre-approved topic was due TODAY, and the op-ed is due by March 26th

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

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

Let’s talk Vaccines...

• Vaccines often very difficult to develop and manufacture
  • Duration, Number of doses, Type of protection, Manufacturing process
  • Limited incentive (e.g., disease most common in developing world)
  • Government often buys in bulk at flat rates (unlike drugs)
  • However, some limits on product liability (National Vaccine Injury Compensation Program)

COVID-19 Vaccine Trials

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<th>Company</th>
<th>Platform</th>
<th>Dos</th>
<th>Non-clinical results</th>
<th>Number of people who got sick</th>
<th>Protect from infection</th>
<th>Protect from severe disease</th>
<th>Protect from hospitalization</th>
<th>Protect from severe illness</th>
<th>Protect from leading diseases</th>
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<td>88%</td>
<td>91%</td>
<td>95%</td>
<td>Phase 3</td>
</tr>
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COVID-19 Vaccines

For any vaccine, efficacy must be weighed in light of the risk of disease occurrence and the incidence and severity of vaccine adverse effects.

After vaccine approval, it is imperative that systems be in place to detect signals of adverse events once the vaccine is in widespread use.
Let's talk COVID-19 Vaccine...

In GREY: a question I posed at the very last Fall 2020 #PharmaPolicy class session of the semester

In RED: those questions now (largely) answered!

Let's talk COVID-19 Vaccine...

A COVID-19 vaccine is especially difficult:

• Tremendous pressure to get it right
  And they did!
• Some vaccine manufacturers attempting completely new vaccines/processes
  And it worked!
• Immunity may wear off after a few months, multiple boosters may be needed
  The two-dose regimen seems to be working well
• Adverse effects are an unknown without a big clinical trial
  They conducted large trials – no hospitalizations, no deaths!
• Phase III most important: safety AND efficacy
  They all conducted Phase III trials

Let's talk COVID-19 Vaccine...

Full approval makes more sense than EUA

• EUA standard for safety/efficacy much lower, could allow an unproven product to be administered to (potentially) hundreds of millions of people
  The FDA adopted an EUA-plus strategy with far more rigorous review than the statute calls for.
• Widespread access to one vaccine will hinder ability to study other vaccine candidates
  This has not been the case, vaccine studies are progressing nicely with two already available for use.
• Dosing regimen unknown. What do we tell people who receive one dose – to resume normal life?
  We’ve told them to continue wearing masks and exercising precautions – infections can occur but only if we let our guard down!

Open Questions on Vaccines:

• Will one be rushed before the election? By EUA or full approval? CDC is already gearing up states for vaccination campaign.
  The vaccine approval was not rushed, and the FDA exercised a higher standard appropriate for a vaccine being given to millions. CDC was right to begin preparing for vaccination but the Trump administration did very little to get it right.
• Who will approve the vaccine?
  There was concern that HHS would override FDA and approve the vaccine without their input. This did not happen.
• Will data from studies be publicly available?
  There was concern about approval by press release, but studies were made available and published quickly.

Open Questions on Vaccines:

Will a COVID-19 vaccine be ready to distribute by November 3rd? No.

• Who gets it first?
  Apparently affluent, older white people, not marginalized populations.
• Will people trust it?
  Some do not, but many are coming around.
• Will it be effective after a single dose?
  The two we have show some efficacy after a single dose, but the booster is what gets them to 95%
Open Questions on Vaccines:

Will a COVID-19 vaccine be ready to distribute by November 3rd? No.

• Will it be monitored/studied as it’s rolled out?
  Postmarket monitoring has been critical and will continue. The next step is to speed the process by eliminating the 15 minute monitoring period after the vaccine is administered.

• Who pays?
  The federal government agreed to several advance market commitments for vaccine candidates early on, ensuring access in the US. Global access is a huge problem (as of 2 weeks ago, 25 doses TOTAL were given in the entire continent of Africa!!!) Insurance companies seem willing to pay and prices (at least by US standards) are moderate.

I just got the 2nd dose of the COVID-19 vaccine. AMA