How We Got Here: FDA Emergency Use Authorization from 9/11 to COVID-19

Food & Drug Law Journal 2020 Symposium, "This Teachable Moment: How COVID-19 Provides Lessons from FDA's Past and Present That Will Benefit Its Future Preparedness"

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Overview

- 1. EUAs: What they are, what they do
- 2. Prologue
- 3. Enactment of EUAs
- 4. Subsequent years
- 5. EUAs against COVID-19
- 6. Reflections
- 7. Looking forward

1. FDA emergency use authorization

- Problem: Emergencies require rapid countermeasures; can’t wait for formal approval from FDA
- Solution: Emergency powers for rapid availability of countermeasures in times of emergency
- Requirements:
  1. Actual or potential life-threatening emergency
  2. “May be effective"
  3. Known and potential benefits > known and potential risks
  4. No alternatives

2. Prologue

- Swine flu affair of 1976: How do you mobilize a nationwide response to a public health crisis quickly?
- AIDS crisis in 1990s: Wait to understand new drugs, or take chances to save lives fast?
- Smallpox vaccine liability: How to compensate people who suffer from unintended side effects? Collective v. individual welfare?

3. Enactment of EUAs

- Project Bioshield (2004): Response to anthrax attacks and fear of bioterrorism
- AVA (2005): The first EUA
  - Mandatory? Voluntary? Opt-in/opt-out policies?
- PREP Act (2005)

4. Subsequent years: 2005-2020

- H1N1 (2009)
- Period of calm 2011-2020: Many threats, few materialized
- Statutory amendments, expansions of emergency power (PAHPRA, PAHPAIA, 21st Century Cures Act)

5. Today: EUAs in response to COVID-19

- Unprecedented issuance of EUAs
  - 22 for H1N1 2009, the most for any emergency until 2020
  - >300 for COVID-19 as of Oct. 2020
- Controversies
  - EUAs for chloroquine and hydroxychloroquine
  - Vaccine: “EUA-plus”

6. Reflections

- What role did the War on Terror (and the specter of bioterrorism) play in preparing us for today?
- Could we have prepared adequately without it?
- How susceptible are emergency powers to misuse, especially by political actors on the eve of reelection?

7.a. Looking forward

- EUAs being used more than ever: Stakes higher than ever before. Minimal precedent. History is happening now.
- What if used too often? Not used often enough?
- Part of a broader policy context
- Need for insulation against nonexpert political interference

7.b. Ethical and policy considerations

- Take the chance, or stick to the rules?
- Act quickly to benefit the collective, or protect individuals against unknown risks?
- What if it disincentivizes participation in clinical trials toward formal approval?
- What precedent will it set?
- What risk is there of undue political influence?

7.c. Three ethical/policy frameworks

- Outcome-oriented
  - Cost-benefit analysis, weigh risks of granting EUAs against risk of waiting and letting emergency continue
- Principle-oriented
  - Grant fewer EUAs, rules exist for a reason, duty not to subject individuals to unknown risks
- Autonomy-oriented
  - Make EUAs available, let individuals decide for themselves

7.d. Example: COVID-19 vaccine EUA

- Should a COVID-19 vaccine get an EUA?
- If so, and if supplies limited, who should receive it?
- Health practitioners on the front lines against COVID?
  - Outcome pro: High risk of infection and transmission
  - Principle pro: They deserve any benefits of a vaccine
  - Autonomy con: They accepted the risks to serve the public
- Should it be made mandatory, voluntary, mandatory opt-out?

The bottom line

- Greater use of EUAs now than ever before, by a staggering amount
- We've seen how high the stakes can get during emergencies
  - And how much higher when political interests are involved (Ford/Trump presidential reelection campaigns, nationwide vaccination programs, Twitter)
- Key ethical issues underlying EUAs that must be addressed whenever granting one
- The bulk of the history of EUAs is being written as we speak