

# The Way Forward for Needs- Driven Public Health Research

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# What Do We Want

- Therapeutic innovation that meets real public needs and that is affordable

# Issues To Think About

- Even if clinical trials are publicly funded drug companies still set priorities for what drugs are researched and developed
  - Drug companies will never do clinical trials for off-patent drugs
  - Drug companies won't develop drugs for unprofitable diseases
- Should we be bribing companies to do research that meets public priorities (prize funds, advanced market commitment)?
  - Companies develop drugs for “profitable” diseases
  - Public money develops drugs for “unprofitable” diseases

# The Simple Solution

- Nationalize the pharmaceutical industry
- NOT GOING TO HAPPEN
- (May have publicly owned facilities to manufacture generic drugs)

# What's Been Tried or Talked About So Far?

- Priority review vouchers
- Product development partnerships
- Prize funds
- Advanced market commitments
- R&D treaty

# What Else – Use the Regulatory System

- No approval unless
  - Clinical trials use hard clinical outcomes
  - Clinical trials are superiority trials
  - Clinical trials use “real world” patients
- Create a public trial option
  - If companies elect to do trials on their own then approval would require additional pre- and post-marketing scrutiny from regulatory authorities

# What Else - Use the Patent System

- No patents for:
  - Minor variations of existing agents with no added therapeutic value
  - Drug isomers
  - Tweaks to drug delivery devices with no major added functionality

# What Else – Use the Payment System

- No public funding for drugs that do not offer
  - Additional therapeutic advantages (more effective in general or in specific populations)
  - Greater safety
  - New useful formulations (e.g., pediatric formulations)
  - Novel characteristics (e.g., vaccines that don't require a cold chain)
  - Improved compliance (e.g., once a day delivery where this has been shown to improve clinical outcomes)

# Conclusion

- No simple answers
- Any solution will require multiple approaches