

“Engaging the War on Pandemics, Bioterrorism and Infectious Diseases”

Featuring

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A Brief History of the War Against Infectious Diseases:

We've been fighting the war against infectious diseases for a long time. In Shakespeare's time, most died fairly young due to smallpox, diphtheria, cholera, typhoid, plague rather than cancer, Alzheimer's, Parkinson's, cardiovascular disease.

We hit a golden age of drug development for infectious diseases between 1935 and 1962 with the development of Sulfonamides, Penicillin, Flu vaccine, Tetracyclines, Polio vaccine, etc.

In an incredible 30-year period, we thought the war was over. However, beginning in 1969, we began to deal with Lassa virus, Ebola, Legionnaire's disease, AIDS, Hepatitis C, Hanta Virus, Mad Cow, West Nile, Anthrax letter attacks, SARS, bird flu, swine flu, MERS CoV, Chinese H7N9 flu, Ebola in the U.S., Zika.

Dr. Mirsalis argues that these diseases are coming at us faster than we can deal with them.

Infectious Diseases May Only Get Worse

Bioterrorism is a real possibility; it's only a matter of time before there is an aerosol version of Ebola. Suicide bioterrorists infect themselves and spread it as fast as they can, as far as they can.

Tropical diseases are moving into the U.S. as the global climate gets warmer and insects migrate North.

Drug Development

The process of drug discovery includes asking the following questions;

- Is it safe?
- How is it administered?
- How do you make it for people? (i.e. taste)
- Does it work? Once sent to the market, continued research: Does it still work?

Development should be easy...but it's not!

- Drug Resistance: Mutation rate is faster than the drug development rate
- Toxic side effects
 - Cultural, religious, educational and political issues (i.e. fear of vaccines)
- The biggest challenge: lack of funds and investment
 - Most funding comes from the federal government
 - Biodefense therapeutics will never be sold or used, so no profit motive for private development
 - Malaria, Chagas disease and TB don't affect Western nations (“diseases of poor people”)
 - Cost of development is great, while profit margin is minimal

The Role of Congress in Infectious Diseases

Dr. Mirsalis suggested that Congress tends to have a short-term view of infectious diseases. In 2014, Congress spent \$1.2 billion into Ebola when \$1.2 billion wasn't needed in 2014—it was needed \$100 million/year for the 12 years prior. If money had been spread out, a drug would have been on the market, with two in the clinical phase and a vaccine developed by 2014.

Examples of Diseases on the Rise

Chagas disease is a blood-borne parasitic disease that affects ~20M people/year and kills about ~50,000. About one-third of infected suffer irreversible heart problems, neurological, or gastrointestinal problems. Mostly a Central/South American disease now starting to show up in Texas. No current effective treatment for Chagas.

What's Old is New

- As diseases become rare, vaccination frequency decreases.
- Whooping cough, measles, etc. are making a comeback.
- Eradicated diseases can be used as bioweapons.
- In global economy, developing nation diseases are our diseases.
- Some organisms evolve so vaccines are less effective.

How Can We Fix This?

Legislation

- Increased funding for R&D
- Stable, long-term funding
- Better coordination
- Eliminate vaccine exemptions other than health reasons

Pharma Incentives

- Tax breaks for anti-infective development
- Start patent clock at market approval
- Market exclusivity periods
- Incentives for cooperation between pharma, NIH, PPPs

FDA

- Expedited development
- Priority review
- FDA needs more funding to speed up this process
- Increased use of Expanded Access Program

Dr. Mirsalis concluded that only temporary victories will exist for many infectious diseases. Bioterrorism concerns have led to an accelerated development of anti-infective therapeutics because even “eradicated” diseases can pose a risk. The product development cycle must accelerate to keep up with drug resistance and the government and private industry need to work together better.