

# **HHS Task Force to Stimulate Medical Innovations**

**David N. Gilbert, M.D.  
on behalf of the IDSA**

**The Infectious Diseases Society of America (IDSA) wishes to thank:**

**Acting Commissioner Crawford**

**Director Gerberding**

**Administrator McClellan**

**Director Zerhouni**

**for the opportunity to share our deep concern of a rapidly evolving problem that threatens the public health.**

# The Problem

- Increasing resistance of pathogenic bacteria to currently licensed antimicrobials
- Concomitant dramatic decrease, or complete discontinuation, of antibacterial discovery and development activities by the pharmaceutical industry
- Hence, the need for innovation and speed in development of new drugs

# **IDSA Response**

- **Over a year, met with leadership of**
  - **FDA, NIAID, and CDC**
  - **Over 15 executive leaders of the pharmaceutical industry**
  - **Members of Congress and their staff**
- **Information derived led to several proposed solutions summarized in “Bad Bugs, No Drugs” report released July, 2004**

# Comments

- This testimony focuses on antibacterials. Suggested solutions are applicable to/for:
  - Pathogens engineered for bioterrorism
  - Vaccine discovery/development
  - Other categories of antimicrobials
- IDSA is here on behalf of our patients. Our advocacy efforts have not resulted from any financial relationship with industry.

# Proposals to Remove/Lessen Existing Disincentives for D&D

Within existing statutes

- **CDC**

## **Surveillance of disease burden**

- Epidemiology, detection, control of resistance
- Early detection of emerging pathogens for which treatment options are inadequate
- Morbidity/mortality projections in absence of effective therapy

# Proposals to Remove/Lessen Existing Disincentives for D&D

Within existing statutes

- **FDA**

- Implement critical path initiative**

- Decrease uncertainty with respect to acceptable design of clinical trials
    - Publish completed guidance documents
    - Continuous integration of advances in genomic diagnostics into clinical trials so as to increase study power with fewer enrolled patients.

# Proposals to Remove/Lessen Existing Disincentives for D&D

Within existing statutes

- **NIAID**

- Study section on point-of-care diagnostics, ID of new drug targets
- Public/private transfer of IP rights
- Possible commitment to screening of potentially useful compounds as part of “bench-to-bedside” research

# To Remove/Lessen Disincentives With New Legislation

- Incentives for large pharmaceutical companies; would apply only to identified dangerous pathogens bereft of treatment options.
- Subsequent to FDA approval:
  - Tax credit for D&D expense
  - Wild card patent extension with payback

# To Remove/Lessen Disincentives With New Legislation

- Incentives for small and/or biotechnology companies
  - Only for dangerous pathogens bereft of treatment options
  - With investigative new drug application
    - Small business grants
    - Re-assessment of FDA fees

# **Proposed Incentive for All Pharmaceutical Companies Regardless of Size**

- **Liability protection for serious, rare, unforeseeable adverse events**
- **Injury compensation as in “childhood vaccine injury program”**

# **IDSA proposes tying new statutory incentives to a list of dangerous pathogens bereft of effective treatment options**

- Our report suggests a “Commission” to prioritize antimicrobial D/D. We suggest an “advisory committee” reporting to Sec. of HHS.
- Regardless of administrative structure, the need is to identify dangerous pathogens for which treatment options are inadequate!!

# Anticipated Objections

- **Generic drug industry will object to any extension of patent protection.**
- **Treasury Department may object to tax credits**
- **Consumer advocates will worry about high drug costs**

# Response to Objections

- **Attributable additional expense of care of patient with pan-resistant pathogen can be many \$100,000s**
- **IOM estimate of annual expense of antibiotic resistance: \$4-5 billion**
- **Pain and human suffering: incalculable**

# What does the IDSA hope the HHS task force will do?

- High priority to incentives that stimulate D/D of antibacterials, vaccines, and related diagnostics in executive branch legislative agenda
- Dept. level evaluation of incentives in “Bad Bugs, No Drugs” report
- Help Congress enact Bioshield II or similar legislation

# Summary

- **“Bad Bugs, No Drugs” is a major threat to the public health**
  - **A re-commitment of the pharmaceutical industry is necessary to avoid a future calamity**
  - **2005 legislation will take 10 years to bear fruit**
- **IDSA hopes the task force shares our concern and will provide the necessary vision and leadership to shape necessary new legislation**