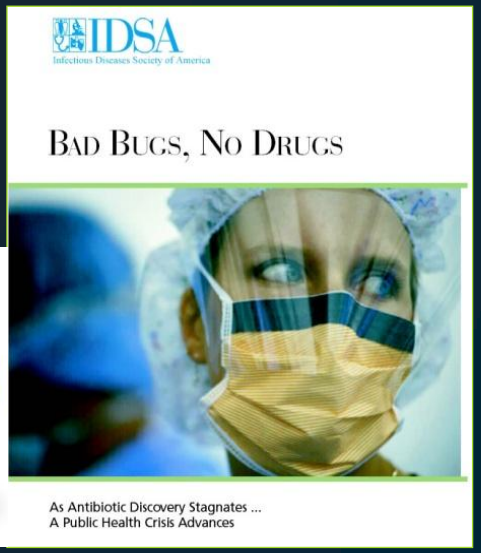
BAD BUGS, NEED DRUGS

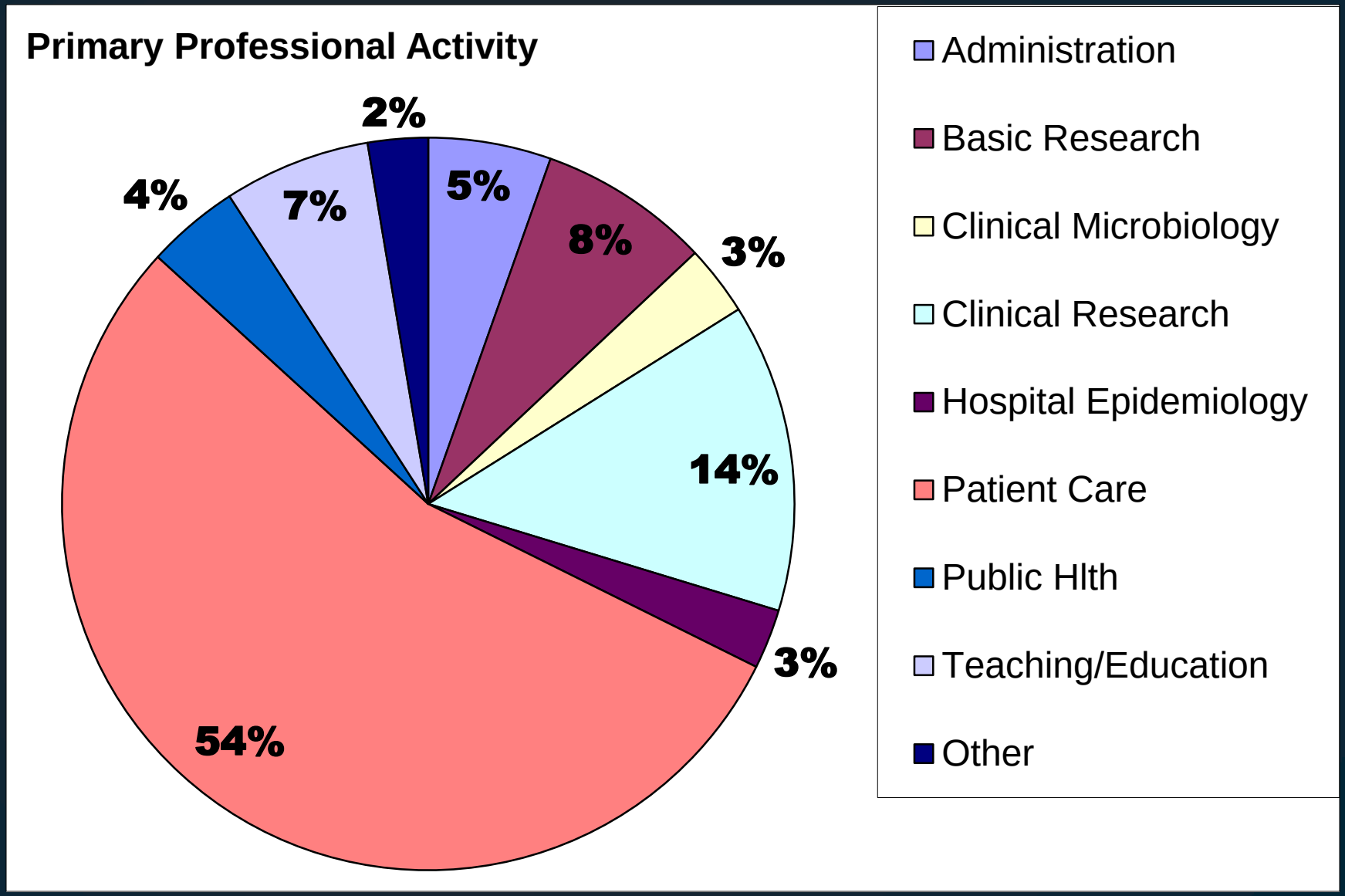
Why Antibiotics Deserve Congress' Attention and Immediate Action

Infectious Diseases Society of America

Robert J. Guidos, JD
IDSA VP, Public Policy & Government Relations



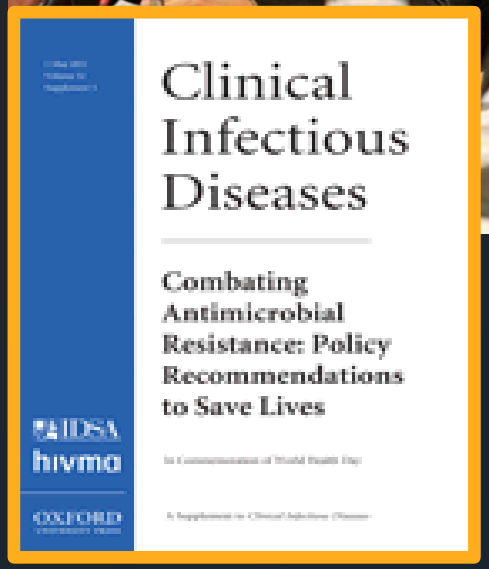
IDSA Membership: 10,000 strong



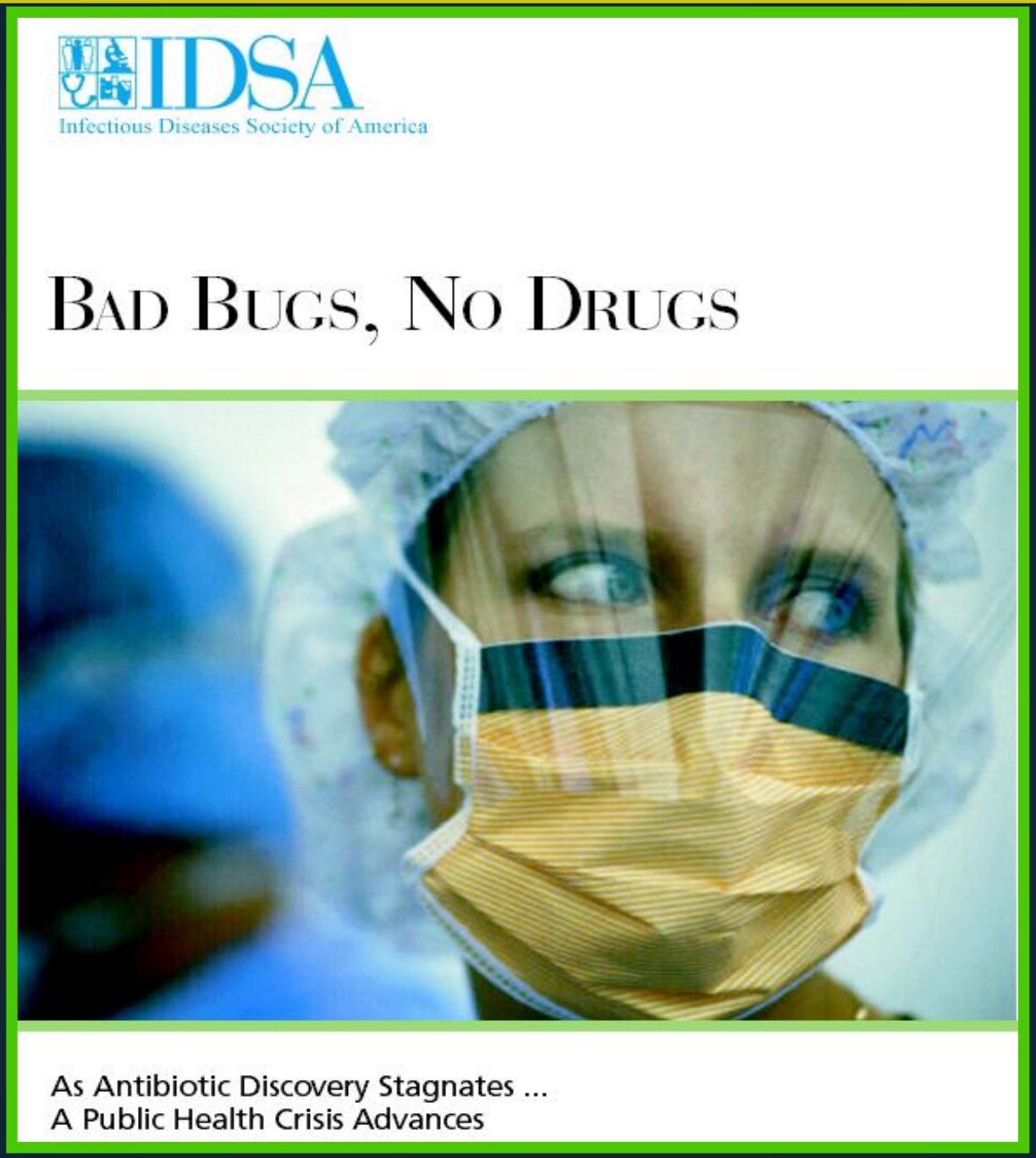
Crisis in Antimicrobial Resistance

- Organisms
  - Bacteria (e.g., MRSA, ESKAPE, TB)
  - Fungi (e.g., Aspergillus)
  - Virus (e.g., HIV, Influenza)
  - Parasites (e.g., malaria)
- Problem in US, worldwide
- Focus of World Health Day 2011; April 7th
  - WHO issued 6 point policy package for all countries to combat resistance

WHO's World Health Day 2011



IDSA Policy Paper "Combating Antimicrobial Resistance: Policy Recommendations to Save Lives" (*CID*) May 2011



IDSA's 2004 Report: "Bad Bugs, No Drugs: As Antibiotic Discovery Stagnates, A Public Health Crisis Brews"

IDSA's Motivation/Perspective

Our patients need new antibiotics to stay healthy and alive!

- Unlike other disease areas (cancer, HIV/AIDS, etc.), there are no easily identifiable patient advocacy groups to push for change and to put a human face on the antibacterial (antibiotic) resistance problem
- IDSA decided it must step in to advocate on our patients' behalf
- We have not taken any pharmaceutical funding to support these advocacy efforts

Antibiotic Resistance Is A Growing Threat

- We face dramatically increasing rates of drug-resistant bacterial infections due to methicillin-resistant *Staphylococcus aureus* (MRSA), AND antibiotic-resistant Gram-negative bacteria (GNB), such as *Acinetobacter baumannii*, *Klebsiella pneumoniae* and *Pseudomonas aeruginosa*, *Escherichia coli (E. coli)*, Clostridium *difficile (C. diff.)* and other emerging threats like (New Delhi metallo-β-lactamase 1 or NDM1)

- GNB infections are primarily healthcare-acquired infections; because of this it is difficult to find GNB patients to bring before policymakers as hospitals don't want to share their patient stories; MRSA patients are easier to find as many of these infections now are occurring in community settings

- Collectively, highly problematic antibiotic-resistant organisms are being referred to using the "ESKAPE" mnemonic: ***E****nterococcus*, ***S****taphylococcus*, ***K****lebsiella*, ***A****cinetobacter*, ***P****seudomonas*, and **E**SBL (*Enterobacter* and *E. coli*)

Crisis in Antibacterial Resistance

- Bacterial Pathogens
  - Nosocomial and community spread
  - Antibiotic pressure due to human use
  - Antibiotic pressure from veterinary use
- Patients
  - Elderly
  - Immunosuppressed
  - Healthy athletes/children now affected
- Approved Drugs
  - Poor antimicrobial stewardship
- Antibiotic Development
  - Not profitable **(e.g. Pfizer action)**

Lives Devastated/Lost Due to Antibacterial-Resistant Organisms

Lives Devastated/Lost Due to Antibacterial-Resistant Organisms

- Number of lives lost/affected by drug-resistant bacterial infections, including "ESKAPE pathogens"[1] is not well-established; available evidence shows it is substantial and growing
- 2005 MRSA infections in U.S.
  - 19,000 deaths; 94,000 infections JAMA. 2007;298:1763-1771
- CDC reports: 2 million HAIs/90,000 deaths annually in U.S.
- ESKAPE-specific numbers: CDC is collecting

[1]Boucher HW, Bad Bugs, No Drugs, No ESKAPE CID 2009; 48:1-12

Additional Costs/Length of Stay Associated with Antibacterial Resistant Organisms

Healthcare costs/lengths of stays also appear to be substantial/growing:

- *Chicago Cook County Hospital Study*[1] extrapolated to national burden
  - $21billion in healthcare costs (2009 dollars using CPI)
  - 8 million additional days stay in hospitals
- Comparing resistant gram negative HAIs versus susceptible gram negative HAIs[2]

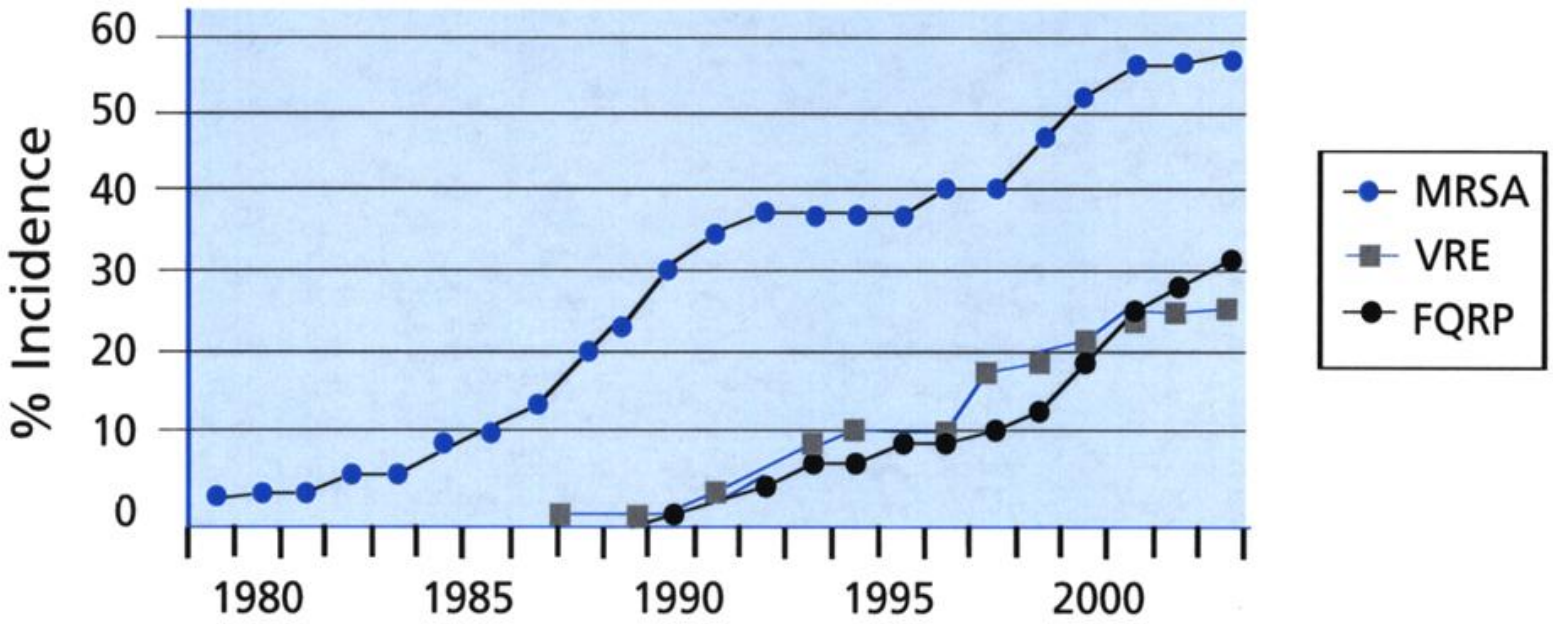
  Hospital Costs: ↑**29.3%** ($144K v. $106K)

  Length of Stay: ↑**23.8%** (36 v. 31 days)

[1]RR Roberts, CID 2009:49, 1175-1184;
[2]PD Maudlin, AAC 2010:54, 109-115

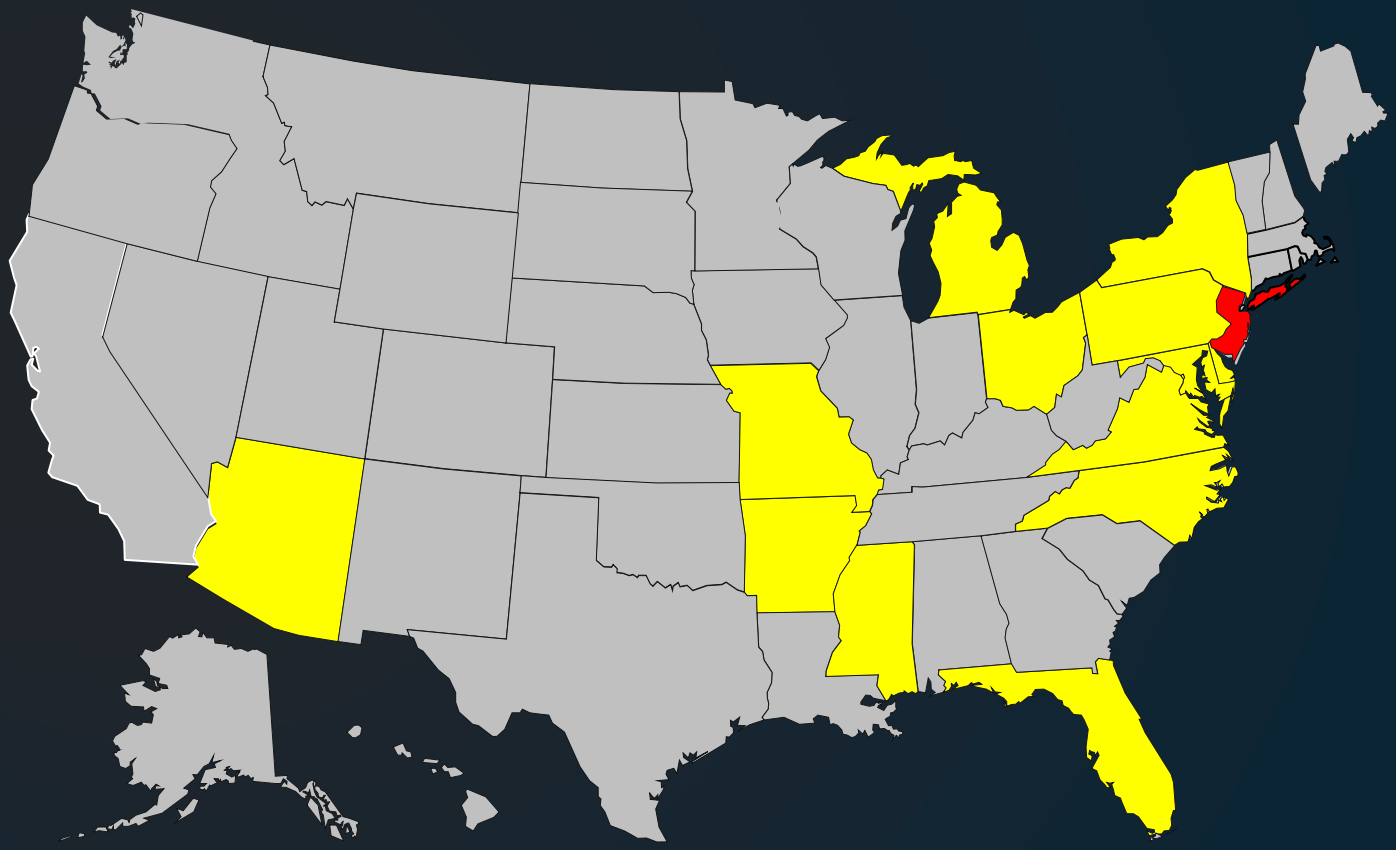
Crisis in Antibacterial Resistance

Chart 1: Resistant Strains Spread Rapidly



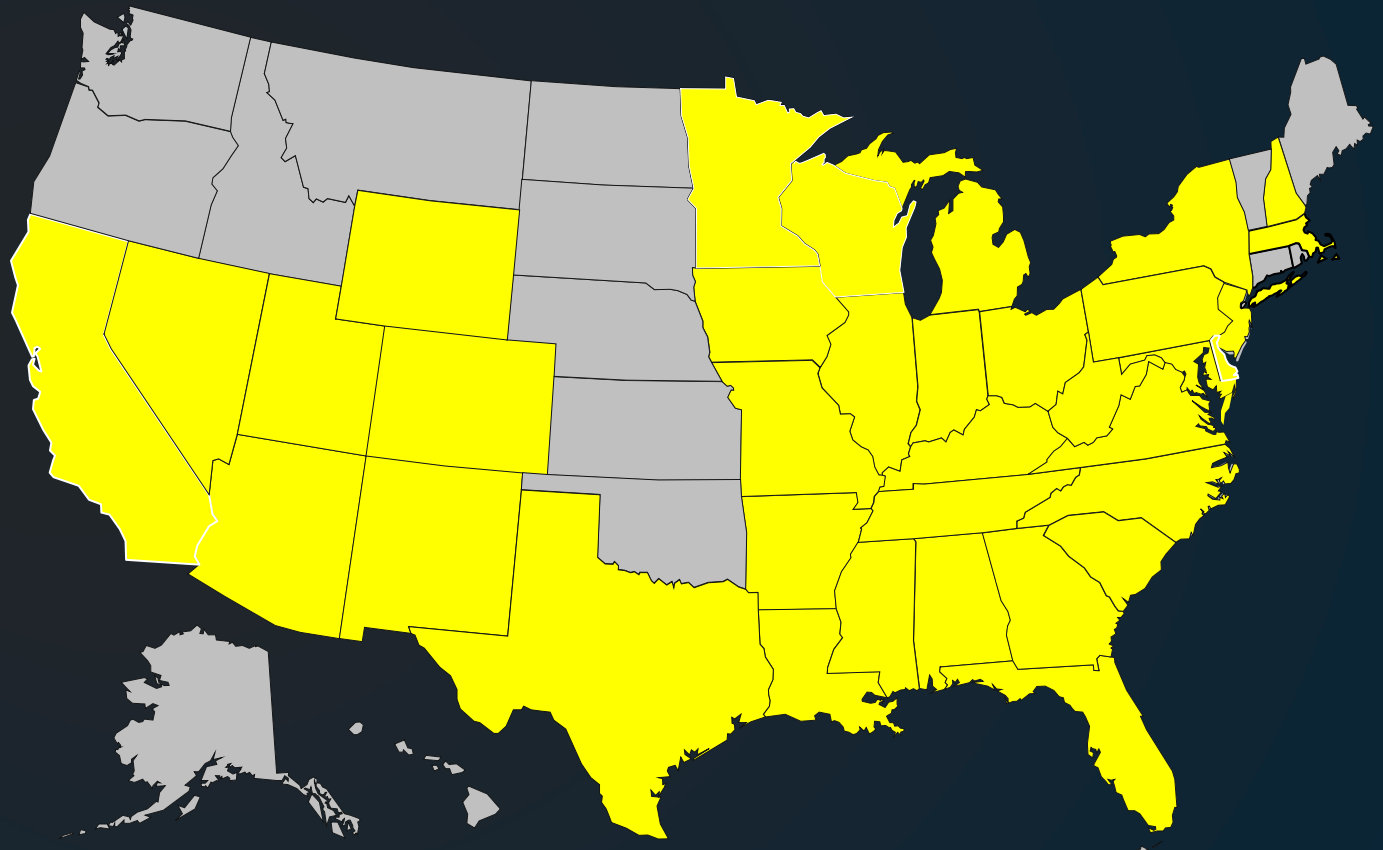
Source: Centers for Disease Control and Prevention

Geographical Distribution of Extreme-Drug Resistant Klebsiella Bacteria



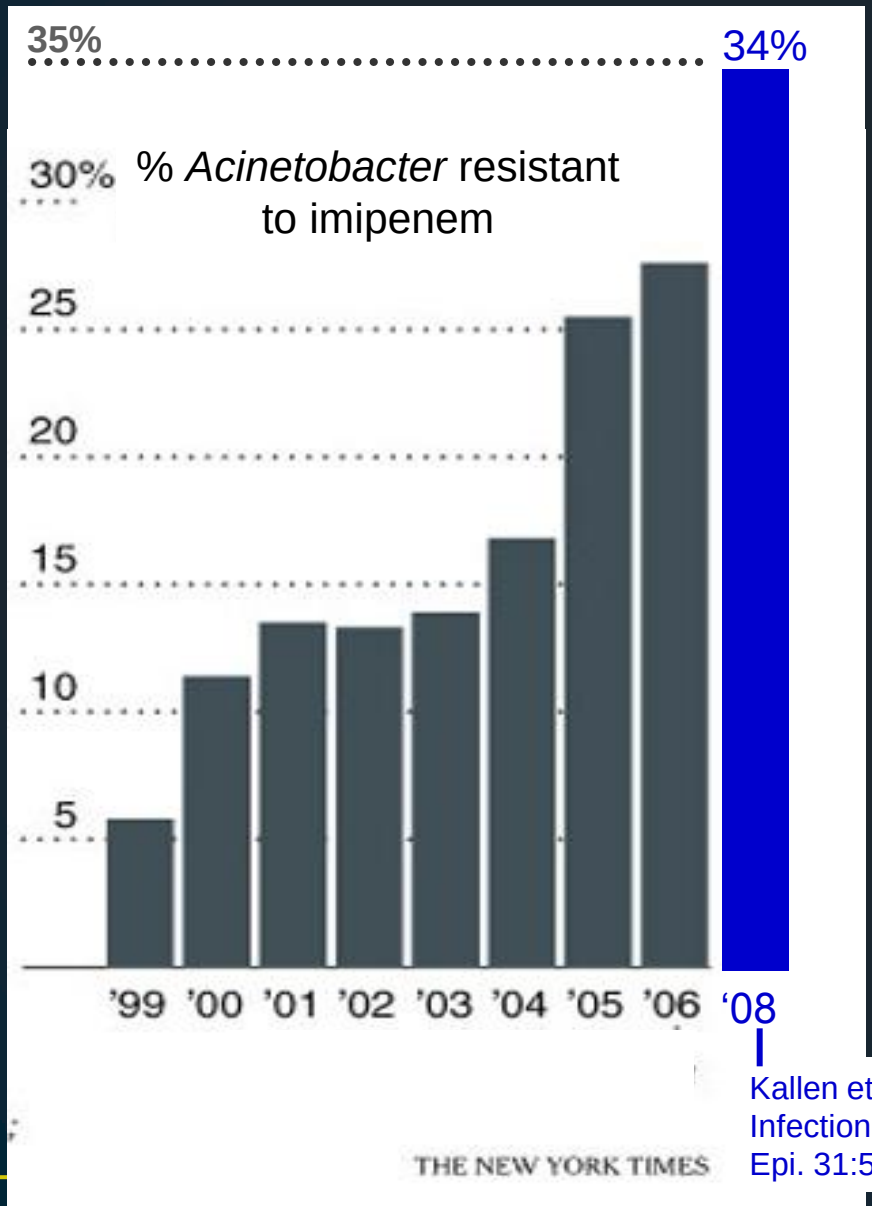
Nov, 2006

Geographical Distribution of Extreme-drug Resistant Klebsiella bacteria



Current

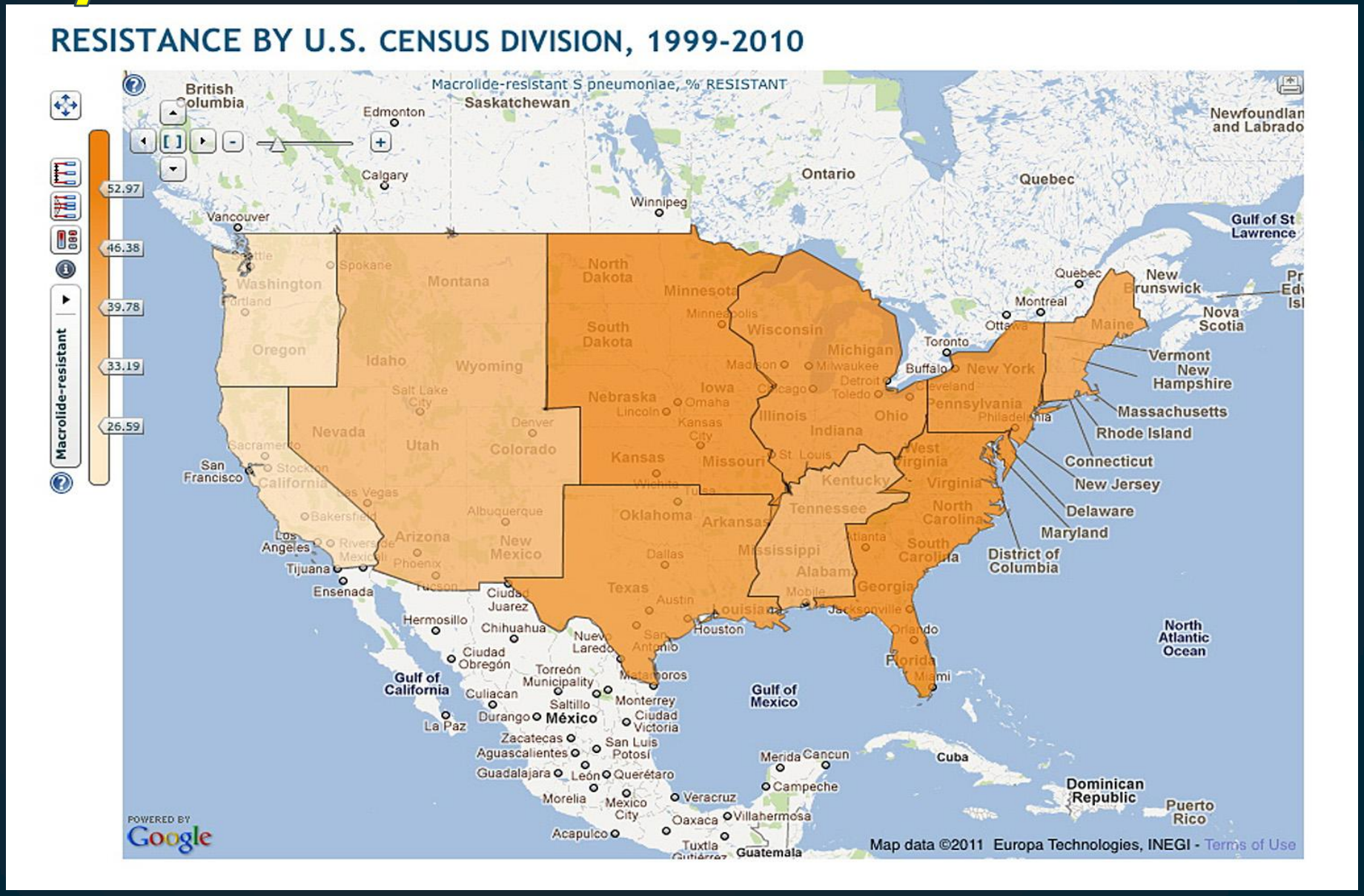
Extreme Drug-Resistant Acinetobacter



Kallen et al. (CDC) 2010 Infection Control Hospital Epi. 31:528-31

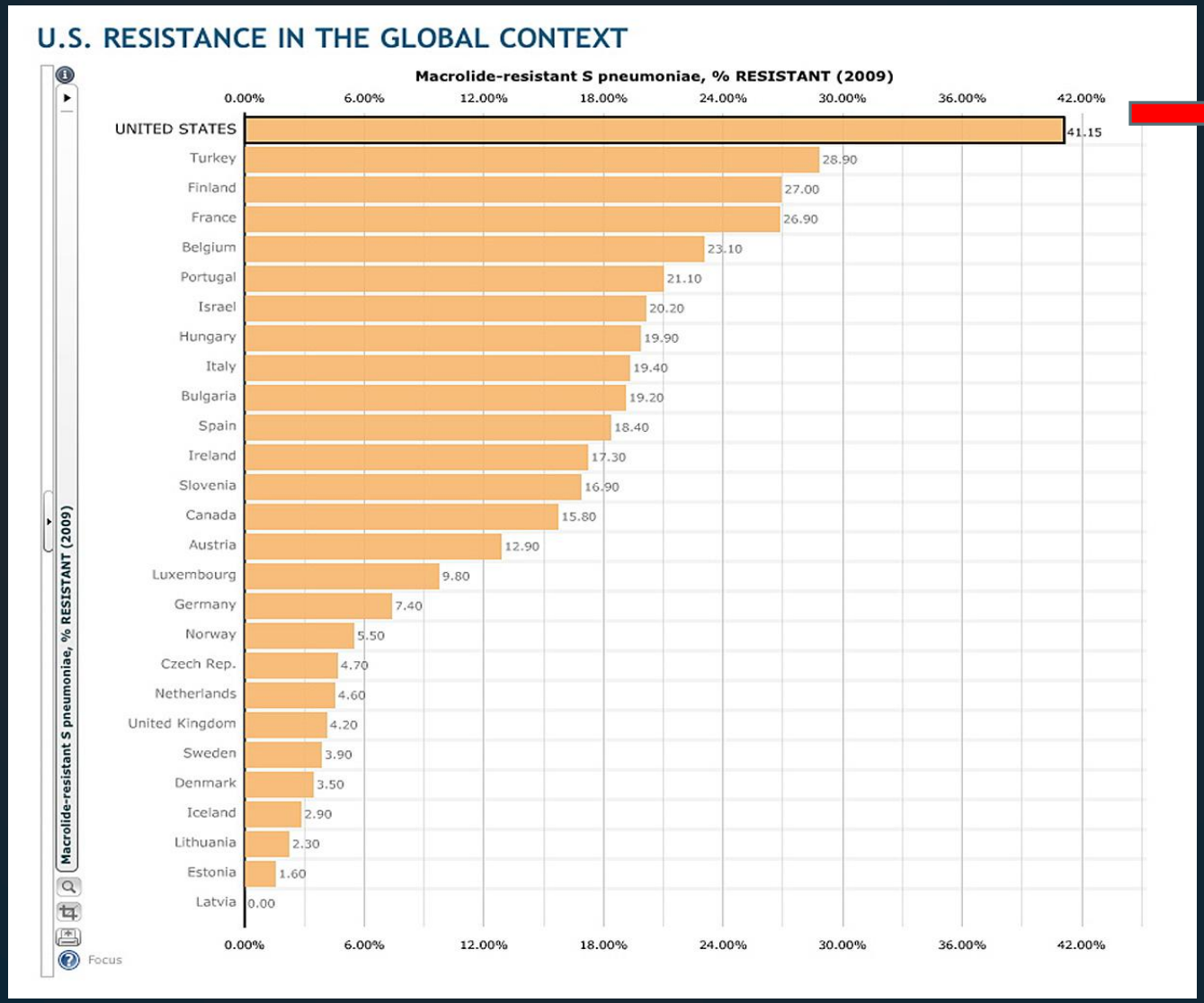
Common Cause of Combat Wound Infections in US Soldiers

S. pneumoniae: Macrolide-resistance



US Resistance in the Global Context

(macrolide-resistant Streptococcus pneumoniae)



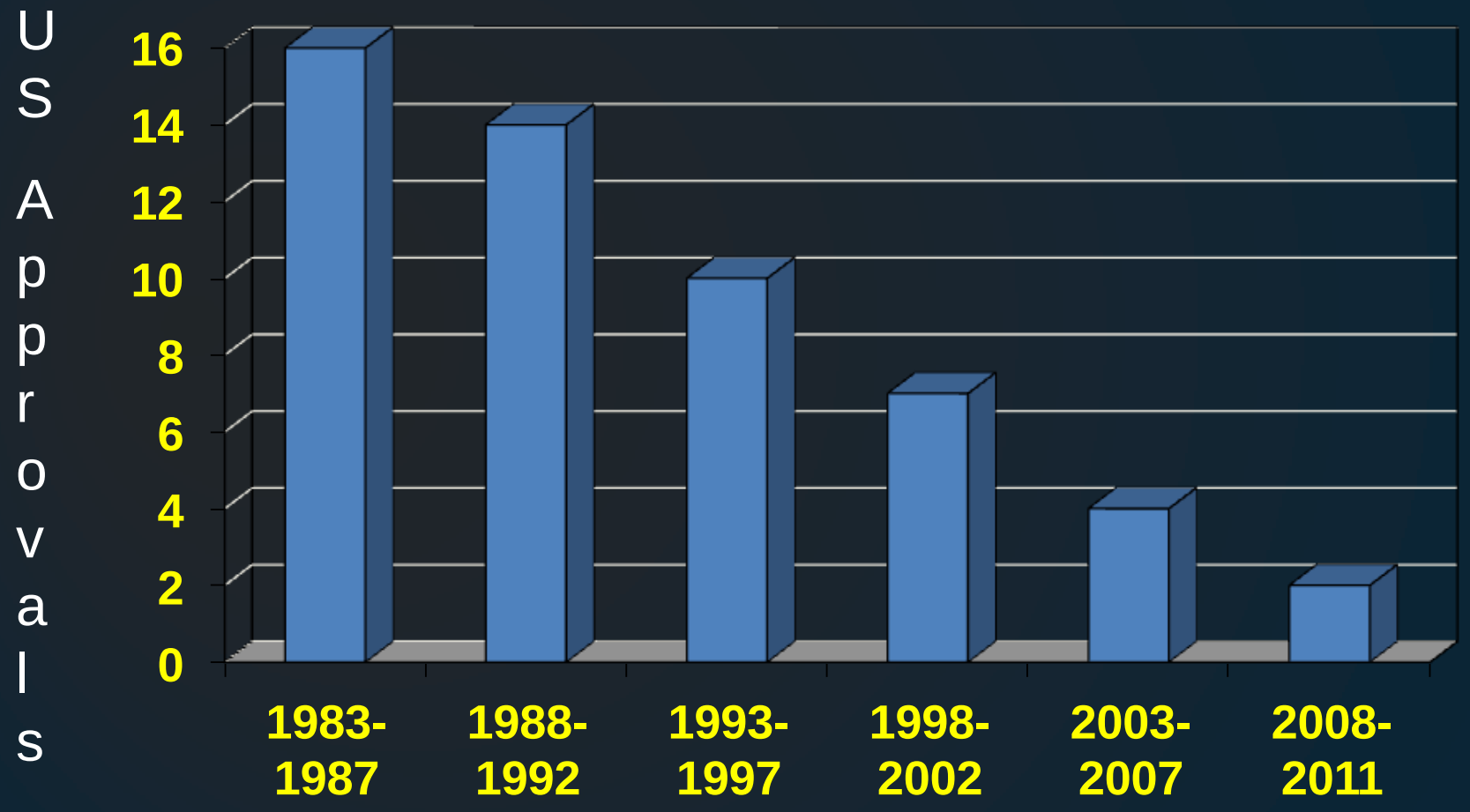
41%

Impact of Multi-Drug Resistant Gonorrhea

- **Without new antibiotics, CDC projects increase in gonorrhea infections over 7 years:**
  - From ~ 600,000 in 2010 to 2.4 million in 2017
  - Represents 5.9 million new cases
- CDC projects health impacts and costs due to increase in GC over 7 years:
  - 775 additional HIV cases ($180 million)
  - 255,000 cases of PID in women ($585 million)
    - 51,000 cases of tubal-factor infertility
  - 50,000 cases of epididymitis ($15 million)
- Total direct medical cost: **$780 million**
- Impact likely to be greatest among:
  - Non-Hispanic blacks
  - Men who have sex with men

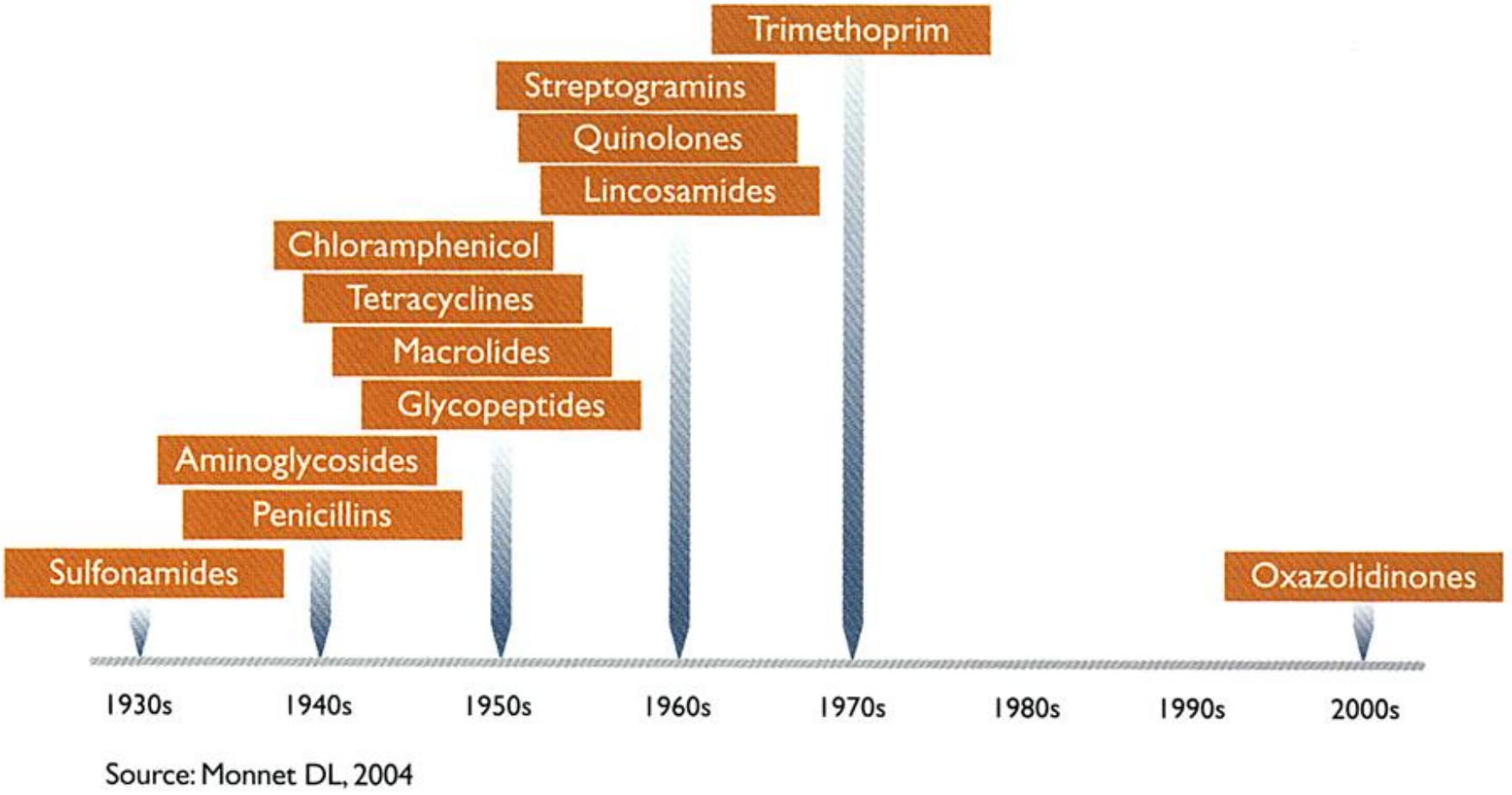
Source: CDC DSTDP, NCHHSTP; 12/19/2011

Declining Antibacterial Approvals, U.S.



Spellberg, *CID* 2004, Modified

New Antibacterial Classes???



State of Antibiotic R&D is Dire

2009 analyses by IDSA & European Centre for Disease Prevention and Control (ECDC)/European Medicines Agency (EMA)

- Only 15-16 antibiotics are in development
  - Only 8 have activity against key Gram-negative bacteria; these cause the most life-threatening infections
    - Of these, NONE have activity against bacteria resistant to all currently available drugs

Boucher et al. Clinical Infectious Diseases 2009; 48:1–12

Few Antibiotics are Being Developed

Two Years Later….2011 IDSA Update

- 10 compounds active vs. resistant Gram-negative bacteria in clinical development as intravenous (IV) therapy
  - It is still the case that NONE have activity against bacteria resistant to all currently available drugs
  - No ongoing studies for the most life-threatening Gram-negative infections (hospital-associated pneumonia, aka HABP/VABP), an infection where > 20% of patients die

Challenges in the Pathway to Antibiotic Approvals

- Antibiotics used for short duration
- Science is difficult (e.g., gram negative cell wall)
- Insufficient research support
- Lack of sufficient diagnostic tools
- Antimicrobial stewardship is essential, but affects profitability
- Pricing: generic competition is cheap
- Drugs in other markets (chronic disease, lifestyle) are more attractive

Challenges in the Pathway to Antibiotic Approvals

MARKET FAILURE

- Economic/Return on Investment
- Regulatory uncertainty—FDA

plus

- Scientific challenges

Why Do Antibiotics Deserve Congress' Help Over Other Drug Categories?

"The discovery of antibiotics in the 1930s fundamentally transformed the way physicians care for patients, shifting their approach from a focus on diagnoses without means to intervene to a treatment-focused approach that saves lives. Seven decades of medical advances enabled by antibiotics are now seriously threatened by the convergence of relentlessly rising antibiotic resistance and the alarming and ongoing withdrawal of most major pharmaceutical companies from the antibiotic market. Without effective antibiotics, diverse fields of medicine will be severely hampered, including surgery, the care of premature infants, cancer chemotherapy, care of the critically ill, and transplantation medicine, all of which are feasible only in the context of effective antibiotic therapy."

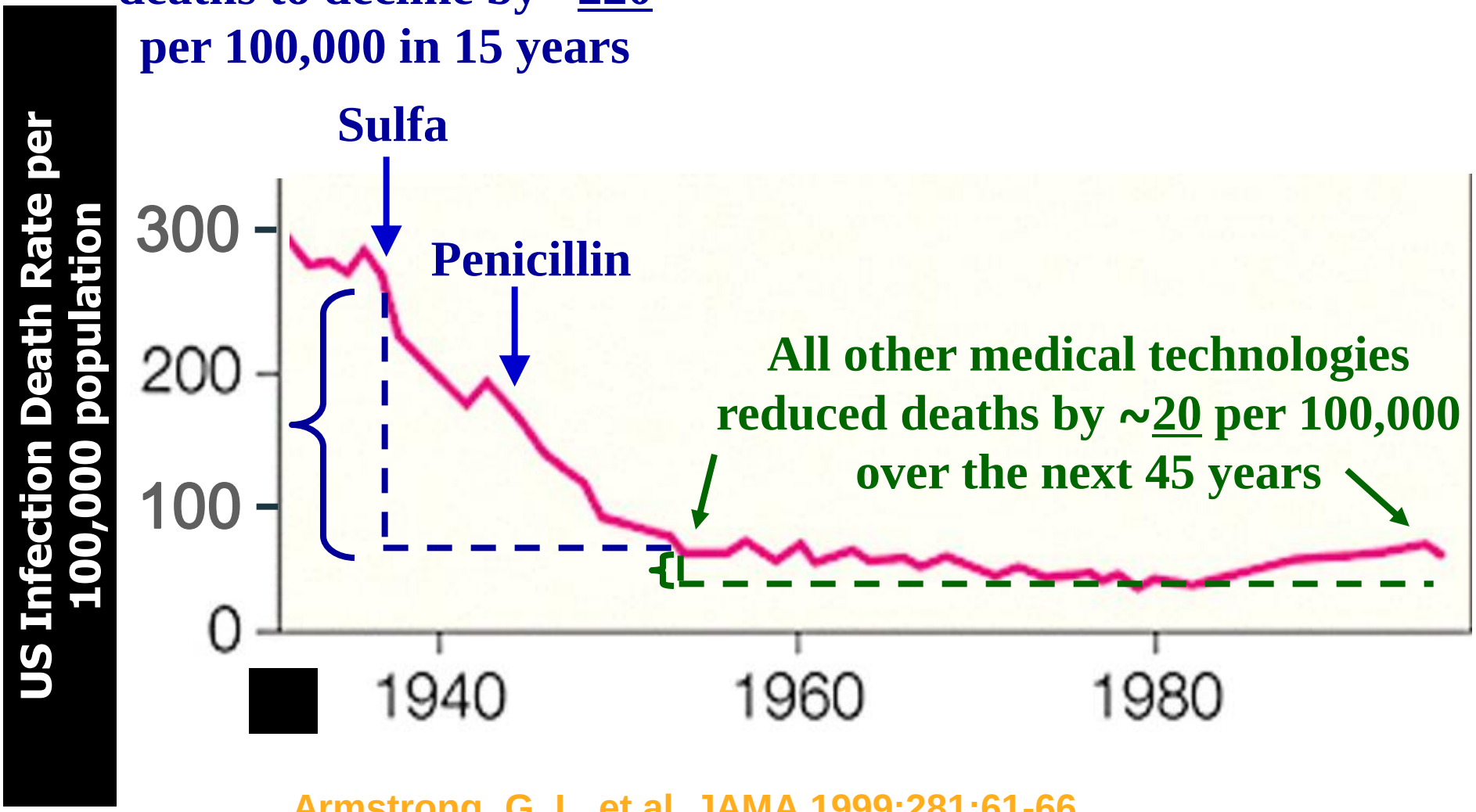
IDSA's 2011 Policy Paper: "Combating Antimicrobial Resistance: Policy Recommendations to Save Lives"

Why Do Antibiotics Deserve Congress' Help Over Other Drug Categories?

- Prior to antibiotics, there were a LOT MORE deaths due to bacterial infections.
- People died from infections that we have been able to treat once effective antibiotics have been available.
- The advent of antibiotics just prior to World War II saved the lives of thousands of soldier's who would have died due to wound infections, burns, etc.
- Without antibiotics, many of us would not be here today.

Antibiotics' Effectiveness

Antibiotics caused US deaths to decline by ~220 per 100,000 in 15 years



Armstrong, G. L. et al. JAMA 1999;281:61-66.

The Power of Antibiotics

Disease	Death Pre-Antibiotics	Death With Antibiotics	Change in Death
Community Pneumonia[1]	~35%	~10%	**-25%**
Hospital Pneumonia[2]	~60%	~30%	**-30%**
Heart Valve Infection[3]	~100%	~25%	**-75%**
Brain Infection[4]	>80%	<20%	**-60%**
Skin Infection[5]	11%	<0.5%	**-10%**
By comparison…treatment of myocardial infarction with aspirin or streptokinase[6]			***-3%***

[1]IDSA Position Paper '08 Clin Infect Dis 47(S3):S249-65; [2]IDSA/ACCP/ATS/SCCM Position Paper '10 Clin Infect Dis In Press; [3]Kerr AJ. Subacute Bacterial Endocarditis. Springfield IL: Charles C. Thomas, 1955 & Lancet 1935 226:383-4; [4]Lancet '38 231:733-4 & Waring et al. '48 Am J Med 5:402-18; [5]Spellberg et al. '09 Clin Infect Dis 49:383-91 & Madsen '73 Infection 1:76081
[6]Lancet 2:349-60

Why Do Antibiotics Deserve Congress' Help Over Other Drug Categories?

Antibiotics protect many lives—not just the life of the immediate patient at hand—because when effective their use prevents the spread of bacterial infections from person-to-person, which can wreak havoc across populations and disproportionately affect our most vulnerable patients.

Why Do Antibiotics Deserve Congress' Help Over Other Drug Categories?

- Antibiotics are essential to national security.
- An October 2011 Bio-Response Report Card issued by the Bipartisan WMD Terrorism Research Center—chaired by former Senators Bob Graham and Jim Talent—concluded that a terrorist armed with an antibiotic-resistant pathogen could produce a large-scale event with "catastrophic consequences," resulting in a "potentially uncontrollable number of illnesses and/or deaths," "civil and political unrest in the affected region," and a "global economic impact".

Why Do Antibiotics Deserve Congress' Help Over Other Drug Categories?

- The only antibiotic remaining to treat many Gram negative bacterial infections like Klebsiella is Colistin.
- Colistin is toxic; it's use causes kidney failure.
- Colistin had not been used in 30 years, but has been pulled off the shelves because there is nothing else.

Current alternatives for these patients: "Do you want to die, or to be on dialysis for the rest of your life or until you can get a kidney transplant?"

- Important: Gram negative bacteria are now developing resistance even to Colistin.
- Soon there will be no alternatives for these patients.

PEW, IDSA, PhRMA Meeting

Home > News & Publications > News Releases from IDSA

Print

PEW HEALTH GROUP IDSA PhRMA

Antibiotics Conference Addresses Lack of New Drugs to Fight Deadly Superbugs

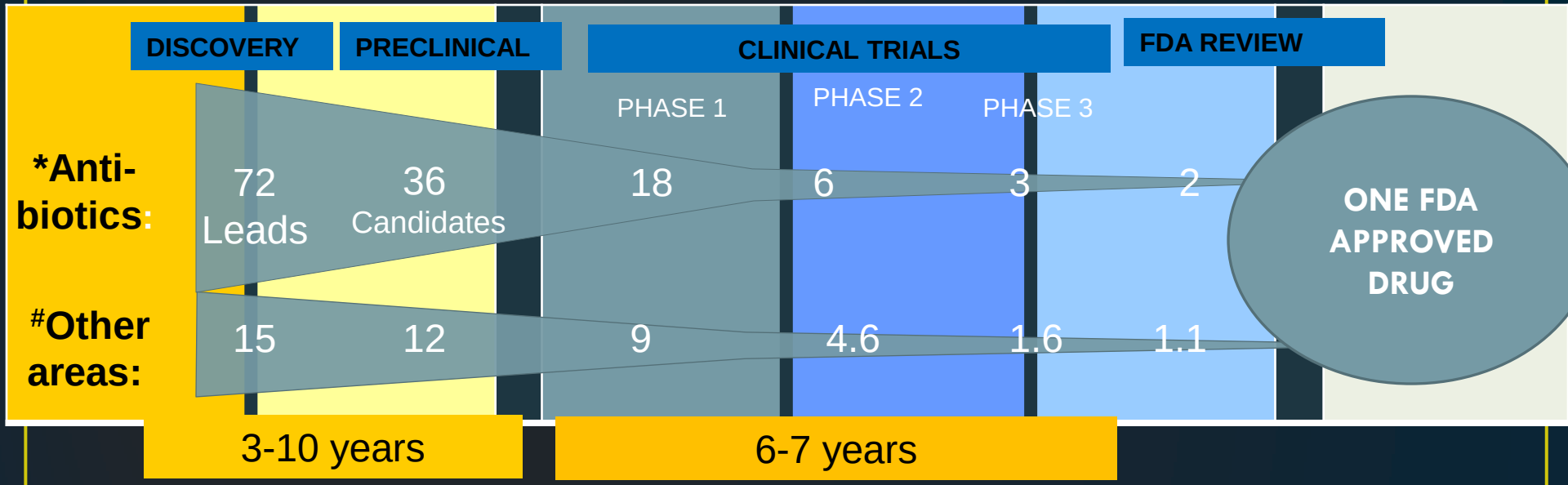
WASHINGTON – Leaders from government, industry, academia, medicine and science today will come together to discuss one of the most pressing health challenges we face: the rising incidence of drug-resistant bacteria and the lack of new antibiotics to fight them. The conference, "Reviving the Pipeline of Life-Saving Antibiotics: Exploring Solutions to Spur Innovation," is organized by the Pew Health Group, the Infectious Diseases Society of America (IDSA), and the Pharmaceutical Research and Manufacturers of America (PhRMA).

Many Disincentives to Antibiotic R&D

Therapy Area	NPV*	Develop-ment ($$)	Develop-ment (years)	Price	Use	Patient pop
Musculo-skeletal	$1150m	$$$$			Chronic	Large
Neurology	$720m	$$$$			Chronic	Large
Oncology	$300m	$$$			Acute/ Chronic	Medium
Anti-bacterials	$100m	$$$			Acute	Small (specialist hospital antibiotics)

David Payne, GSK, September 2011 IDSA/Pew/PhRMA conference
*Projan 2003

Antibiotics have high attrition rates



*Discovery to Phase 2 attrition based on real data for 12 novel mechanism antibiotic candidates at GSK

*Hit to Phase 2 based on novel mechanism AB discovery (GSK) #Based on Paul, et al (2010), Nature Reviews Drug Discovery 9: 203-214. David Payne , GSK, September 2011 IDSA/Pew/PhRMA Meeting

Antibiotics' Net Present Value (NPV)

- NPV describes the relationship between a drug's R&D costs vs. its potential return on investment.
- Companies use NPV to decide whether to moving forward with one drug vs. a competing drugs the company is able to available to invest in at a given time.
- A 2011 Office of Health Economics (OHE) report confirms the NPV for antibiotics is very low compared to other drug categories. See OHE report: http://news.ohe.org/2011/07/06/news-release-fighting-superbugs/
- OHE report calls for a shake up in the way antibiotic developers should be rewarded so that companies will focus on the most urgent needs. It calls for greater dialogue between the EU and US and others.
- OHE report says a combination of push/pull incentives will be necessary.

How to Stimulate Antibiotic R&D?

Bottom Line

- We can't make companies develop new antibiotics
- We have to make them want to develop new antibiotics

What Will Motivate Industry?

To Improve Antibiotic Return on Investment/ Net Present Value (NPV)

Need a variety of types of push and pull incentives—there is no single, rate-limiting step to overcome—although economic modeling shows that push incentives likely are more helpful.

Push: Decrease cost of development and share the risks (e.g. tax credits, grants, contracts, milestone payments, public/private collaborations)

Pull: Increase income linked to antibiotics approval/sales (e.g., prizes at time of approval, data and/or market exclusivity, patent extensions)

Need to change societal/payor valuation of antibiotics—their true value is not recognized

What Will Motivate Industry?

A Greater Return on Investment for Antibiotics

IDSA suggests that in addition the GAIN Act data exclusivity incentive, Congress provide market exclusivity similar to what is provided for pediatric exclusivity that attaches to the end of all existing exclusivity and patent periods, to prohibit the approval of competitors' drug applications during the protected period, including:

- A 5-year period of exclusivity for covered antibiotics.
- An additional 3-year period of exclusivity if the antibiotic is the first of a new class, as new classes are urgently needed.
- Additional extensions of one year for each subsequent approval (up to 3 approvals) an antibiotic receives for treating an additional infection or pathogen where FDA deems the subsequent approval(s) address a critical unmet need.

Structured in this manner, the exclusivity proposals will likely not produce a score for the next decade or two

What Will Motivate Industry?

A Clearly Defined and Viable Regulatory Approval Pathway

- After a decade of collaborative work (FDA/IDSA/industry), still no clear FDA pathway to antibiotic approvals for many indications
- Several FDA issued clinical trial guidances are not feasible
- Industry sponsors are at a loss as to how to proceed
- October 2011: IDSA urged the FDA Commissioner to ask the Institute of Medicine for its opinion on the agency's approaches
- One positive note: In 2010, FDA contacted the Foundation for the NIH (FNIH) Biomarkers Consortium to assist
  - Independent collaboration with academia, industry, IDSA, others to advance development of antibacterial trial endpoints
  - Initial focus skin infections and pneumonia (often the first studies of a new drug)

GAIN Act should support additional work under the FNIH

Clarifying the FDA Approval Pathway Recent FDA/IDSA Interactions and Related History

- Early-1990s: FDA contracted with IDSA to develop antibiotic clinical trial guidances
- 2001-2002: following upheaval over FDA discussions with companies over changing non-inferiority margins (to a 10% delta) and a subsequent public meeting, IDSA recognized the need for updated FDA guidance documents and offered several times to take the lead role in drafting revised guidelines; FDA declined. Multiple guidances are needed.
- Nov. 2002: FDA/IDSA/PrRMA Workshops (need for guidances for resistant infections)
- April 2004: FDA/IDSA/ISAP antibiotic development workshop (PhRMA refused to participate because FDA still hadn't published any guidances)
- February 2007: The Ketek Debacle; Congressional hearings on falsified drug study data adds to on-going paralysis of FDA anti-infective review division's activities
- January 2008: FDA/IDSA Workshop on Community-Acquired Pneumonia (CAP); IDSA published *CID* Supp., November 2008
- April 2008: FDA Advisory Committee on CAP; IDSA position statement on non-inferiority studies
- November 2008: FDA Adv. Comm. on Complicated Skin and Skin Structure Infections (cSSSI); IDSA presentation on historical data for cSSSI non-inferiority studies
- April 2009: FDA/IDSA workshop plan on Hospital-Acquired Pneumonia (HAP) and Ventilator-Associated Pneumonia (VAP); IDSA published *CID* Supp., August 2010
- December 2010: IDSA submitted draft superiority guidance document to FDA on multi-drug-resistant infections (organism-specific).
- July 2010: FDA/NIAID Workshop on antibacterial resistance & drug, diagnostics R&D
- November 2011: IDSA presented at two FDA Adv. Comm. meetings on CAP, HAP, and VAP

Regulatory Challenges
Uncertain path to registration in United States

EXAMPLE – Pneumonia - After 7 years of asking for new guidances, in 2007, questions came to a head about how to best study antibiotics for pneumonia. FDA to industry (paraphrased): "proceed at your own risk, do not follow FDA's current guidance documents".

- January 2008 public workshop on clinical trial designs for community acquired pneumonia (CAP)
- April 2008 public FDA advisory committee meeting
- March 2009 Guidance for Industry: Community-Acquired Pneumonia (CAP): Developing Drugs for Treatment
- December 2009 another public workshop
- November 2011FDA Advisory Committee meetings held
- TODAY: Still no updated CAP guidance for industry!!!!!!
- Important: securing CAP and skin indications are fundamental. Without them companies are typically not able to pursue more complex indications for their antibiotics.

What Will Motivate Industry?

Finding Answers to Tough Scientific Questions and a Commitment to Share the Risk through Research Funding and Public Private Partnerships

- NIH, Biomedical Advanced Research and Development Authority (BARDA) need to invest more resources
- IDSA analysis of 2009 NIH/NIAID funding found that, because of investments in other serious medical problems, NIAID's total funding commitment for antibacterial resistance research < $100 million; support for antibacterial drug discovery research < $70 million; that level has increased
- Oct 2011 awarded $150 million in grants to companies with promising antibiotics/antivirals
- IDSA supports significantly expanding NIAID's commitment further to a total of $500 million to support antibacterial resistance and R&D and related diagnostics.

Diagnostics are a "Game Changer"

The value of new rapid point-of-care diagnostics cannot be understated. These diagnostics will:

- reduce the costs of antibiotic clinical trials by making it easier to identify patients for the drug trial study population; and
- help ensure that antibiotics will be used appropriately post-approval.

The GAIN Act begins to address the need with the companion diagnotics exclusivity provision. IDSA also supports creation of a centralized patient clinical specimen repository lead by NIAID to support diagnostic development, etc. (See draft legislative language on the repository concept in your package which only asks that agencies explore the repository idea at this point.)

Additional Research Support

Biomedical Advanced Research and Development Authority (BARDA)

- Recent contracts for advanced R&D of Gram-negative active drugs awarded to:
  - Achaogen ACHN 490
    - $27M over the 1st two years; up to $64.5M
  - GSK 2251052
    - $38.5M over the 1st two years; up to $94M
- Strategic Investment Firm (PAHPA) will be very helpful, but the Investor and BARDA's antibiotics program must be well funded

European Commission Announcement

- Plan to promote, in a staged approach, unprecedented collaborative antibiotic R&D efforts
- Use existing Innovative Medicines Initiative (IMI) -- a public-private partnership jointly funded by industry and the Commission
- To encourage "unprecedented open sharing of knowledge" between companies at the pre-competitive research stage
- Use flexibility in the current pharmaceutical legislation to give rapid approval to new antibiotics and work with governments to make sure they enjoyed "adequate market and pricing conditions."

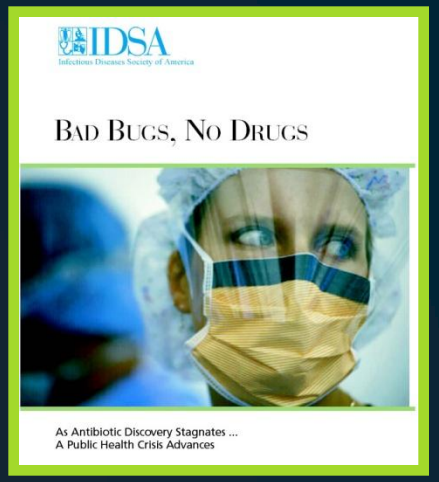
Communication from the Commission to the European Parliament and the Council; Action plan against the rising threats from Antimicrobial Resistance. November 17, 2011.

Public Private Partnerships are Key to Antibiotics' Future

We must establish a US effort similar to the EU PPP effort or run the risk of further eroding our competitive edge, not to mention losing more U.S. jobs and intellectual capital (remember Pfizer and all the other companies who have left this market).

- IDSA seeks for the GAIN Act:
  - a designated lead US agency to explore public private collaborations focused on early antibiotic discovery potentially in collaboration with the EU and to report back to Congress with options/funding requirements within 1 year.
  - Currently companies do not know where in the Administration to turn to begin this dialogue.

The 10 x '20 Initiative



Bad Bugs
Need Drugs

10x'20

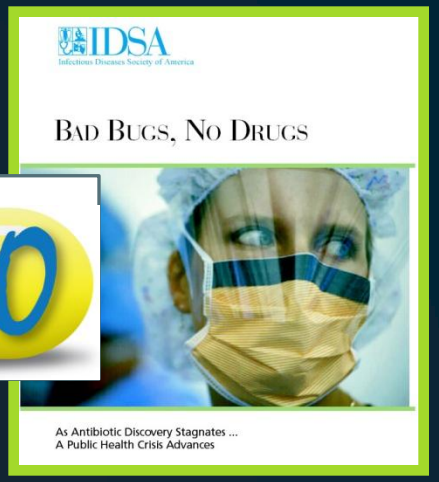
Ten new **ANTIBIOTICS** by 2020

The 10 x '20 Initiative

- Global Commitment to Develop 10 new systemic antibiotics by 2020 (CID; April 2010)
- Bring together essential leaders: global political, scientific, industrial, economic, intellectual property, policy, medical and philanthropic leaders to determine the right combination of incentives necessary to establish a sustainable R&D enterprise

Current Status of the 10 x ‘20 Initiative

IDSA Priorities



"High-Priority" Products

- novel systemic antibacterial drugs through the discovery of new drug classes as well as exploring possible new drugs from the existing classes of antibiotics (includes oral formulations)
- products that treat serious/life-threatening infections that are resistant to current antibiotics (the "ESKAPE" pathogens, e.g., emerging gram-negative bacteria, S. *aureus*)

Suggested New Definition of "Qualified Infectious Disease Product" Within the GAIN Act

To address the infections of greatest concerns to ID physicians, ensure the GAIN Act is applicable for drugs and related diagnostics that treat and detect new infectious pathogens as they emerge, and best fits the way FDA approves antibiotics (by indication based on infection and not pathogen), as well as cover antifungal drugs, which IDSA supports, IDSA agrees with others that it would be best to modify the GAIN definition of `qualified infectious disease product' to mean:

> ***"an antibacterial or antifungal drug for human use that meets the statutory definition of a new chemical entity; is indicated for use in a serious or life-threatening bacterial or fungal infection; and which demonstrates the potential to address unmet medical needs for such disease or condition."***
>
> ***(includes modifications to Pew Health Group's suggested definition)***

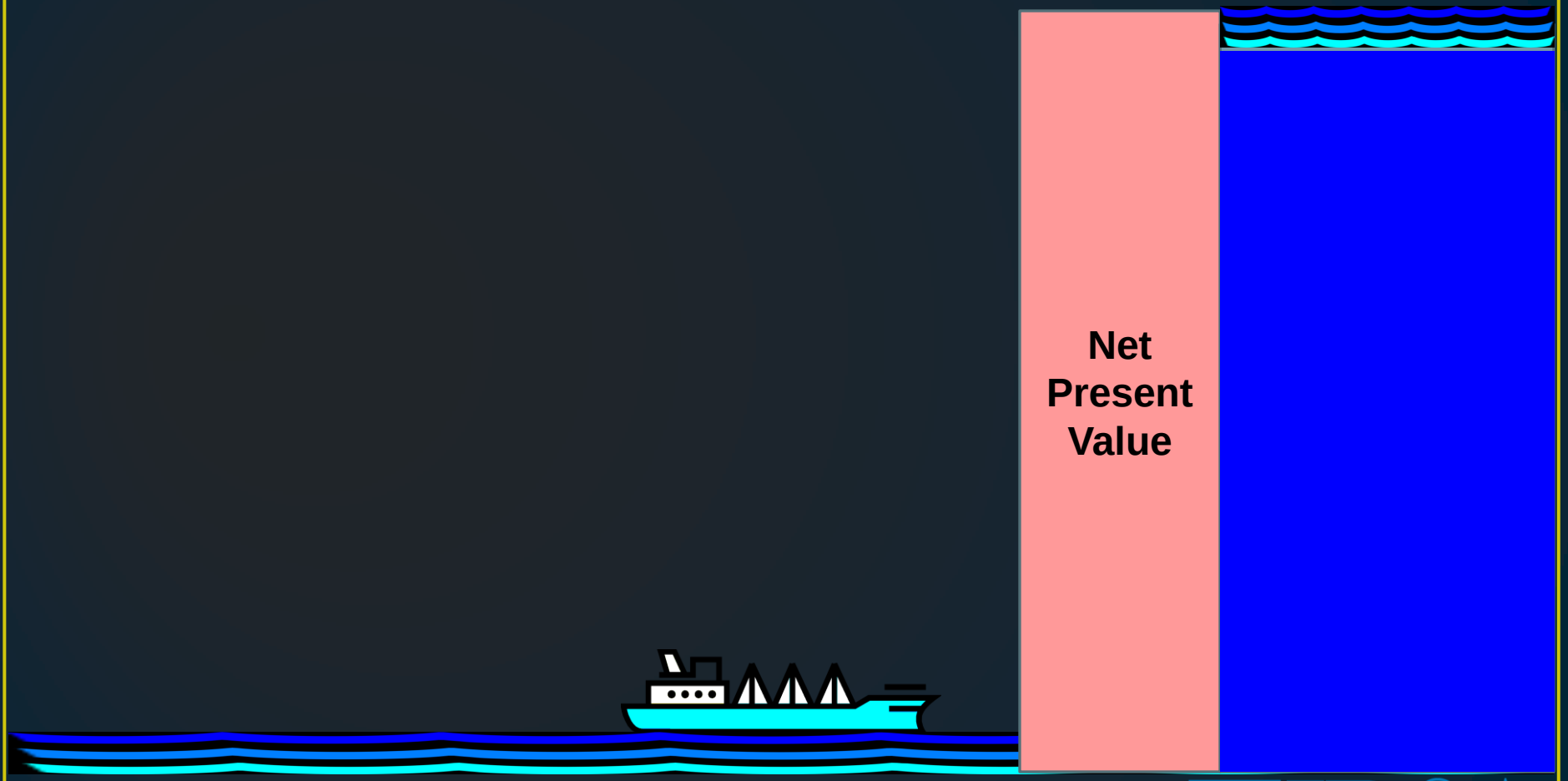
Suggested New Language on Antibiotic Stewardship/Appropriate Use for the GAIN Act

- "The Secretary shall, in cooperation with CDC and CMS, promote measurement of antibiotic usage across all health care settings and support adoption and implementation of comprehensive antimicrobial stewardship* programs across all health care settings to promote the appropriate use of antibiotics. Flexibility in program requirements must be allowed based on facility size and type."

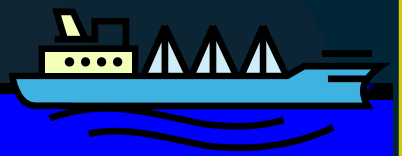
- GAIN's definition of "qualified infectious disease product" could be further modified to require the sponsor's new drug application to FDA for the antibacterial to contain a plan to educate health care providers in all health care settings on the antibiotic's appropriate use* and reinforce precautions to reduce the risk of resistance .

*The terms "antimicrobial stewardship" and "appropriate use" encompass the selection of antibacterial drug regimens, doses, duration of therapies, routes of administration, and other actions as needed to protect the health and well-being of the patient as well as the public health.

Raising Antibiotics Net Present Value (NPV)



Requires a Combination of Incentives



More $$$ (NIAID/BARDA)

R&D Tax Credits (a la Orphan Drug)

Strategic Investor Firm (PAHPA)

PPP—Designate a lead (a la Europe)

Post-Patent Term Exclusivity (a la Pediatrics Model)

Diagnostics!! (GAIN Act +)

Data Exclusivity (GAIN Act)

FDA: Clear Requirements (GAIN Act)

NET PRESENT VALUE

IDSA

IDSA's Position on the GAIN Act

- The GAIN Act provides a critical first step for discussing what incentives will succeed in promoting novel antibiotic and related diagnostics R&D.
- GAIN provides some helpful incentives, but they alone will not lift the antibiotics "boat" and change the state of antibiotic development in the U.S.
- The additional incentives that IDSA focuses on in the next slide also are unlikely to raise the antibiotics boat sufficiently, but they will help.
- Greater funding (NIH, BARDA, FNIH, PPP) and other push incentives (R&D tax credits) will be needed, and we are pursuing those incentives as well.

Strengthening the GAIN Act

IDSA believes the GAIN Act can be strengthened in the following ways:

- Modify definition of "qualified infectious disease product" which will help to meet our 10 x '20 priorities (novel drugs to treat serious and life-threatening infections).
- Market exclusivity at the end of patent time to increase antibiotics' return on investment and NPV
- Centralized clinical specimen repository for diagnostics, etc (NIAID)
- Lead U.S. Agency to explore a PPP (including with EU)
- Support for the FNIH initiative to advance endpoint development
- Encourage appropriate use through better stewardship

In addition, Congress needs to provide greater oversight of FDA's efforts to provide a clear approval pathway for antibiotics.

Protect This Global Treasure

Prior generations gave us the gift of antibiotics.

Today, we have a moral obligation to ensure this global treasure is available for our children and future generations.

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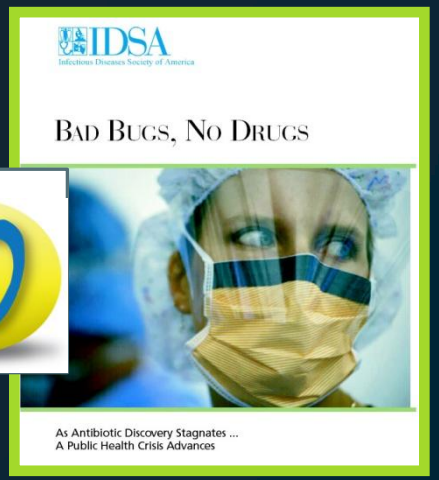
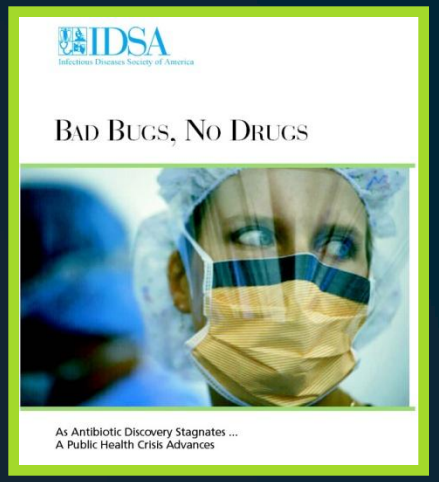


Additional Related IDSA Policy Reports/Continued Advocacy



Additional Reports:

- "The Epidemic of Antimicrobial Resistant Infections: A Call to Action to the Medical Community", Spellberg et al, *CID* Jan. 2008
- "Bad Bugs, No Drugs; No ESKAPE"; IDSA's latest update on the antibiotic drug pipeline; Boucher et al, *CID*, January 1, 2009
- Numerous position papers focused on FDA clinical trial designs (CAP; cSSSI; HAP/VAP, superiority for MDR organisms)
- The 10 x '20 Initiative, Global Commitment, April 15, 2010
- Combating Antimicrobial Resistance: Policy Recommendations to Save Lives, Spellberg, Guidos et al, *CID* supp., May 2011