

Antibiotic Resistant Bacteria: Economic & Legal Threats

**Thomas Blanz-Gilbert, Global Casualty Manager,
Zurich Insurance Group**

11th Annual Liability Regimes Conference
Keeping the Floodgates Shut? Mastering Accumulation
and Bodily Injury Exposures in a Rapidly Changing Environment

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Antibiotic Resistant Bacteria: Economic & Legal Threats

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Annual Liability Regimes Conference 2015



Antibiotic Resistant Bacteria

- Economic Burden
- Case Study: CRE Outbreak at UCLA
- National Health Care, Health Insurance and Jurisdiction

ARB = Antibiotic Resistant Bacteria

CRE = Carbapenem Resistant Enterobacteriaceae

ERCP = Endoscopic Retrograde Cholangiopancreatogram

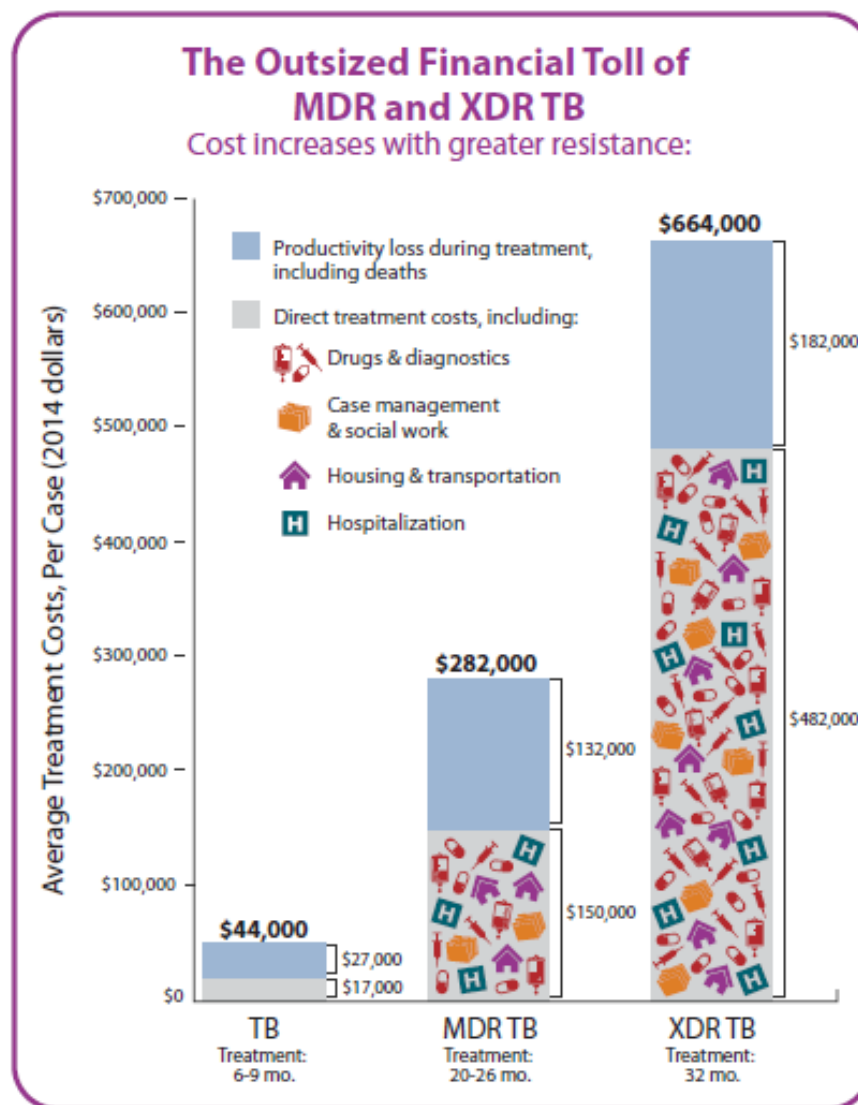
Antibiotic Resistant Bacteria

Health and Economic Burden

- death toll: 50'000 EU and USA combined, 700'000 world-wide
- additional medical costs: USD 10'000 – 40'000 per case
- additional non-medical costs, e.g. loss of earnings, expenses related to disabilities

Antibiotic Resistant Bacteria

Multi-Drug-Resistant Tuberculosis



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Financial Impact on Healthcare and Social Benefit Systems

Medical costs and disability

- EUR 940mio (ECDC and EMEA estimate in 2009)
- CAD 1bn (Government of CDN in 2015)
- USD 20bn (CDC 2013)

Loss of earnings other societal costs

- USD 35bn in the US (2010 US study quoted in OECD Report)
- EUR 600mio per year in the EU

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Endoscopy Cases in the USA

“Malpractice Trends Influenced By UCLA Superbug”



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Endoscopy Cases in the USA

- **18.02.2015:** UCLA reported 179 patients been exposed to Carbapenem-resistant Enterobacteriaceae (CRE), of which 7 infected, of which 2 died; outbreak linked to duodenoscopy (LA Times)
- **19.02.2015:** FDA released “Awareness Letter” regarding Duodenoscopes used for Endoscopic Retrograde Cholangiopancreatogram (ERCP) ; “Design may impede effective cleaning” (FDA MedWatch)
- **20.02.2015:** lawyers targeting UCLA and Olympus (Associated Press)
- **25.02.2015:** first UCLA patient suing Olympus (Law360)
- **04.03.2015:** Cedars-Sinai Medical Centre reports 37 exposed patients of which 4 were infected (LA Times)
- **07.04.2015:** first lawsuit against Olympus after 2012 Pittsburgh outbreak (Meyers Evans & Associates)

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Endoscopy Cases in the USA

- **20.04.2015:** Olympus had warned European hospitals in 2013 about risks related to endoscopes. No warning to US hospitals. (Seattle Times)
- **07.05.2015:** FDA reporting 142 incidents since 2010 (121 injuries, 13 deaths); 670'000 ERCP procedures per year (LA Times)
- **12.05.2015:** LA Times reports about Dutch report on outbreak in a Rotterdam hospital in 2012 (22 infected) and an outbreak at the Charité hospital in Berlin (12 infected); these were followed by the Olympus warning in Europe (LA Times)
- **12.05.2015:** Seattle hospital to join lawsuit against Olympus (after CRE outbreak in 2012 (11 died). Widow of victim filed lawsuit against Olympus (Reuters)
- **14/15 May 2015:** FDA Advisory Panel Meeting. Olympus holds a 85% US market share. Others: Pentax, Fujifilm. "Custom Ultrasonics" (main reprocessing machine manufacturer)

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Endoscopy Cases in the USA

- **03.08.2015:** Other types of endoscopes affected: bronchoscopes, cystoscopes, colonoscopes. Issues were known for years. FDA blamed for inappropriate gathering of data and reporting. (LA Times)
- **04.08.2015:** FDA Safety Communication. Recommend additional cleansing steps when reprocessing. (FDA)
- **06.08.2015:** Heavy criticism of FDA's reluctance in monitoring and warning. New lawsuit in Pittsburgh (2012 outbreak) (USA Today)
- **12.08.2015:** FDA "Warning Letter" to Olympus
- **19.08.2015:** Huntington Memorial Hospital Pasadena. Suspected causation. (LA Times)
- **17.09.2015:** FDA recommendations on reprocessing of flexible bronchoscopes.

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Claims Farming through Patient Advocate Groups



drugwatch Drugs & Devices Current Lawsuits FDA Recalls

Did you contract the Superbug Infection from an Endoscopy?

If you or a loved one caught the Superbug CRE or another dangerous bacteria after undergoing a routine Endoscopic Procedure, you may have legal options.

Name Phone Number

Email Address

Comment

Get Your Free Case Review

Let Us Help You Understand Your Options



The Peterson Firm
Washington, D.C.

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Legal Considerations US

- Preparation of law suits is expensive and time consuming
- Proof of causation is not guaranteed
- Hospitals will not blame the victims of an infection as often is the case in negligence cases

Who will finally bear the economic burden?

- Health Insurance Carriers? (state funds or private)
- Social Security System?
- Employment Benefits Insurance?
- Health Care Providers?
- P & C Insurance Carriers?

- **Who finally assumes liability?**

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USA: health care provider

- 2015 Study: Surgical site infections (occurring 30 days after patient is discharged) are most common reasons for unplanned hospital readmission (Northwestern Medicine and American College of Surgeons, 03.02.2015)
- **Medicare** will reduce reimbursement to hospitals with too many unplanned readmissions (under the Affordable Care Act 2010) (WSL, 11.02.2015)
- **Seattle hospital** (Virginia Mason Med. Center) to join lawsuit against Olympus (after CRE outbreak in 2012 with 11 fatalities)

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Germany: Hospitals

- **Flat-Rates for medical treatment** to cover all medical/nursing costs during hospital stay
 - Rates based on original diagnosis which lead to hospitalization.
 - Additional costs during hospital stay are born by the hospital
 - => financial loss to hospital

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Germany: Health Insurance Carriers

- **Additional medical treatment** after patient's discharge from hospital: => financial loss to the health insurance carrier
(Hospital's negligence leads to infection)
- **Cost-Sharing Agreements** between health insurance carriers and the liability insurance carriers of hospitals;
45% of additional costs caused by hospital acquired infections are born by liability carrier.
- Boston Scientific Medizintechnik: health insurance carriers **subrogated** medical costs for replacement of probably defective pacemakers (EuGH 03/2015).

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Germany: Patient

- Financial losses born by **patient**:
loss of earnings, pain and suffering, other extra expenses related to disabilities.
- Reversal of **burden of proof in case infection** arose out of the so-called “hygienic fully controllable range“ (hygienisch beherrschbarer Bereich) and have not been caused by any professional act of the medical staff (Federal Supreme Court decisions 2007/08)



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Potential Litiagation

- Europe?
- USA?
- Product Liability
- Medical Malpractice
- Public Liability (hospital operations)
- Business Interruption (closure of hospital ward)

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Endoscopy Cases in the USA: prior to UCLA 2015

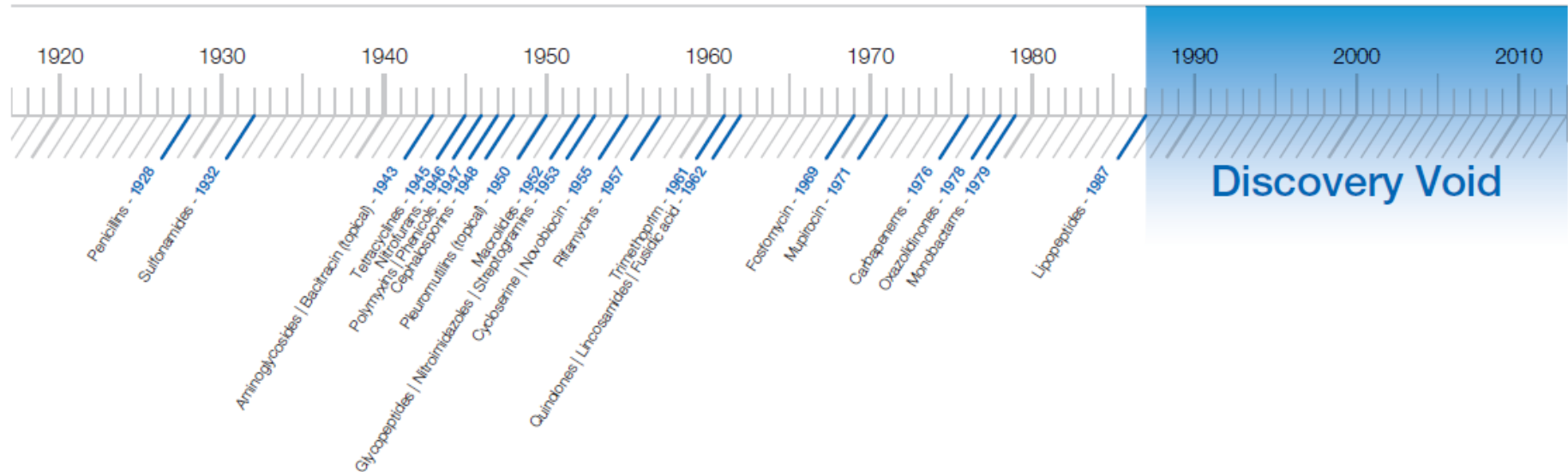
- **April 2005:** Class action with 200 claimants against Forbes Regional and West Penn Alleghany
- **2011:** Maryland (11 deaths)
- **2012:** University of Pittsburgh Medical Center
- **2012/1014:** Virginia Mason Medical Center, Seattle. 37 infected of which 11 died
- **2013:** Advocate Lutheran General Hospital, Park Ridge (IL). 38 exposed, of which 10 infected, of which 2 died.

Antibiotic Resistant Bacteria

Dynamics of Spread of ABR

The Antibiotic Discovery Void (WEF Report 2013)

The discovery dates of distinct classes of antibiotics. No new classes have been discovered since 1987.



Source: World Economic Forum, adapted from Silver, L.L. Challenges of Antibacterial Discovery. In *Clinical Microbiology Reviews*, 2011, 24:71-109.

Antibiotic Resistant Bacteria

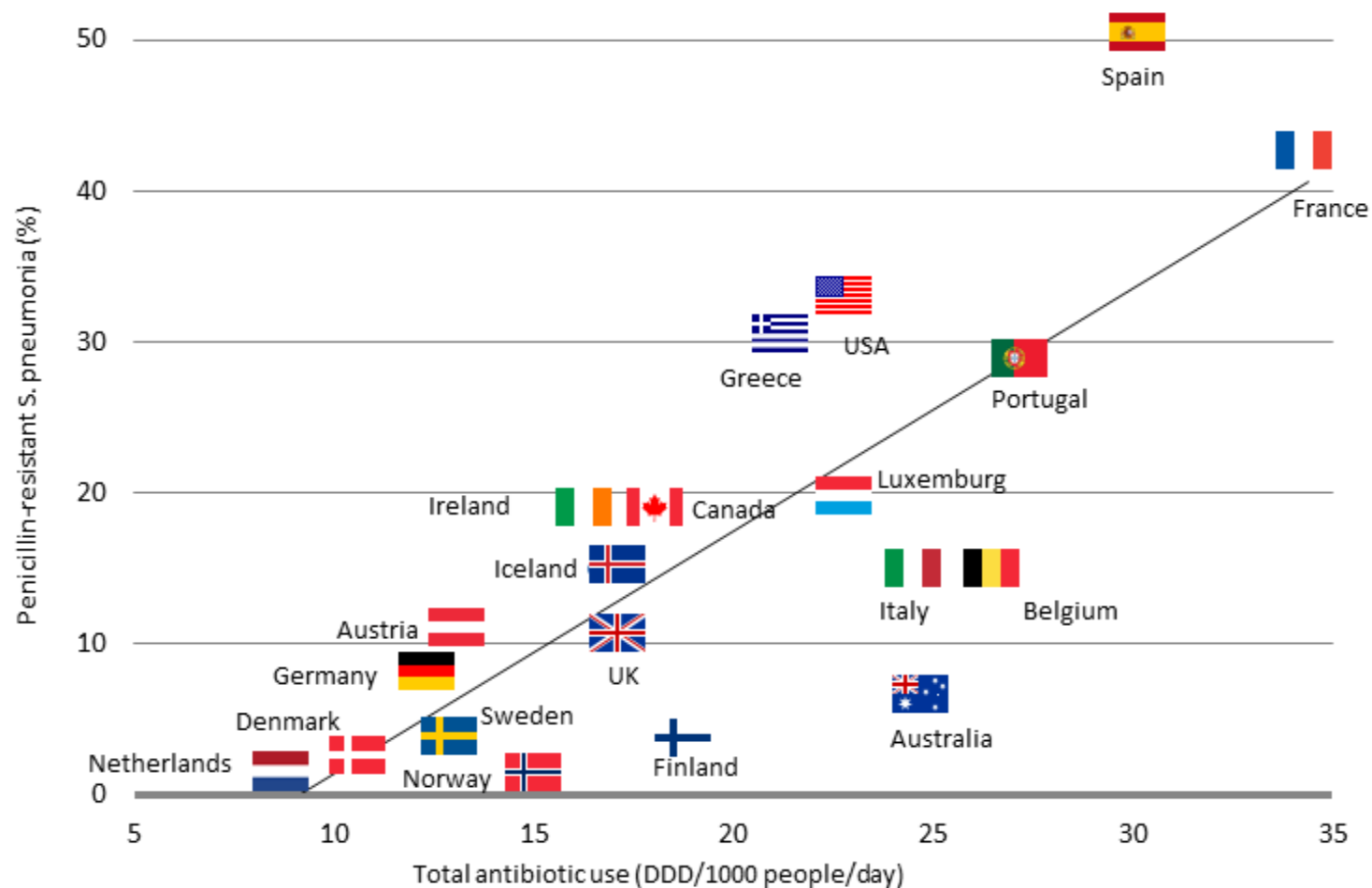
Use of Antibiotics strongly associated with Resistance

Selection and growth of ARBs in humans is largely man-made

- inappropriate prescription of antibiotics (e.g. for viral infections)
 - poor adherence to the prescribed therapy
 - utilization of counterfeit and sub-standard antibiotics
 - insufficient hygiene practices in hospitals, nursing homes etc.
-
- Use of antibiotics in livestock production (therapy and growth promoter)
 - In the USA, 80% of total annual antibiotics consumption used for livestock

Antibiotic Resistant Bacteria

Use of Antibiotics strongly associated with Resistance



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ARBs are a Global Health Challenge



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Affected Insurance

- General Liability
- Product Liability
- Workers Compensation / Employers Liability
- Medical Malpractice
- Business Interruption following enforced closure by public authorities (ABI 1989)

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Health Burden

- patients more likely to develop complications
- patients 3 times more likely to die
- time to agree on the appropriate therapy is up to 6 times longer during which the ARBs can spread to other organs