

New Business Models for Antibiotics:

Results from the Chatham
House Working Group

Uppsala Health Summit

Prof. Kevin Outterson

Gain-Of-Function Research



- Lipsitch M., Galvani AP. Ethical alternatives to experiments with novel potential pandemic pathogens. PLoS Med 11(5):e1001646 (May 20, 2014)
- US Government gain-of-function deliberative process and research funding pause on selected gain-of-function research involving influenza, MERS, and SARS viruses (Oct. 17, 2014)

Policy tripod

- Access
- Conservation
- Innovation



Hoffman SJ, Outterson K, et al. Bulletin of the WHO 2015;93:66; other papers forthcoming in Journal of Law, Medicine & Ethics (Summer 2015).

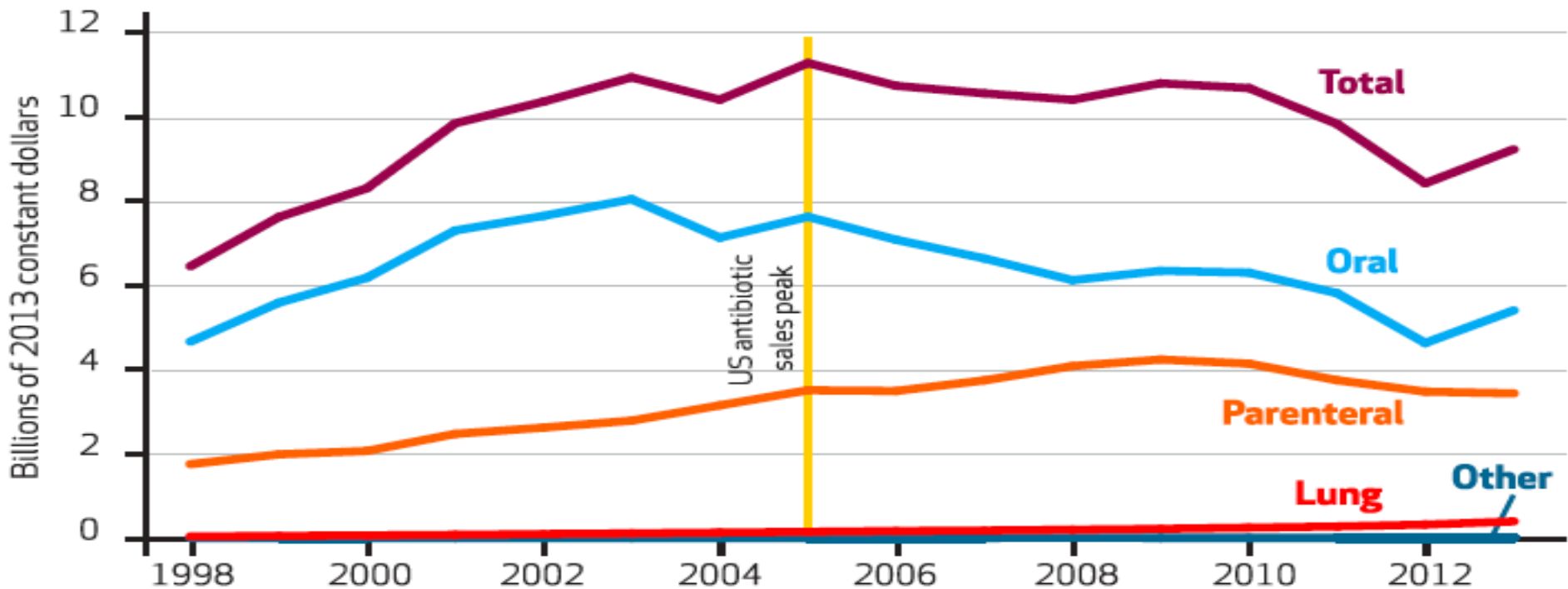
Recommendation 1.1

Phase	Incentives	Standards
Preclinical	Research grants	Very broad
Clinical	Tax credits PPP contracts	QIDP/PR Threat assessment
Post-registration	Delinkage	Threat assessment

Peak antibiotics

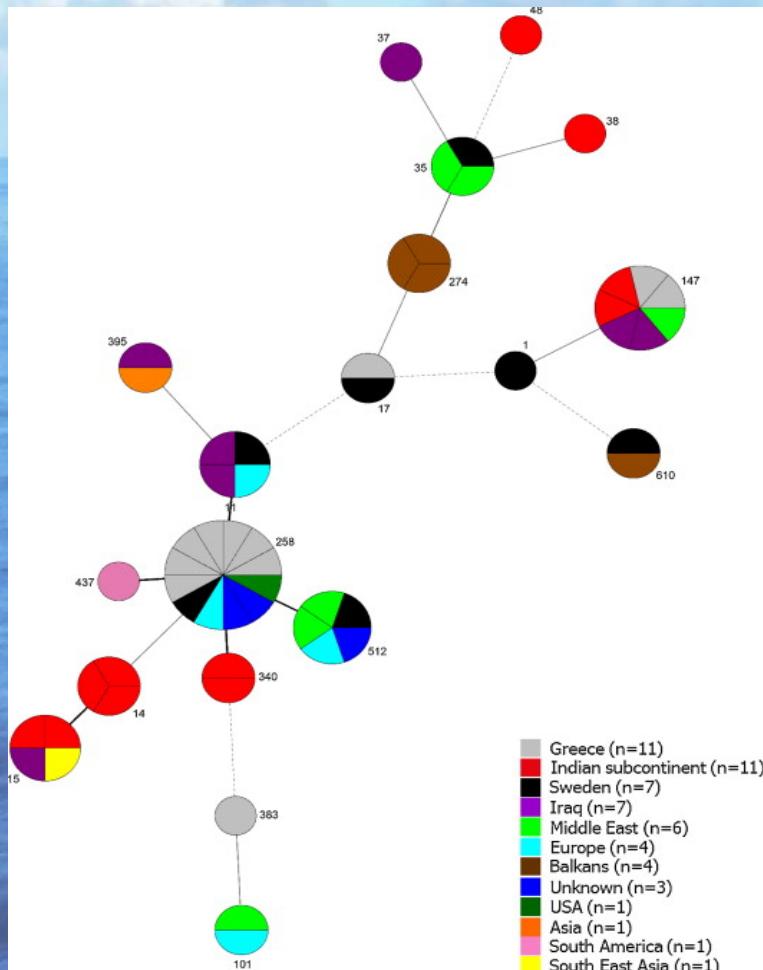
EXHIBIT 2

US Antibiotic Sales For Human Use, In 2013 Constant Dollars, By Mode Of Administration, 1998-2013



SOURCES IMS Health (US manufacturer US dollar sales at ex-manufacturer prices), and St. Louis Federal Gross Domestic Product deflator (2013 = 100).

CPE in Sweden, 2007-2013



- National mandatory reporting
- 24 clinical infections, 70 other colonized
- 81% associated with travel abroad
- 84% with hospitalization abroad
- Only 1 transmission chain in a Swedish hospital
- 28% possibly XDR
- 1 case – colistin only

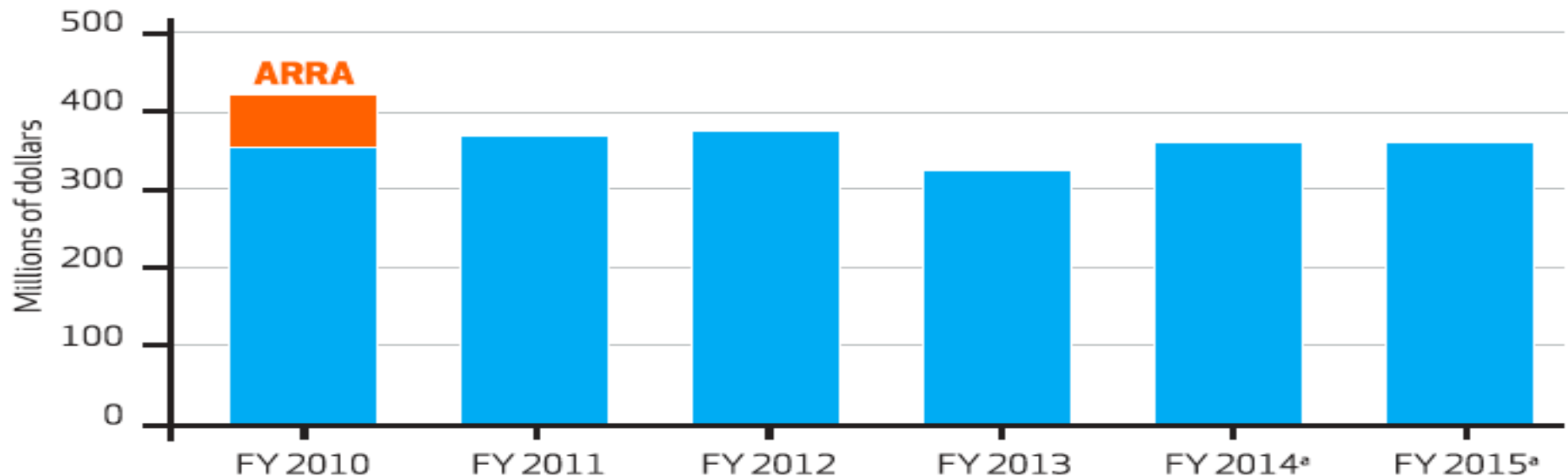
Commercial Implications

- 9.6 mm people
- GDP US\$580 bn (2013)
- 24 cases over 7 years, every case was susceptible to at least one current abx
- Market value of a CPE drug in Sweden = 0
- Insurance value might be many millions/year.

NIH AMR funding

EXHIBIT 3

National Institutes Of Health Research Spending On Antimicrobial Resistance Research, United States, Fiscal Years 2010-15



SOURCE National Institutes of Health (National Institute of Allergy and Infectious Diseases) Research Portfolio Online Reporting Tool, Estimates of Funding for Various Research, Condition, and Disease Categories (August 20, 2014). **NOTES** Adjusted annually for US Consumer Price Index, fiscal year (FY) 2010 base. American Recovery And Reinvestment Act (ARRA) funding is for FY 2010 only. *Estimated.

Strategic Alternatives

- Higher Prices
- Delinkage
- Hybrids

Delinkage Analogies

- Prizes
- Insurance
- Defense/Big Science
- Strategic Antibiotic Reserve

Magnitude of Incentives

Model	Payments from Governments	eNPV benchmark at start of R&D
Sharma & Towse	\$2.5 bn (\$500m/yr over 5 years)	\$300m
Eastern Research Group	\$919m (over R&D cycle)	\$100m
O'Neill	\$1-\$4 bn	Not stated

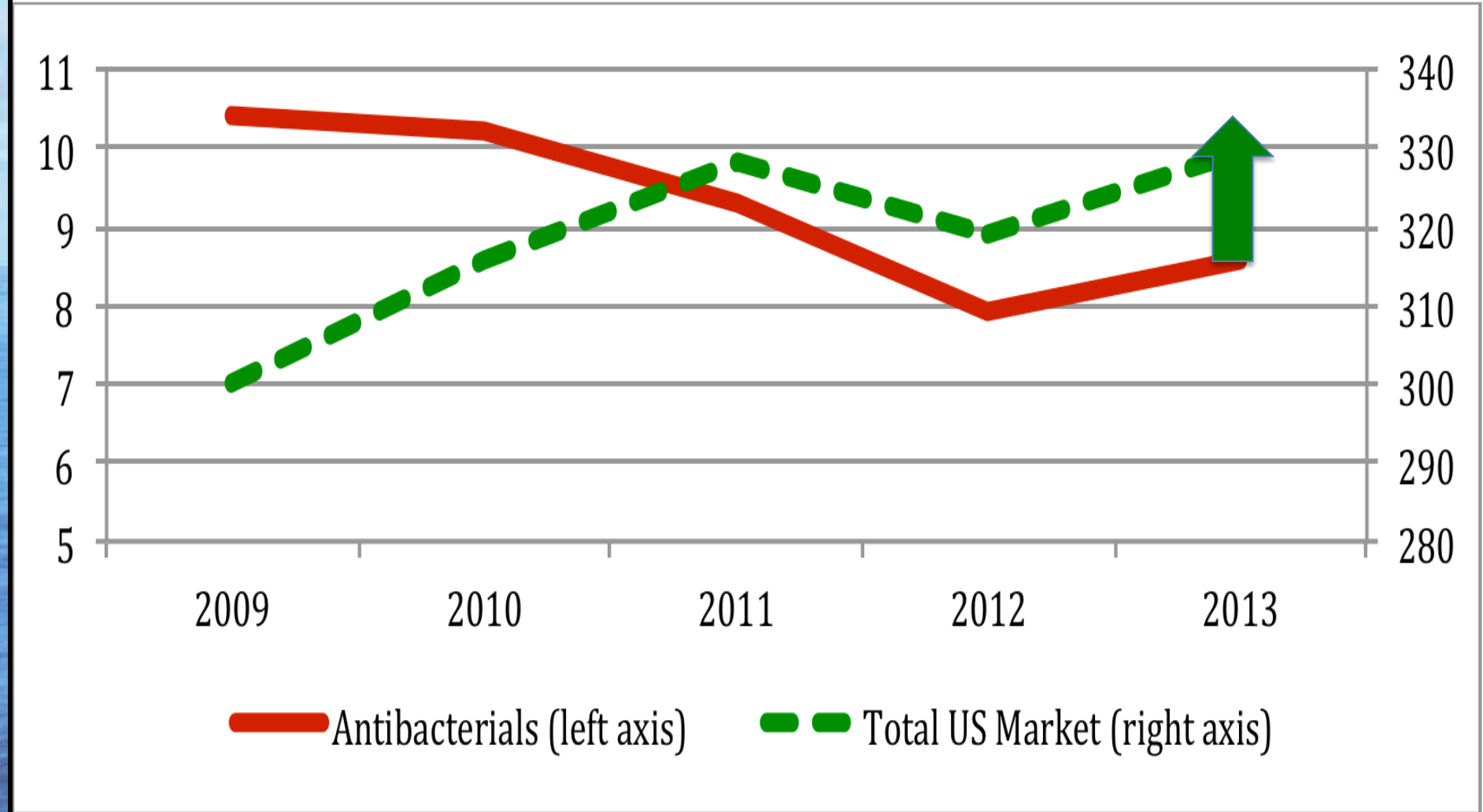
Rex & Outtersson, 2015 (in review)

NATIONAL STRATEGY FOR COMBATING ANTIBIOTIC- RESISTANT BACTERIA



Vision: The United States will work domestically and internationally to prevent, detect, and control illness and death related to infections caused by antibiotic-resistant bacteria by implementing measures to mitigate the emergence and spread of antibiotic resistance and ensuring the continued availability of therapeutics for the treatment of bacterial infection.

Figure 1b. Non-discounted US spending, antibacterials & all prescription drugs, US\$ billions, 2009-2013



Source: IMS Health 2014.

Financing

- \$1.8bn = 0.5% 2013 US Rx



0.006% 2013 US NHE

\$5.68 US per capita

- User fee on non-human uses (Hollis, NEJM 2014; Health Policy 2014)

Chatham House WG

- **Broad ranging discussion leading to a workshop on new business models Oct. 2013**
- **Reports were prepared in advance for the workshop, covering all known proposals**
- **Workshop report published: Outterson K. *New Business Models for Sustainable Antibiotics* (Feb. 2014).**

Chatham House WG

- **March 2014: new *functional* approach**
- **6 subgroups, with a broad range of Members and Observers**
- **Iterative process**
- **Full day workshop in Geneva Oct. 2014**
- **Editors: Charles Clift, Unni Gopinathan, Chantal Morel, Kevin Outterson, John-Arne Røttingen, Anthony So**

Key delinkage elements

- **Delink revenues from sales volume (conservation);**
- **Increase total incentives for antibiotics; and**
- **Preserve access without regard to ability to pay.**

Functional elements

- 1) Structuring the reward
- 2) Product scope
- 3) Financing
- 4) IP
- 5) Rationalizing antibiotic use
- 6) Geographic scope

Recommendation 1.1

Phase	Incentives	Standards
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Recommendation 1.2

Create a fully transparent and independent process to evaluate the fairness and effectiveness of all antibiotic development incentives.

Recommendation 2.1

- **Global threat assessment**
- **Data-driven, transparent, and focused on threats posed by resistant pathogens**
 - **Triage list outcome**
- **Goal is to maximize public health**

Recommendation 4.1

- **The delinkage business model should guarantee global access to antibiotics together with appropriate use.**
- **Appropriate responsibilities should be allocated between governments and the innovator when negotiating the terms of the delinkage payments.**

Recommendation 5.3

- **Ban the use of antibiotics as growth promoters in agriculture, backed by an international health regulation and coherence with global trade rules.**
- **Alternative ways of preventing infection in agriculture should be researched and implemented.**

Recommendation 6.1

- While complete global coverage is the ultimate goal, the geographic scope of participation can vary in the early years.**
- Financial participation can begin with a core group of countries.**
- Every country should participate through surveillance, hosting clinical research, conservation and public health initiatives.**

Recommendation 6.2

A globally harmonized antibiotic approval process, acceptable in particular to countries with weaker national drug regulatory systems, should be established for antibiotics resulting from the new business model.

Recommendation 6.4

Evaluate the Medicines Patent Pool as an entity to hold and coordinate global IP licences for antibiotics.

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