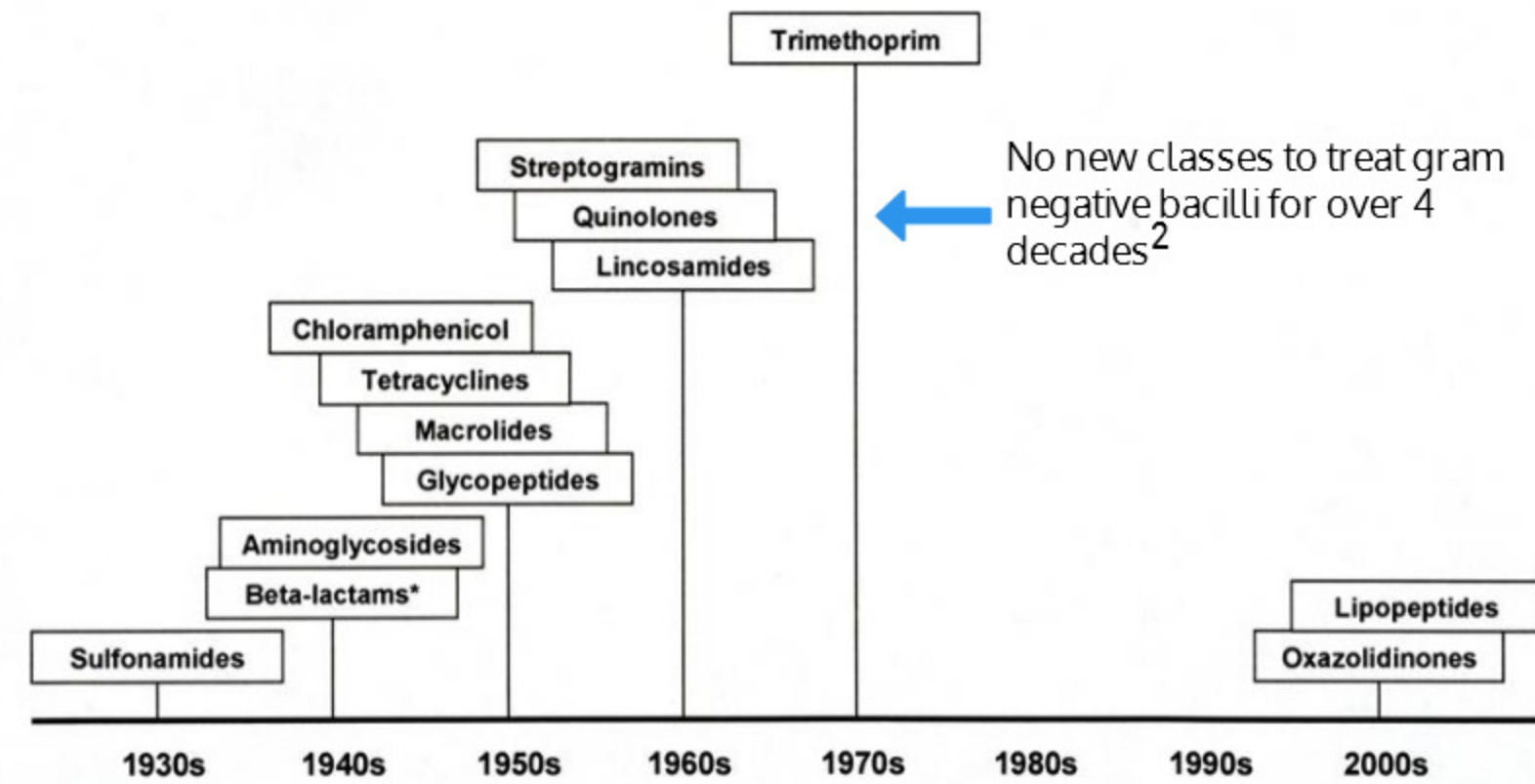
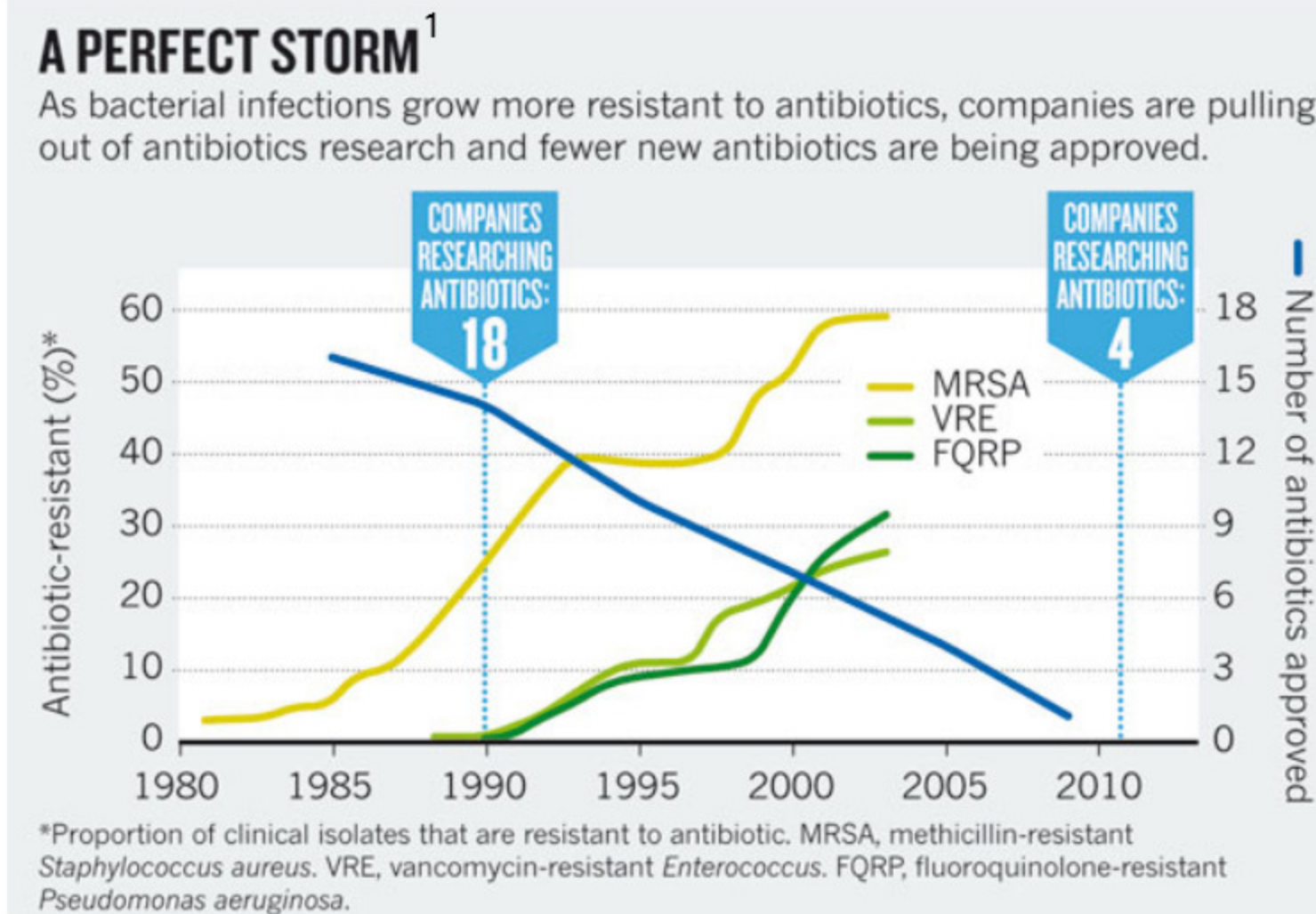


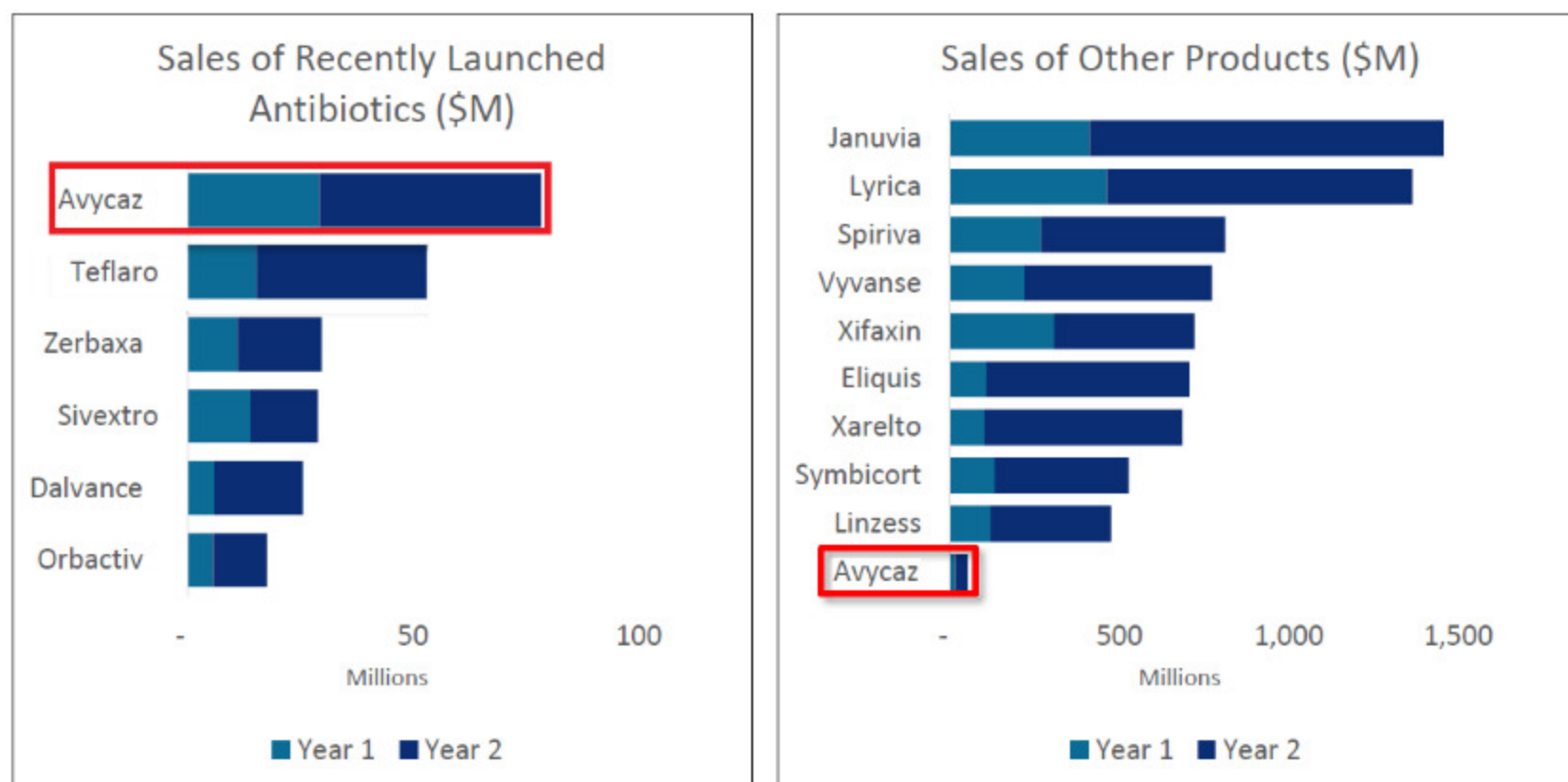
## NO NEW DRUGS TO COMBAT ANTIMICROBIAL RESISTANT BUGS

Discovery and development of new antibiotics has slowed dramatically. Every current antibiotic is a derivative of one discovered between 1900 and 1984, and the rapid increase of antibiotic resistance has led to infections that are untreatable. Most major drug companies have reduced or quit antibiotic R&D, leaving the critical job of discovering new antibiotics to small companies with limited budgets and R&D capacity.



Antibiotic research and development poses unique scientific, regulatory, and economic challenges, which often makes antibiotic R&D riskier than R&D for other types of drugs. Some companies report that over a 10-year period, it took 72 lead candidate antibiotic compounds in the early discovery phase to yield one FDA-approved product; other drug types only took 15 leads to yield FDA-approval.<sup>3</sup> Antibiotics also provide less financial reward for companies as they are used for a short duration, are priced low, and are encouraged to be held in reserve to protect against the development of resistance, rather than used widely as most other drugs are once approved.

## THE ANTIBIOTICS MARKET IS BROKEN



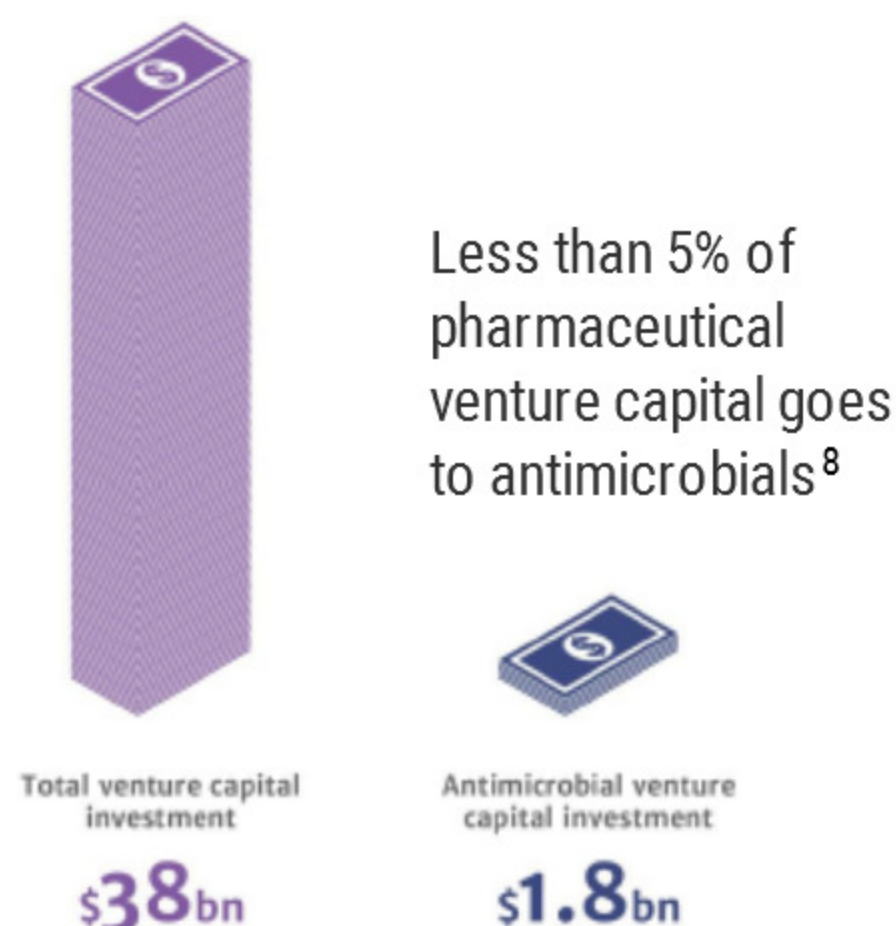
Disappointing sales of recently launched antibiotics 2 years post launch; Avycaz, a 3rd generation antibiotic indicated for complicated intra-abdominal infections (cIAI), had sales of \$75M post launch, other classes of drugs have sales between \$500M - over \$1B in sales.<sup>4</sup>

The risk/benefit and profitability of pursuing development is determined by net present value (NPV), the sum of all investment costs in development and expected present value of future revenues, given a discounted rate of the time value of money of a given development program.

**A \$200 million NPV is necessary to incentivize investment. At best, the NPV for antibiotics is \$50 million.<sup>5</sup>**

Economists are in agreement that without incentives, **many antibiotics have negative NPVs.<sup>6</sup>** Compared to the NPV of approximately \$720 million to \$1.1 billion for neurological or musculoskeletal drugs,<sup>7</sup> it is clear that incentives are needed to spur antibiotic development.

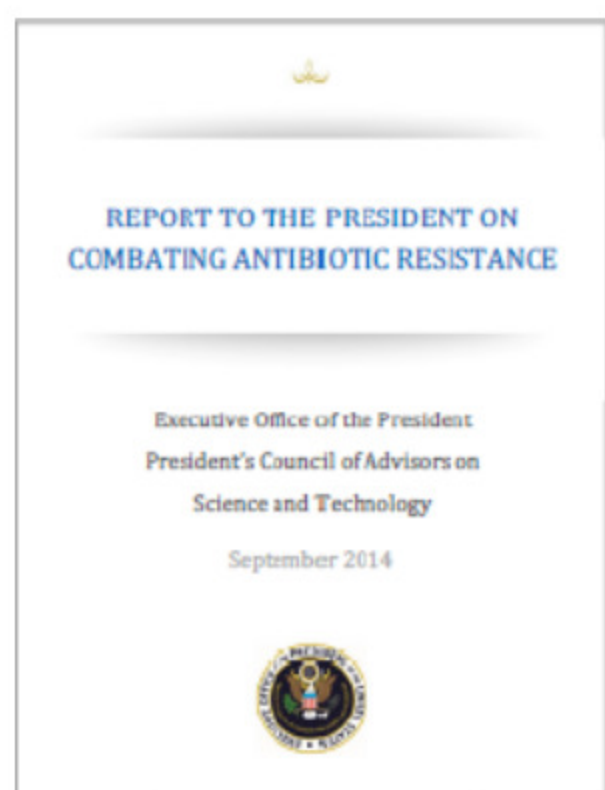
# NEED FOR FINANCIAL INCENTIVES



In order to address the difficulty and financial cost inherent in developing antibiotics, companies need incentives.

- Push incentives focus on removing barriers to developer entry by affecting the cost to the developer for investments in R&D and tend to impact the earlier stages of the development process (e.g., tax credits and grants)
- Pull incentives provide the promise of financial reward after a technology has been developed (e.g., prizes and intellectual property extensions)

## A UNITED CALL TO ACTION



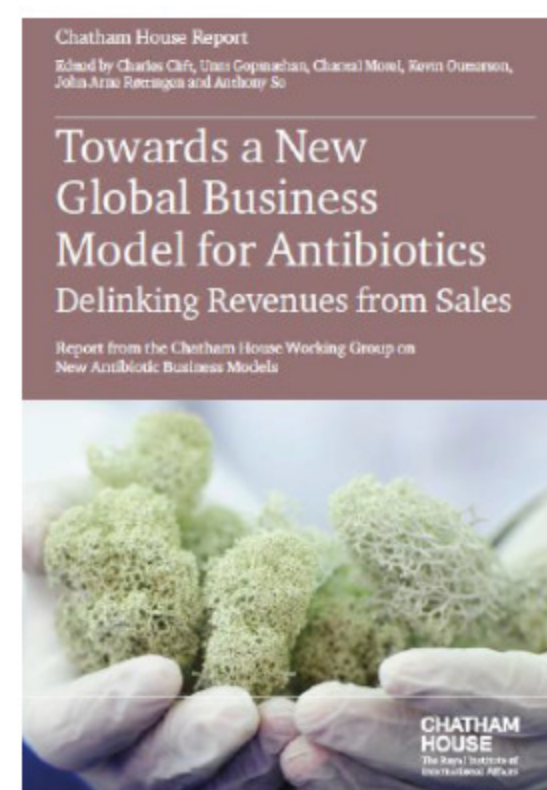
President's Advisory Council on Science and Technology



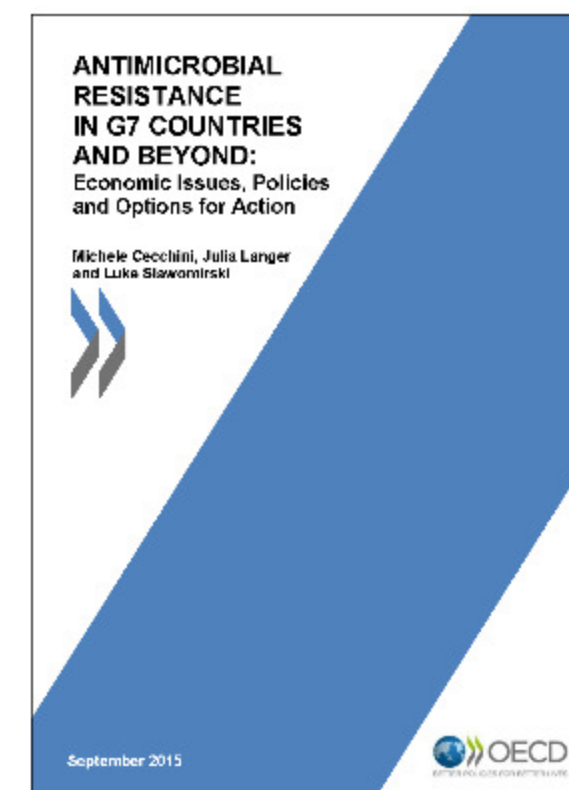
O'Neill Antimicrobial Resistance Review for the UK Government



Boston Consulting Group Report to the German Federal Ministry of Health



The Royal Institute of International Affairs (Chatham House) Report



The Organisation for Economic Co-operation and Development (OECD)

There is wide consensus in the U.S. and globally that government and private stakeholders must work together to incentivize the research and development of new antibiotics to address current and future threats to patients and public health.

For more information, visit us at [www.idsociety.org/AR\\_Policy](http://www.idsociety.org/AR_Policy)

1 Cooper, M. & Shlaes, D. (2011). Fix the Antibiotics Pipeline. *Nature*. Vol. 472 (7341).

2 Biomedical Advanced Research and Development Authority. (2016). BARDA's Antibacterial Program. Exploring Practical Implementation of Economic Incentives for Antimicrobial Development in the U.S. Expert Workshop. 20 July 2016, Durham, NC.

3 United States Congress House Committee on Energy and Commerce Subcommittee on Health. Promoting Anti-Infective Development and Antimicrobial Stewardship through the U.S. Food and Drug Administration Prescription Drug User Fee Act (PDUFA) Reauthorization. 08 March 2012. Washington, DC (statement of the Infectious Diseases Society of America).

4 IMS Health. (2016). National Sales Perspective.

5 Towse, A. & Sharma, P. (2011). Incentives for R&D for New Antimicrobial Drugs. *International Journal of the Economics of Business*. Vol. 18 (2), p. 331-350.

6 Ibid.

7 Ibid.

8 Wellcome Trust. (2016). An Overview of the Review on Antimicrobial Resistance. Exploring Practical Implementation of Economic Incentives for Antimicrobial Development in the U.S. Expert Workshop. 20 July 2016, Durham, NC.