



# ANTIMICROBIALS

## WORKING GROUP

### **Urgent Need for Novel Incentives in a Broken System**

**Emily E. Wheeler**

Associate Director, The Conafay Group

PACCARB Public Meeting

February 26, 2020



## The Antimicrobials Working Group



Responsible for nearly  
**40%** of the antibiotics in  
development in the  
United States; **25% WW\***

**12** member companies

**CARB-X**

**8** companies with  
CARB-X contract  
awards or BARDA  
portfolio development





# The New York Times

DEADLY GERMS, LOST CURES

*Crisis Looms in Antibiotics as Drug Makers Go Bankrupt*

## AXIOS

**U.S. pushes global effort to fight antibiotic resistance at UN meeting**

By EILEEN DRAGE O'REILLY

TUESDAY, SEPTEMBER 24, 2019



The 'post-antibiotic era' is here: Drug-resistant superbugs sicken 2.8M and kill 35K each year

By KEN ALLTUCKER | Wednesday, November 13, 2019



*A Fever in the Drug Industry*

By ANDREW SIDONS | October 28, 2019

Bloomberg Government

**Drug-Resistant Superbugs Spur Pharma's Plea for More U.S. Help**

By ALEX RUOFF  
August 5, 2019

# TIME

**A tiny bug ended my NFL career – and almost my life**

By BRANDON NOBLE

# THE WALL STREET JOURNAL.

**Antibiotic Makers Struggle, Hurting War on Superbugs**

Commercial prospects dim as doctors prescribe new drugs sparingly; some companies run out of cash

# The Philadelphia Inquirer

THURSDAY AUGUST 8, 2019 | PHILLYINQUIRER | CITY & SUBURBS | C | \$2.95

**Senator Casey's bill to fight 'superbugs' can help save lives**

By CORNELIUS J. CLANCY

## International Business Times

**Developing New Antibiotics Is A Matter of Life and Death**

By KASIM KUTAY on 11/09/19



**How Best To Use The Few New Drugs To Treat Antibiotic-Resistant Germs?**

By RICHARD HARRIS • November 13, 2019

## MORNING CONSULT

**Solving the Looming Superbug Crisis Will Require Bold Action From Congress**

By JIM GREENWOOD

October 25, 2019

FIRST OPINION

**Antibiotics need a special place in the drug pricing debate**

# STAT

By ALLAN COUKELL / JANUARY 7, 2020



# State of the Market: Largest Public Antibiotic R&D Companies Down 9-95% February 2019 – February 2020

Achaogen



Tetraphase



Paratek



Melinta



Nabriva



Entasis



**Biotech & NASDAQ up 31% in same period** \*As of 20 February 2020 4



## Legislative Efforts to Stimulate Antimicrobial R&D

### The GAIN Act

- The Generating Antibiotics Incentives Now (GAIN) Act created an expedited approval pathway and five years of market exclusivity for Qualified Infectious Disease Products (QIDP)

### 'Push' Incentives

- The US government (BARDA, NIAID) and CARB-X has provided critical support for research and development of innovative antimicrobials

### LPAD

- The Limited Population Antibacterial/Antifungal Drug (LPAD) Pathway allows FDA to rely on and consider alternative endpoints, limited data sets, PK/PD data, and Phase 2 data for approval

**Industry responded with 14 new molecular entity (NME) antibiotics approved by FDA between 2010 and 2019**





## Key Issue: Addressing the Reimbursement Landscape

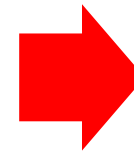
**Hospital inpatient antimicrobials are reimbursed as part of the Medicare Diagnostic Related Group (DRG) Part A bundle**

- Hospitals lose money when more expensive drugs are used



**Existing reimbursement structure impacts hospital utilization and beneficiary access to appropriate antimicrobials**

**AWG believes CMS has the existing statutory authority to implement policy without action by Congress**



**Absent a 'fix' on the 'pull' side we risk additional bankruptcies of small/mid-size companies, and innovative products stalling prior to – and immediately following – FDA approval**

*Stakeholders agree urgent, near-term action to address reimbursement is required to stabilize the antimicrobial ecosystem.*



## Addressing Antimicrobial Resistance in the CMS' IPPS Final Rule for FY 2020

- **AWG applauds CMS's leadership and special attention to measures that support antimicrobial innovation in the FY 2020 IPPS final rule, and ongoing communications with stakeholders to explore viable solutions within CMS' purview.**
  1. CMS created a new, alternative New Technology Add-on Payment (NTAP) pathway specifically for QIDP-designated antimicrobials.
    - Increased payment from 50% to 75%
    - No longer need to meet "substantial clinical improvement (SCI)" criteria
  2. CMS also increased the number of AMR diagnosis codes that are designated as a 'complication or comorbidity (CC), which generally results in assignment to a higher severity MS-DRG.
  3. On Sept. 25, 2019 CMS also promulgated a final rule including antimicrobial stewardship requirements as a Condition of Participation (COP) for Medicare.
  
- **While a positive first step, stakeholders agree that additional action is needed to stabilize and sustain the marketplace for antimicrobials to ensure physicians and patients have appropriate access to novel products.**





## AMR Incentives Under Discussion

### Antimicrobial Reimbursement Initiatives

- The DISARM Act / Separate payment outside the Medicare Part A DRG

### Additional Efforts by HHS/ASPR/BARDA

- New funding/authority to support antimicrobials post-approval

### Novel Pull Incentive

- Market Entry Reward (MER) or Transferable Exclusivity Extension (TEE)

### Subscription / Site-license / 'Netflix' Model

- Example: UK Pilot Project



## CMS has Acknowledged an Intent to Lead a Broader Effort Related to Antimicrobials

***“...In the long-term, CMS will lead a broader effort to modernize Medicare’s payment systems for antibiotics and other endangered innovations...”***

***Antibiotic drug resistance is like a hydra — cut off the head of one infection using a drug and another emerges in its place with newly acquired defenses. To keep Americans safe, we need to be vigilant in our care and focused on transforming Medicare to bring payment policies in line with public health needs. By removing regulatory roadblocks and reimagining financial incentives, we can fire up the engine of American innovation to arm our doctors for their battle against drug-resistant bacteria.”***

- CMS Administrator Seema Verma, STAT News (Nov. 6, 2019)

**Stakeholders have continued engagement with CMS into the FY 2021 rulemaking process with maintained focus on action to stabilize the antimicrobial ecosystem**



# ANTIMICROBIALS

## WORKING GROUP

AWG looks forward to continued work with US government partners and AMR stakeholders on the urgently needed package of solutions to stabilize the fragile antimicrobial ecosystem.

**Emily E. Wheeler**

Associate Director, The Conafay Group

[ewheeler@conafaygroup.com](mailto:ewheeler@conafaygroup.com)