COMMITTEE ON THE LONG-TERM MEDICAL AND ECONOMIC EFFECTS OF ANTIMICROBIAL RESISTANCE

FDA Involvement on the National Strategy for Combatting Antimicrobial Resistant Bacteria

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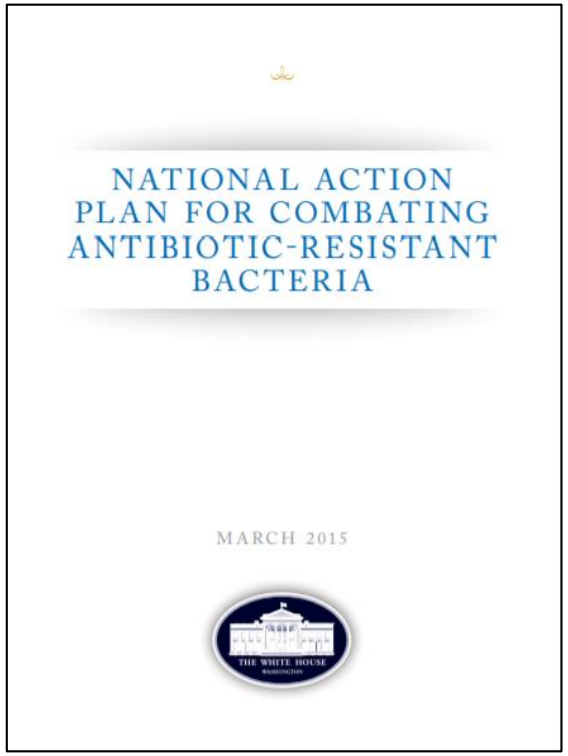
FDA Involvement in CARB Strategy

Multiple FDA Centers contributing:

- **Center for Veterinary Medicine (CVM)**
  - antimicrobial drugs for animal use
- **Center for Drug Evaluation and Research (CDER)**
  - antimicrobial drugs for human use
- **Center for Devices and Radiological Health (CDRH)**
  - medical devices including in vitro diagnostic products
- **Center for Biologics Evaluation and Research (CBER)**
  - biological products for humans



FDA was involved in about 40 action items included in the 2015-2020 National Action Plan

Note: FDA does not have pre-market review authority for animal devices; biologics for animals are regulated by USDA's Center for Veterinary Biologics

Center for Veterinary Medicine (CVM) AMR Activities

Antimicrobial stewardship in veterinary settings is needed to optimize antimicrobial use and slow the development of antimicrobial-resistant bacteria

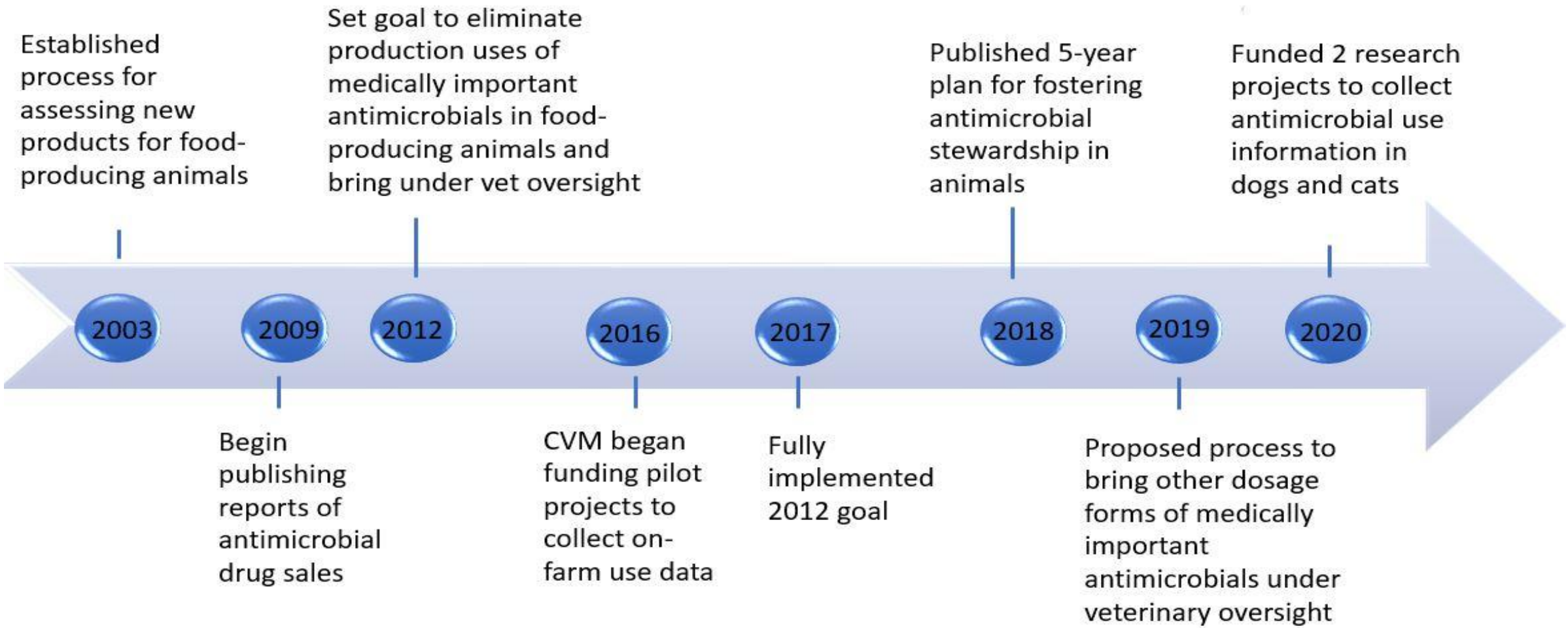
CVM's Key Areas of Focus (Goals of 5-year plan)

- Evaluating use conditions of approved animal antimicrobial products
- Promoting antimicrobial stewardship at the user level
- Collecting data to monitor animal antimicrobial use and antimicrobial resistance

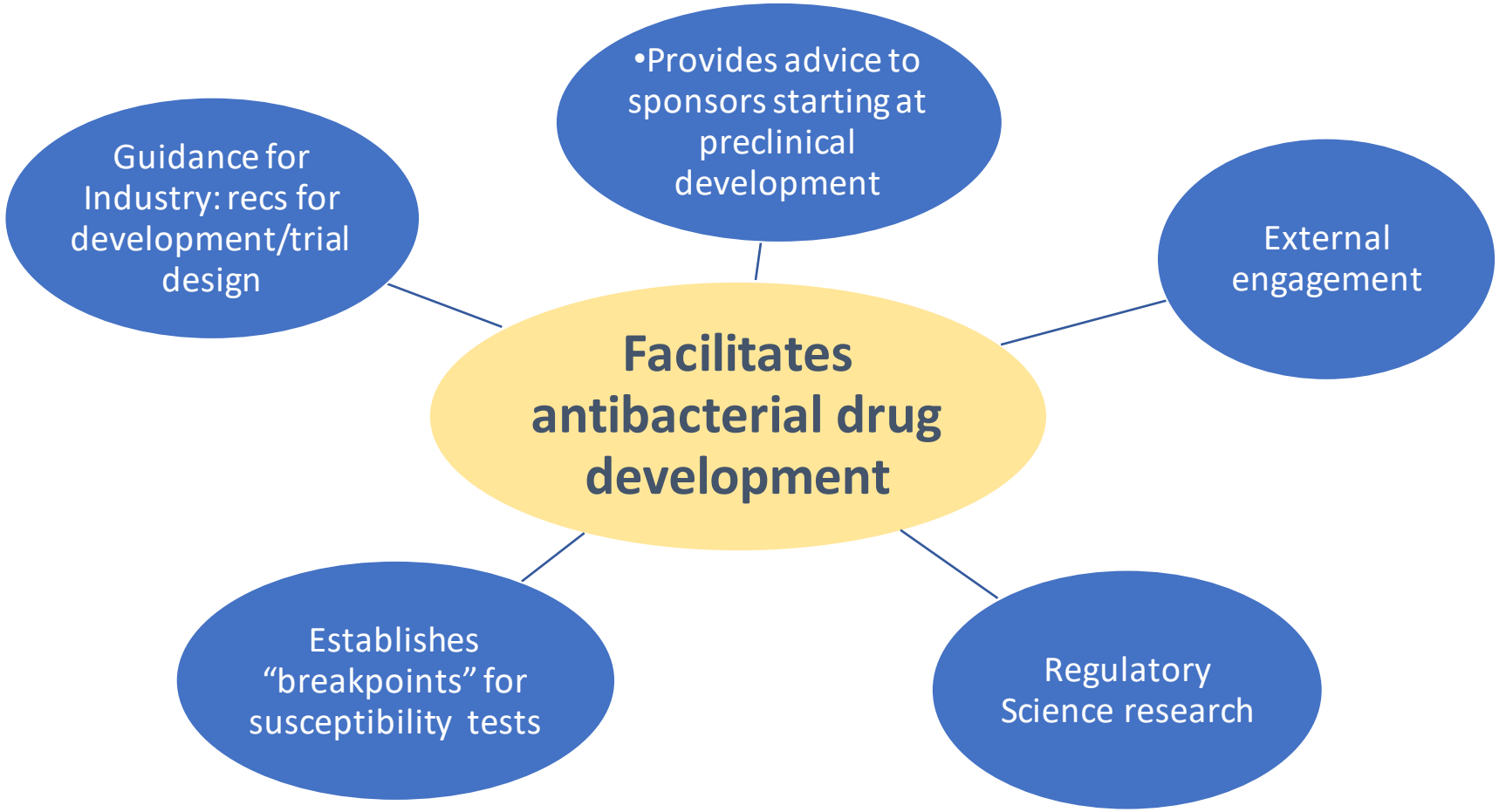
CVM's Approach for Implementing Change

- Focusing actions or mitigations on drugs of greatest concern: drugs that are important human therapies ("medically important antimicrobials")
- Emphasizing collaboration and seeking cooperation from industry to take action voluntarily

CVM's Key Actions to Date



Center for Drug Evaluation and Research (CDER): Facilitates antibacterial drug development



Encouraging Antibacterial and Antifungal Drug Development

- Generating Antibiotic Incentives Now (GAIN) Act, July 2012
  - A drug intended to treat serious or life-threatening bacterial or fungal infections can be designated as a "Qualified Infectious Disease Product" (QIDP)
    - Incentives: priority review, fast-track designation, and 5-year extension of marketing exclusivity
    - FDA has designated 207 QIDPs. This includes about 95 novel drugs. Since the enactment of GAIN, 26 QIDPs (NDAs) have been approved by FDA.
- Streamlined development in areas of unmet medical need; balancing disease severity, unmet need, benefit, risk, and uncertainty to address patient need
- 21st Century Cures established the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD pathway) for antimicrobials intended to treat serious and life-threatening infections in limited patient populations

Center for Devices and Radiological Health (CDRH): Antimicrobial Resistance

- CDRH oversees regulation of in vitro diagnostic products relevant to antimicrobial resistance:
  - Phenotypic tests: Examining microbial growth in the presence of antibiotics
  - Molecular tests: Screening for microbial genes/mutations that can mediate drug susceptibility, including use of next generation sequencing
  - Stewardship: Determining viral vs. bacterial infection, early identification of sepsis or antibiotic de-escalation
- CDRH regulates device-led combination products coated or embedded with antimicrobials

CDRH AMR Initiatives

- Facilitating incorporation of current breakpoints into AST devices
- CDC-FDA Antimicrobial Resistance Isolate Bank
- SHIELD (semantic interoperability of laboratory results)
  - Enabling real-world evidence clinical trials, facilitating traditional studies
  - Incorporation of real-time epidemiology into clinical decision support tools
- Database recognition
  - ReSeq TB2 database model
  - Genotypic/phenotypic associations
- Evaluating impact of simulated wound fluid on testing to improve antimicrobial effectiveness of topical products/dressings
- Use of “big data” and machine learning for sepsis diagnosis and clinical decision support

Thank you!

For updates about FDA's AMR Activities, please see:
Antimicrobial Resistance Information from FDA