

# 21<sup>st</sup> Century Cures Act

Implications for Antibiotic Development  
and Antimicrobial Resistance

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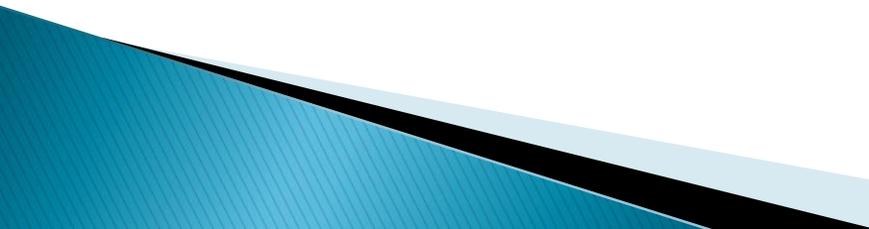
# The Cures Act: Overview

- ▶ Approved in December, 2016
    - Senate: 94 to 5
    - House: 392 to 26
  - ▶ Authorizes \$500 million in new FDA funding over 10 years
    - Funding remains subject to annual appropriations
  - ▶ Pay-for funds derived from the ACA Prevention and Public Health Fund and the Strategic Petroleum Reserve
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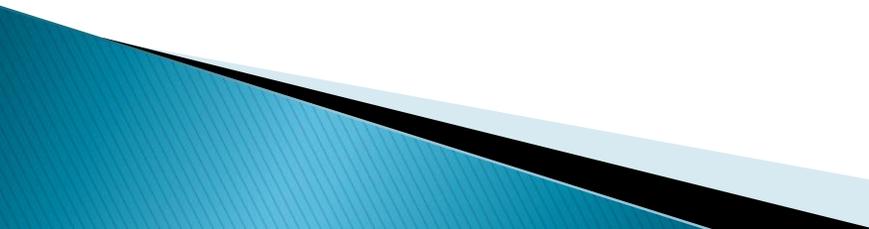
# FDA Antimicrobial Provisions

- ▶ Establishes a new approval process (LPAD) for antimicrobials intended for the treatment of serious infections in limited patient populations with an unmet medical need
  - ▶ Provides a mechanism to establish, update, and communicate susceptibility test interpretive criteria for antimicrobial drugs
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# LPAD Approvals: Evidence

- ▶ Enables approval based on a “streamlined development program” agreed to by FDA and the sponsor
  - ▶ Applications may be based on:
    - Traditional or alternate endpoints
    - Datasets of limited size where appropriate
    - Additional confirmatory evidence, including data from phase 2 clinical trials
  - ▶ May not deviate from the established approval standard of “substantial evidence”
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# LPAD Approvals: Labeling

- ▶ Antimicrobials approved under this process must be prominently labeled with the statement “Limited Population”
  - ▶ Prescribing information must include the statement, “This drug is indicated for use in a limited and specific population of patients.”
  - ▶ No restrictions on off-label prescribing
  - ▶ Sponsors must submit copies of all promotional materials at least 30 days prior to dissemination
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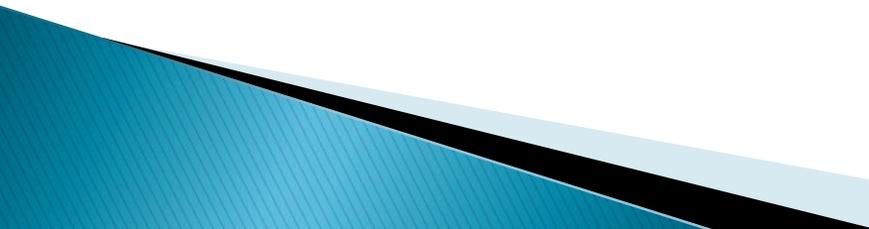
# Interpretive Criteria: Initial Identification

- ▶ Specifies that FDA initially identify susceptibility test interpretive criteria using evidence including preclinical and clinical data
  - ▶ Requires that FDA identify such criteria on the date of drug approval or licensure, or as soon as possible thereafter
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# Interpretive Criteria: Publication

- ▶ By one year after enactment, requires a dedicated FDA website containing a list of any new or updated interpretive criteria standards
  - ▶ The website is required to list:
    - New or updated interpretive criteria standards established by certain standard development organizations and recognized by FDA; and
    - Interpretive criteria that FDA considers appropriate for a particular drug, where no FDA-recognized standard applies
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# Interpretive Criteria: Updates

- ▶ Requires that FDA evaluate new or updated standards every 6 months, and publish a notice with any relevant modifications to the list
  - ▶ Specifies that FDA evaluation of new or updated standards can include:
    - Factors used in the initial identification of interpretive criteria; and
    - Information provided by interested third parties
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# Interpretive Criteria: Labeling and Limitations

- ▶ Labeling for drugs required to include a link to the website in lieu of providing susceptibility test interpretive criteria in the labeling
- ▶ Website required to include statements that:
  - Direct healthcare providers to the labeling for information on approved uses;
  - Note that susceptibility information provided on the website may relate to off-label use, for which safety and efficacy may not have been demonstrated in well-controlled trials