Re-Valuing Anti-Microbial Products (REVAMP) Act of 2018—HR 6294
Summary

- Establishes Sec. 530 of Food, Drug and Cosmetic Act providing for an award of 12 additional months of market exclusivity to a drug designated as a "priority antimicrobial product."

- Priority antimicrobial product determination
  - Committee on Critical Need Antimicrobials, appointed by Secretary and consisting of one representative from each FDA, CDC and BARDA as well as five from antimicrobial physician community, within 60 days, shall develop a list of critical need antimicrobial priorities, taking into account infections for which there are an unmet medical need and multi-drug resistance.
  - The Secretary, after receiving the list and holding public meetings, shall finalize and publish the list within 180 days. The list can be updated as necessary; initial priorities are set for 5 years.
  - Antimicrobial drug sponsor may request designation as a 'priority antimicrobial product' before or after filing for licensure; the Secretary, in coordination with he Committee, shall approve the request if the product treats or prevents a disease attributable to a multi-drug resistant bacterial or fungal pathogen that is listed a s critical need antimicrobial priority.

- Conditions of designation as a priority antimicrobial product. Sponsor must:
  - Ensure availability of product for susceptibility device manufacturers
  - Identify, track and publicly report product resistance data and trends
  - Develop written guidelines and procedures for products appropriate use, which includes appropriate promotion practices, education, surveillance, monitoring and stewardship.
  - Develop education and communications strategies for health care professions about appropriate use
  - Submit a stewardship activity assessment to agency every two years
  - Contribute five percent of the total value of consideration received from the conveyance to the Foundation for the National Institute of Health for early stage antimicrobial research.

- Conveyance Award
  - The award must be conveyed to another drug product and can be parceled for periods less than 12 months and to one or more drugs. Conveyances must be immediately reported to the Secretary,
  - The recipient of such award must be a new chemical entity drug product, first licensed after 1/1/2023, which also receives fast-track designation. Biologicals, cosmetic and drugs seeking licensure under the supplemental approval pathway are not eligible.
  - Conveyances apply to all remaining exclusivity periods and parallel-running patents and must be used at least 4 years prior to the expiration of either.
  - Only 10 awards are permitted; 180 days after issuance of the 9th award, a recommendation for reauthorization shall be provided to Congress.

- Required Studies
  - Five years after enactment, or after the fifth exclusivity extension, the CDC and GAO shall study the effectiveness of this program for developing priority antimicrobial products and examine the: indications, usage, development of resistance and private and societal value of priority antimicrobials as well as the impact on patients and markets of products using the conveyance.