In 2019, the FDA issued guidance on drug development for UTIs. To explore the impact of this guidance, we compared clinical and microbiological outcomes of the fluoroquinolones norfloxacin and ciprofloxacin (CIP) with a lower than has been published in the past. Healthcare providers should be aware that newer antibiotics may appear to have a lower efficacy than older antibiotics due to the application of more stringent definitions in the FDA guidance.

Results. When assessed in accordance with the 2019 FDA guidance, clinical and microbiological efficacy of both fluoroquinolones and β-lactam antibiotics appears lower than what has been published in the past. Healthcare providers should be aware that newer antibiotics may appear to have a lower efficacy than older antibiotics due to the application of more stringent definitions in the FDA guidance.

Disclosures. Anne Santerre Henriksen, MS, Advanze (Consultant); Shinogi BV (Consultant); UTILITY Therapeutics (Consultant); Lindsay Nicolle, MD, Entos (Consultant); GSK (Consultant); Iterum (Consultant); Utility Therapeutics (Consultant); Anita F. Das, PhD, Adagio Therapeutics, Inc. (Consultant)