Competition and Innovation Act of 2009). In this context, extrapolation occurs across drug products (i.e., from the reference product to the proposed biosimilar product).

Under PREA, a single sponsor with a single drug or biological product or drug or biological product line may conduct studies in an indication in one population (e.g., adults or older pediatric populations) and extrapolate efficacy findings to satisfy, in part, PREA requirements regarding use of that same product or product line in additional populations (e.g., younger pediatric populations). In this context, "extrapolation" occurs in a single product or product line without relying on studies comparing the product to an approved product and without conducting a full complement of additional studies in those additional populations. Under PREA, extrapolation of efficacy (but not safety or dosing) from adult populations to pediatric populations in a single drug or biological product or drug or biological product line may be permitted if the adult and pediatric indications are the same indication and the course of the disease and the effects of the drug are sufficiently similar in adult and pediatric patients. Extrapolation from one pediatric age group to another pediatric age group for a single drug or biological product or drug or biological product line also may be appropriate to fulfill a PREA requirement under these circumstances. However, under PREA, extrapolation of dosing or safety from adult populations to pediatric populations in a single drug or biological product or drug or biological product line generally is not permitted and will not satisfy a PREA requirement.

In the discussion that follows, the term "extrapolation" generally refers to extrapolation from the reference product to the proposed biosimilar product under the BPCI Act, not to extrapolation from adults or older pediatric populations to younger pediatric populations within a single product or product line under PREA.

- Adequate pediatric information in reference product is labeling
  - If the labeling for the reference product contains adequate pediatric information (information reflecting an adequate pediatric assessment) with respect to an indication for which a biosimilar applicant seeks licensure in adults, the biosimilar applicant may fulfill PREA requirements by satisfying the statutory requirements for showing biosimilarity and providing an adequate scientific justification under the BPCI Act for extrapolating the pediatric information from the reference product to the proposed biosimilar product. See question and answer I.11 in the FDA's