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Interchangeability

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Why Now?

Analytical and clinical data expectations do not differ between biosimilars and interchangeables

Analytical Data: Always consistent across biosimilars and interchangeables

Clinical Data:

"Any given patient"

- Since 2017, FDA acknowledged that this prong would not require additional clinical data*

"Switching"

- General recognition that clinical studies are "blunt instruments," with the CAA providing a "more sensitive evaluation for potential differences"**
- Interchangeability originated from a hypothetical immunogenicity concern—with the 2019 guidance published before approving a single interchangeable—that has not been borne out by research or experience (*e.g.*, pivotal Herndon et al. paper and approval of majority of interchangeables without a clinical switching study)

*FDA, Draft Guidance, Considerations in Demonstrating Interchangeability With a Reference Product (2017)
**Cavazzoni & Yim, JAMA, 2024 Sep 18

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Why Now?

Statutory standards have not changed—but, scientifically, FDA has become increasingly comfortable with the conclusion that no additional analytical or clinical data is necessary

Criticality of disentangling what information is necessary for regulatory decision-making versus what information may inform education and uptake

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Benefits of a Legislative Change

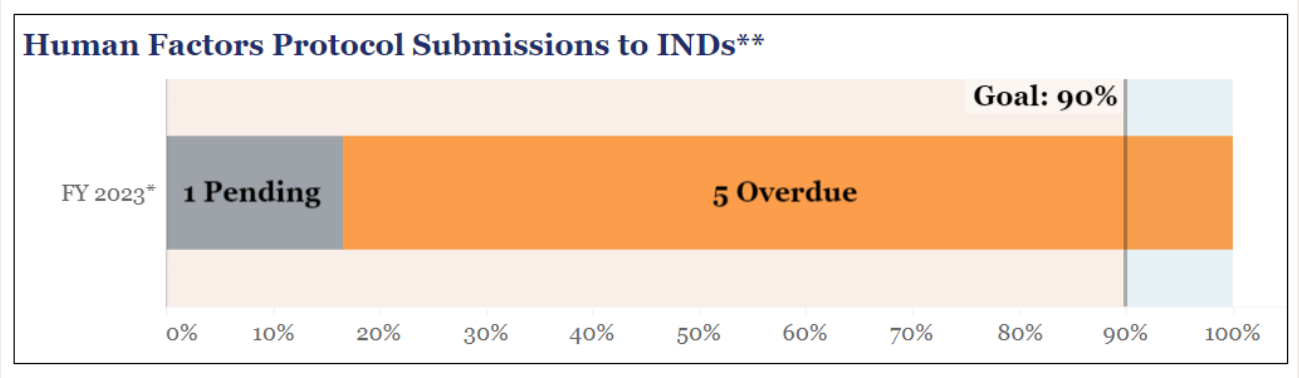
- While FDA has taken significant steps, there are limits to what the agency can achieve
- Proposals from both FDA and Congress to “deem” approved biosimilars to be interchangeable
  - FDA FY25 Budget Proposal
  - Latest version of the interchangeability legislation
- If interchangeability is only a legal distinction, why bother with a statutory change? A statutory change would:
  - ☑ Provide certainty and clarity
  - ☑ Combat deeply entrenched misinformation and misperceptions regarding biosimilars and interchangeables

Devices

- With respect to device differences, FDA has historically treated biosimilars and interchangeables differently
  - FDA's data requirements and review process, particularly for interchangeables, continue operate as barriers to development and approval

- Timely and meaningful feedback is critical to efficient development and approval, and, critically, patient access

- FY23 reported a 0% on-time review of HF protocol submissions*



*BsUFA III Tracker (FY23)

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What Else?

Earlier feedback

Amendment and supplement timelines

First interchangeable exclusivity

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