Survey Methodology

• 202 Prescribers were recruited from specified practice areas in the United States
• 10 practice areas: Dermatology, Endocrinology, Gastrointestinal, Immunology, Nephrology, Neurology, Oncology, Ophthalmology, Rheumatology
• All N-size targets (country/practice area combinations) were reached
• 5 minute web-based survey
• Data were collected in May 2019
DEMOGRAPHIC DATA/
SAMPLE CHARACTERISTICS
Primary Therapeutic Area

S1. Please indicate your primary practice area or therapeutic area in which you practice. (n=202)

- Rheumatology: 11%
- Gastrointestinal: 11%
- Endocrinology: 11%
- Dermatology: 11%
- Neurology: 11%
- Ophthalmology: 11%
- Nephrology: 11%
- Immunology: 11%
- Oncology: 10%
S2. Are you aware that a biosimilar may be approved for several or all indications of the reference product on the basis of clinical trials in only one of those indications? (n=202)
S3. For how many years post-residency have you been practicing medicine? (n=202)

- 1-5 years: 17%
- 6-10 years: 28%
- 11-20 years: 25%
- 21-30 years: 23%
- More than 30 years: 7%
On March 8, FDA released updated draft guidance regarding their policy on the naming of biologic and biosimilar products: *Proposed Suffix for the Proper Name of a Biological Product (Docket No. FDA-2013-D-1543).* The Draft Guidance is intended to reflect FDA's current thinking on nonproprietary names of certain biological products. According to the guidance:

- Originator biologics previously approved without a suffix as part of the name would not be renamed to incorporate a suffix;
- Biological products previously approved without a suffix under the Food, Drug and Cosmetic Act (e.g., insulin products, desirudin products, somatropin products) that will transition to be regulated under the Public Health Service Act in 2020, would not be renamed to incorporate a suffix;
- Biosimilars subsequently designated as interchangeable would not be renamed; each product would retain the unique suffix it was given at the time of biosimilar approval;
- Biologics approved as interchangeable would receive a unique 4 letter suffix, consistent with the naming practice for biosimilars and newly approved originator biologics.
Use of Suffixes

Please rate your level of agreement with the FDA’s decision to use 4-letter suffixes to clearly distinguish biosimilars from the originator product on which they are based, and from other biosimilars to that product? (n=202)

84.6% Agree
Retrospective Renaming

Please rate your level of agreement with FDA's decision not to rename previously approved biologics to incorporate a suffix? (n=202)

- Strongly Agree: 24.2%
- Somewhat Agree: 46.5%
- Somewhat Disagree: 16.8%
- Strongly Disagree: 7.4%
- Unsure: 4.9%

70.7% Agree
Retrospective Renaming

Please rate your level of agreement with FDA’s decision not to rename biologics previously approved under the Food, Drug and Cosmetic Act (e.g., insulin products, desirudin products, somatropin products) that will transition to be regulated under the Public Health Service Act in 2020 to incorporate a suffix? (n=202)

- Strongly Agree: 22.7%
- Somewhat Agree: 44.5%
- Somewhat Disagree: 18.3%
- Strongly Disagree: 4.4%
- Unsure: 9.4%

67.2% Agree
Renaming Post-Interchangeability Designation

Please rate your level of agreement with FDA's decision not to rename biosimilars subsequently designated as interchangeable; instead each product would retain the unique suffix it was given at the time of biosimilar approval? (n=202)

- Strongly Agree: 22.2%
- Somewhat Agree: 45.0%
- Somewhat Disagree: 19.8%
- Strongly Disagree: 3.9%
- Unsure: 8.9%

67.2% Agree
Use of Suffixes

Please rate your level of agreement with FDA’s decision to give a biologic approved as interchangeable a unique 4 letter suffix, as it does for biosimilars and newly approved originator products? (n=202)

- Strongly Agree: 29.2%
- Somewhat Agree: 52.9%
- Somewhat Disagree: 7.4%
- Strongly Disagree: 1.4%
- Unsure: 8.9%

82.1% Agree
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