

Generics and Biosimilars

Sorting Out Fact From Fiction



THIS WEBINAR IS
SPONSORED BY:

SANDOZ



UPCOMING PROGRAMS

TOMORROW - Thursday, August 22

JUMPSTART

MS Tech Toolbox: Streamline Your Daily Life

Wednesday, August 28

MS MOVES MEETUP

Starting Tuesday, September 24

COACHING SERIES

Bowel and Bladder Health: Finding Comfort, Control, and Freedom



CANDO-MS.ORG

MS COMMUNITY PROGRAMS



REGISTER TODAY!

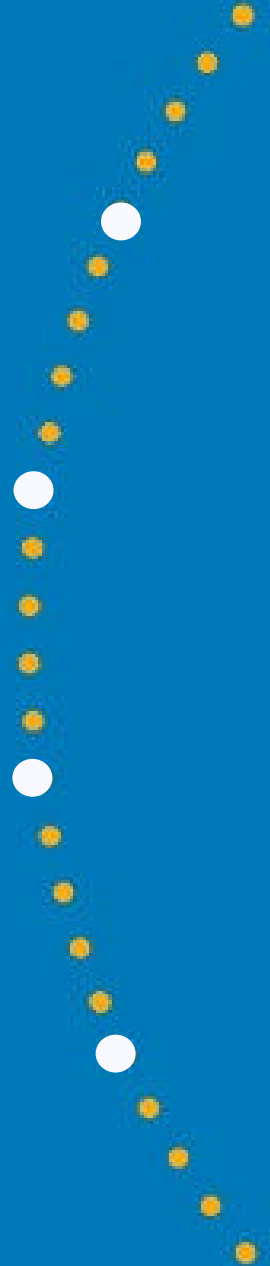
CanDo-MS.org/CP
More Dates & Locations

CLEVELAND, OH
SEPTEMBER 14

NEW ORLEANS, LA
SEPTEMBER 28

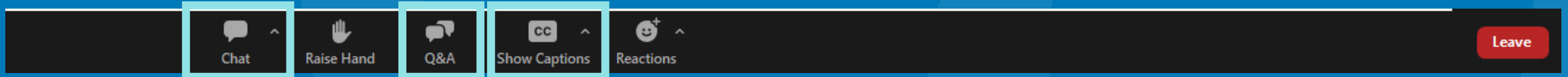
TROY, MI
OCTOBER 5

AUSTIN, TX
NOVEMBER 16



How to Ask Questions During the Webinar

Type in your questions
using the Questions Box



Provide comments and engage
with the speakers and audience
using the **Chat Box**



NEW! Closed captioning



YOUR SPEAKERS



Roz Kalb
Psychologist

Maine



Nancy Sicotte
Neurologist

California



Bari Talente
EVP, Advocacy and
Healthcare Access, NMSS

Virginia

A Glossary for Today

- **Pharmaceutical drug** – created through chemical synthesis in an ordered process; has a known structure
- **Biologic** – large, complex molecule(s) manufactured in a living system (microorganism or plant or animal cells)
- **Generic** – A follow-on medication to a brand medication that contains the same active ingredient as brand medication
- **Biosimilar** – A follow-on medication to a biologic medication that is highly similar in purity, molecular structure, and bioactivity to a reference product, with no clinically meaningful differences in safety, purity, or effectiveness
- **Reference drug** – a biologic product that has been approved by the FDA and is used to compare a proposed biosimilar.

Generics vs. Biosimilars

A Generic Pharmaceutical Drug:

- Contains the same active-ingredient formula as a drug that was originally protected by chemical patents.
- Can be sold after the original patents expire.
- FDA considers them to be as safe and effective as the patented product
- May differ in other ways (manufacturing process, other substances included with the active ingredient)
- Usually less expensive than the branded drug

A Biosimilar:

- A biologic medicine is made in a living system (yeast, bacteria, animal cells).
- A biosimilar is close enough in structure and function to the brand name biologic medicine to accomplish the same therapeutic and clinical results
- Because a biosimilar is made from living organisms and isn't identical to its brand name counterpart, it requires extensive testing, which makes it more expensive than a generic

Generics vs. Biosimilars



Biosimilars

Generally made from living sources

Require a specialized process to produce

Nearly identical to original biologics

Faster development process

Usually less expensive than original biologics



Generics

Generally made from chemicals

Have a simpler process to copy

Copy of brand-name drugs

Faster development process

Usually less expensive than brand-name drugs



Credit: U.S. Food and Drug Administration



Biologic

A new treatment

Made from
a living source

15 years to develop

\$1.2 billion
to develop

Patentable



Biosimilar

Nearly identical to
FDA-approved biologic

Made from
a living source

8–10 years to develop

\$100–\$200 million
to develop

Non-patentable



National
Multiple Sclerosis
Society

Currently Available Generic and Biosimilar MS DMT Medications

Generics

Copaxone®

- glatiramer acetate
- Glatopa®

• **Gilenya®**

- fingolimod

• **Tecfidera®**

- dimethyl fumarate

• **Aubagio®**

- teriflunomide

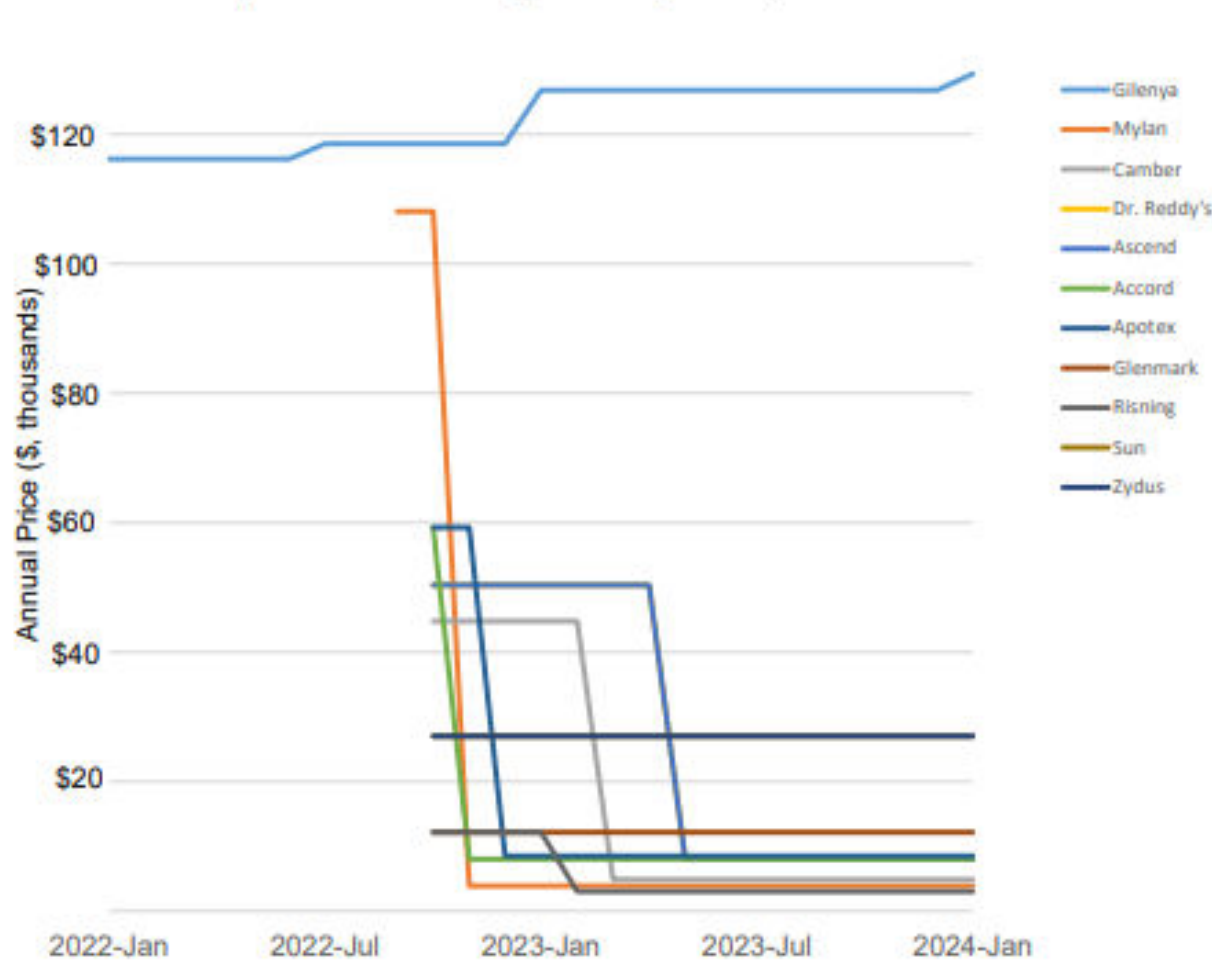
Biosimilars

Tysabri®

- Tyruko®

Price Differences Between Brand and Generics

Trends in annual price for brand and generic fingolimod; 2022 to 2024



| Manufacturer | Annual Acquisition Cost |
|--------------|-------------------------|
| Originator | \$129,349 |
| Accord | \$8,030 |
| Apotex | \$8,517 |
| Ascend | \$2,679 |
| Camber | \$4,867 |
| Dr. Reddy's | \$8,030 |
| Glenmark | \$12,167 |
| Mylan | \$3,893 |
| Risning | \$3,042 |
| Sun | \$27,022 |
| Zydus | \$27,022 |

Notes: Annual price estimated from wholesale acquisition costs (First Databank)
Updated 2.19.2024 (Data through January 2024)

Q+A



CONNECT WITH US



TIKTOK

@CanDoMultipleSclerosis



FACEBOOK

@CanDoMultipleSclerosis



TWITTER

@CanDoMS



INSTAGRAM

@CanDoMultipleSclerosis

THIS WEBINAR IS
SPONSORED BY:

SANDOZ





The preceding program is copyrighted by Can Do Multiple Sclerosis. It is provided for your personal educational and referential use only. Any repurposing or dissemination of its content requires the consent by Can Do Multiple Sclerosis.

© CAN DO MULTIPLE SCLEROSIS