Fueling
COMPETITION

The US government, healthcare agencies, consumers, and payers are all calling for a change in prescription drug prices. In response, the Food and Drug Administration (FDA) has released a plan for generics and the United States Supreme Court has published a decision on biosimilars. **Both make competition the name of the game.**[1,2]

GENERICS

today

4,205 awaiting FDA approval[3]

47 months average FDA approval time[4]

The FDA now plans to prioritize the entry of new generic drugs and branded generics in categories where there is only a single drug on the market.

TOMORROW

As more generics and branded generics come to market, they will be added to formularies quickly if not automatically, increasing competition and reducing costs for payers.

Find the full list of drugs here.

THE DETAILS +

BIOSIMILARS

today

797 in the pipeline[5]

13 months average FDA approval time[6-9]

The Supreme Court has unanimously decided that biosimilar manufacturers no longer have to wait 180 days post FDA approval to market their product.

TOMORROW

As a result of payers knowing about new biosimilars sooner, formulary considerations may occur before FDA approval, potentially creating more timely access for patients.

Read the full decision here.

THE DETAILS +

THE BOTTOM LINE FOR

Originals manufacturers +

Generics manufacturers +

Biosimilars manufacturers +

IN A BUSINESS WHERE COMPETITION IS ALREADY FIERCE, *differentiation is of the utmost importance.*

Let's work together to set your brand apart.

References: 1. Lovelace, B. FDA commissioner takes on Martin Shkreli-wannabes over huge drug price hikes. CNBC website. https://www.cnbc.com/2017/06/28/fda-commissioner-gottlieb-takes-on-shkreli-wannabes-overdrug-price-hikes.html. Published June 28, 2017. Accessed July 31, 2017. **2.** Robinson + Cole Health Law Diagnosis. Supreme Court decision allows faster marketing of biosimilars. JDSupra website. http://www.jdsupra.com/legalnews/supreme-court-decision-allows-faster-46047/. Published July 3, 2017. Accessed July 31, 2017. **3.** Brennan Z. FDA continues to reduce generic drug backlog. Regulatory Affairs Professionals Society website. http://www.raps.org/Regulatory-Focus/News/2017/02/22/26933/FDA-Continues-to-Reduce-Generic-Drug-Backlog/. Published February 22, 2017. Accessed August 1, 2017. **4.** Lupkin S. FDA fees on industry haven't fixed delays in generic drug approvals. National Public Radio website. http://www.npr.org/sections/health-shots/2016/09/01/492235796/fda-fees-on-industry-havent-fixed-delays-in-generic-drug-approvals. Published September 1, 2016. Accessed July 31, 2017. **5.** BiosimilarsPipeline.com. Biosimilars/biobetters pipeline directory. http://www.biosimilarspipeline.com/. Accessed July 31, 2017. **6.** US Food and Drug Administration, Center for Drug Evaluation and Research. Zarxio BLA 125553 approval letter. Approved March 6, 2015. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/125553Orig1s000ltr.pdf. Accessed August 1, 2017. **7.** US Food and Drug Administration, Center for Drug Evaluation and Research. Amjevita BLA761024 approval letter. Approved September 23, 2016. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/761024Orig1s000ltr.pdf. Accessed August 1, 2017. **8.** US Food and Drug Administration, Center for Drug Evaluation and Research. Erelzi BLA 761042 approval letter. Approved August 30, 2016. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/761042Orig1s000ltr.pdf. Accessed August 1, 2017. **9.** US Food and Drug Administration, Center for Drug Evaluation and Research. Inflectra BLA 125544 approval letter. Approved April 5, 2016. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/125544Orig1s000ltr.pdf. Accessed August 1, 2017. **10.** Food and Drug Administration. List of off-patent, off-exclusivity drugs without an approved generic. https://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/UCM564441.pdf. Accessed September 25, 2017. **11.** Sandoz Inc. v Amgen Inc., 582 US 1, 8, 9, 10, 15, 16 (2017).

CONTACT ANDREW GOTTFRIED
agottfried@entreehealth.com / 212-896-8026

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