Follow-on Biologics Workshop Tweets

On February 4, 2014, the FTC's Office of Policy and Planning hosted a one-day workshop about follow-on biologics in Washington, D.C. FTC staff live-tweeted the event from the Commission's @FTC Twitter account.

The following is a transcript of those tweets in chronological order for ease of reading. All Tweets, without handles redacted, remain publicly available on the @FTC account for as long as Twitter allows.

Promotional tweets

Happening at 8:30am: FTC follow-on biologics workshop: Impact of recent legislation & regulatory naming proposals on #competition. #FTCfob

Want to learn more about what follow-on biologics are & why they're important? Read this blog post: http://go.usa.gov/BDc3 #FTCfob

Watch the FTC follow-on biologics here: http://bit.ly/1bgdyNZ #FTCfob

Watch the FTC's follow-on biologics workshop here at 8:30am ET: http://bit.ly/1bgdyNZ #FTCfob

We're about to start the FTC's workshop on follow-on biologics! 8:30am-5pm ET. Agenda, more info: http://go.usa.gov/BjSB #FTCfob

Workshop tweets

Andrew Gavil, FTC's Director, Office of Policy Planning, welcomes all to FTC workshop on follow-on biologics. #FTCfob

FTC Chairwoman Edith Ramirez provides the opening remarks at #FTCfob workshop: pic.twitter.com/xHlNcypAxX

This Competition Matters blog post explains biologics: http://go.usa.gov/BDc3 #FTCfob

Watching our follow-on biologics workshop today? Here's how to submit your questions online: http://go.usa.gov/BWYF #FTCfob

Now up, a quick road map on the mornings presentations from FTC's Susan DeSanti. #FTCfob

You can find bios for FTC staff, workshop panelists & presenters here: http://go.usa.gov/BDvC #FTCfob

Full room at the FTC's workshop on biologics! #FTCfob pic.twitter.com/5ryEocYK4O

Harvard's Aaron Kesselheim now up: Lessons for regulation of follow-on biologics from experiences w/small molecule drugs. #FTCfob

Kesselheim explains Hatch-Waxman market outcomes from 1980-on. By 2012, 84% prescriptions filled w/generic drugs (up from 19%). #FTCfob

Barriers to generic drug: ?s abt safety & comparability; brand-name marketing; & physicians not knowing about costs - Kesselheim. #FTCfob

Kesselheim says the state drug product selection laws are a big part of the success of generic drugs. #FTCfob

Science will continue to evolve in this space, says Kesselheim at the #FTCfob workshop. pic.twitter.com/Y2CQ91AbQk

Emily Shacter, ThinkFDA, explains rigorous FDA review process for biosimilars & interchangables. #FTCfob

Biological product highly similar to reference product; only minor differences in clinically inactive components. - Shacter #FTCfob

Shacter: FDA will only approve a biosimilar that can be expected to perform similarly to a U.S.-licensed reference product. #FTCfob

Significant differences in molecular attributes can't be overcome w/clinical studies. - Shacter #FTCfob pic.twitter.com/BLt516jJIY

Want to join our follow-on biologics workshop? Webcast: http://bit.ly/1bgdyNZ Agenda, more info: http://go.usa.gov/BjSB #FTCfob

Now up, Leigh Purvis, AARP, w/a presentation on the consumer overview of biosimilars. #FTCfob

Purvis: Biologics represent the future of the drug industry. #FTCfob pic.twitter.com/IOhUZqM9tF

Ronny Gal, Bernstein Research, discusses the current state of follow-on biologics in the U.S. & Europe. #FTCfob

Gal says adoption of biosimilars is critically dependent on market infrastructure; varies significantly between countries. #FTCfob

We're taking a quick break. See you back here at 10:10am ET. #FTCfob

We're back w/ Jessica Mazer. She presents an introduction to state biosimilar substitution laws. Watch: http://bit.ly/1bgdyNZ #FTCfob

Mazer discusses 2014 biosimilar legislation. #FTCfob pic.twitter.com/lBRod7isxo

Up now: Geoffrey Eich, Amgen, with the industry perspective on state substitution laws. #FTCfob

Eich: Biologic adverse event attribution will be difficult w/o complete & accurate patient records. #FTCfob

Steven Miller, Express Scripts, provides the customer perspective on biosimilars. #FTCfob

(Retweet) Dr Miller: based on conservative assumptions, US savings potential for #biosimilars could be $250B through 2024 #FTCfob

Key takeaway from Miller: Payers & plan sponsors are v. concerned about rising & unsustainable Specialty Rx cost. #FTCfob

Now, Bruce Leicher, Momenta Pharmaceuticals, with a presentation on the innovation of interchangeable biosimilars. #FTCfob

Why is substitution so important? Leicher says substitution eliminates need for sales & marketing to physicians & payors. #FTCfob

Leicher: Innovative biosimilar & interchangeable biologics matter 4 patient access: brands expensive/cost increasing; future of med. #FTCfob

We're taking another quick break before our first panel. We'll be back at 11:30am. #FTCfob

State Substitution Laws Panel

Welcome back to FTC workshop on follow-on biologics. 1st panel discusses state substitution laws, moderated by FTC's Jex & DeSanti. #FTCfob

Q: How would particular provisions in new state substitution laws (or similar legislative proposals) likely affect #competition? #FTCfob

Panelists discussing state substitution laws at #FTCfob workshop. pic.twitter.com/oD7IeexnbB

Shd FDA create new pub providing authoritative listing of FDA-approved biosimilar, interchangable & ref biologic? Panelists say no. #FTCfob

As FTC's workshop on biologics continues before lunch break, we're switching gears to tweet about privacy, data security hearing. #FTCfob

We'll be back to tweeting the #FTCfob workshop after lunch. Catch up w/ us at 1:35pm. Note: You may need to refresh your browser then.

We're jumping back into our workshop on follow-on biologics! Agenda + info: http://go.usa.gov/BjSB Webcast: http://bit.ly/1bgdyNZ #FTCfob

Reminder - you may need to refresh ur browser! Now, FTC's Elizabeth Jex provides brief overview of afternoon presentations & panel. #FTCfob

Now up, an intro to drug naming by Angela Long & Tina Morris, U.S. Pharmacopeia. #FTCfob

Long discussing international nonproprietary names (INN) sponsored by World Health Org; US doesn't follow, no role in fed law. #FTCfob

US Adopted Names Council plays role in nonproprietary naming in U.S.; INN/USAN working toward alignment, says Long. #FTCfob

Morris: USP Expert Committees consider existing USAN name(s) & compendial standards in other pharmacopeias where they may exist. #FTCfob

Mark McCamish, Sandoz, up now to discuss the effect of naming on #competition & innovation. #FTCfob

McCamish describes the current pharmacovigilance system during #FTCfob workshop. pic.twitter.com/7fx1psHFdw

McCamish: Dif INNs for biosimilars lead to confusion of physicians & discrimination, impacting affordability & patient access.#FTCfob

Amgen's Gino Grampp discusses the science-based naming policy for biologics. #FTCfob

Grampp: Nonproprietary names play important role in product id & thus patient safety: Prescribing-Dispensing-Recording-Reporting. #FTCfob

Next presenter: Sumant Ramachandra, Hospira, discusses lessons for the U.S. re: biosimilar market development worldwide. #FTCfob

Ramachandra: Biosimilars are not generics; biosimilar development longer, much more costly & riskier than generic development. #FTCfob

Want to know more about our speakers? You can find bios for FTC staff & panelists here: http://go.usa.gov/BDvC #FTCfob

Helen Hartman, Pfizer, presentation is looking into the future of the biosimilar landscape. #FTCfob

Hartman: Distinguishable identifier (dif nonproprietary or trade name) essential to safeguard safety & is supported by reg science.#FTCfob

Happening now, Emily Alexander, AbbVie, discussing the reference biologic perspectives on naming. #FTCfob

Emily Alexander discusses the limitations of using distinct brand names at #FTCfob workshop. pic.twitter.com/AcqC2Vo3Qc

Alexander says all patients deserve to have access to these life-changing biologic therapies, including biosimilars. #FTCfob

Alan Lotvin, CVS, gives us the customer perspective on consumer safety, access, & interchangeable biosimilar #competition. #FTCfob

Biologic patent expirations create new possibilities for #competition from biosimilars & interchangeable biologics. - Lotvin #FTCfob

Lotvin says CVS believes providing biosimilars w/unique names will create barriers to substitution. #FTCfob

[redacted] Hi! If we didn't mention it yet, transcript & archive will post to http://FTC.gov/videos. #FTCfob

Harry Travis, Aetna, now discussing the privacy payer perspective on growth of specialty medicines & naming. #FTCfob

Naming Panel

FTC's Neal Hannan gives a brief introduction to naming discussion before the final panel. #FTCfob

Hannan: Should adverse event reports rely on drug name only? Even for branded drugs, are the names sufficient? #FTCfob

For a list of panelists, see agenda: http://go.usa.gov/BjSB. For bios: http://go.usa.gov/BDvC. For webcast: http://bit.ly/1bgdyNZ. #FTCfob

Panelists continue to discuss how unique or distinguishable USANs or non-proprietary names affect competition. #FTCfob

Panelists at #FTCfob workshop discuss naming & pharmacovigilance. pic.twitter.com/X9vfBx1qff

Closing Remarks

FTC's Andy Gavil is back to the podium for closing remarks. #FTCfob

Thanks everyone for participating today in #FTCfob workshop! pic.twitter.com/iZtRCiyF95

Public comments re: follow-on biologics are due by March 1st. Link, more info: http://go.usa.gov/BjSB #FTCfob

We will post slides, webcast archive, and transcript as soon as possible to http://ftc.gov/videos. #FTCfob