Insights from Industry Leaders

Sue Naeyaert, Global Head Pricing, Market Access and Policy, Biosimilars, 
Merck, a business of Merck, KGaA Darmstadt, Germany

Dominic Robinson, Global Market Access, Specialty Franchise Partner, GSK

Rakesh Dixit, Vice President, R&D, Global Head Biologics Safety Assessment, MedImmune

Ambrose Carrejo, PharmD, Pharmaceutical Contracting, Kaiser Permanente

Sheila Arquette, R.Ph., Director, Pharmacy, Independent Health

Noah Greenberg, Pharmacist, Specialty Medication Services, UVA Health System

Joseph P. Fuhr Jr., Lecturer, College of Population Health, Thomas Jefferson University
What is the most important aspect of the FDA naming policy for the future of the U.S. biosimilars market?

“The naming policy of the FDA will enable the distinction of each biosimilar, and may help with track and trace. It will also help ensure that the biosimilar intended to be prescribed by the clinician gets dispensed. With unique names, there is no room for confusion about which biosimilar should be dispensed and will prevent unintended substitution.”

Sue Naeyaert, Global Head Pricing, Market Access and Policy, Biosimilars, Merck, a business of Merck, KGaA Darmstadt, Germany

“A rose by any other name is still a rose. That is great for flowers, but naming a biosimilar can have significant consequences. I believe the most notable issue would be adding a prefix to a given biosimilar product. The prefix would alter the alphabetical listing of a product in electronic medical record systems. It would complicate an electronic search for a covered biosimilar at a particular institution. The FDA’s use of the suffix seems to have averted any of the above risk for now.”

Ambrose Carrejo, PharmD, Pharmaceutical Contracting, Kaiser Permanente

“The most important aspect of the policy is the proposed suffixes for these products. The August 2015 draft guidance from the FDA outlines a tag composed of four randomly-assigned consonants; the WHO also utilizes this method of naming follow-on biologics. The method by which these suffixes are assigned has been hotly debated, with some manufacturers seeking for FDA to assign a company-derived suffix while other groups are questioning the need for them altogether. As a pharmacist, I am used to working with products that have identical generic names with distinct formulations; I feel that these can be adequately distinguished (from a dispensing perspective) through proprietary names and National Drug Code (NDC) numbers.”

Noah Greenberg, Pharmacist, Specialty Medication Services, UVA Health System

“Biosimilars are highly similar but not identical so they should have different names from the reference product. This will not affect uptake since most of the biosimilars are being marketed by brand name companies. Accordingly, physicians, patients and payers will have confidence in the quality of their biosimilars.”

Joseph P. Fuhr Jr., Lecturer, College of Population Health, Thomas Jefferson University

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How do you think payer adoption of biosimilars will differ based on type of payer (IDN, commercial, Medicare, etc.)?

“The availability of biosimilars in the US market will mean different things to different payers and it is likely we will see contrasting behaviors in this regard. Large commercial payers will have to weigh the potential loss of rebate dollars as they consider adding biosimilars to formulary. Part of this decision making must be based on HCPs assumed willingness to prescribe biosimilars. However, for IDNs, ACOs and other HMO type payers, their greater influence over providers within their network can make potential savings through biosimilars more certain.”

Dominic Robinson, Global Market Access, Specialty Franchise Partner, GSK

“The net price will determine the ultimate adoption of the biosimilars. If there are savings relative to the innovator product, there will be higher adoption rates compared to a scenario where the biosimilar is parity priced to the innovator. One must examine the full cost of using a biosimilar in place of the innovator product

Patients that are placed on the biosimilar may request to be placed back on the original branded product when their disease states exhibits natural progression or flare. In some organizations (IDN, commercial, Medicare, etc.), moving back to the innovator could be a costly maneuver. The branded product may not be contracted or on formulary any longer, in the worst case. The best case may have the innovator contracted at a higher price. Either scenario means additional cost will be borne by the organization.

Organizations with a large Medicare Part D population will experience greater risk of patients demanding to be placed back on the branded product. Currently, the biosimilar manufacturers cannot finance part of the cost of the donut hole as branded manufacturers do today. This will have negative financial consequences for patients that enter the donut hole. If the patient has been on the product for at least a year, he/she will experience a significant change in out of pocket costs. This change could motivate the patient to demand to be moved back to the branded product due to cost concerns.

The full cost of using a biosimilar would then be the unit cost of the biosimilar multiplied by the utilization of the patients that stay on the biosimilar, plus the unit cost of the innovator product (however high that may be relative to the biosimilar) multiplied by utilization of patients in the donut hole and those that have experienced subjective dissatisfaction with the biosimilar.”

Ambrose Carrejo, PharmD, Pharmaceutical Contracting, Kaiser Permanente

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“The adoption and acceptance of biosimilars will be contingent on the payer’s ability to convince patients and payers that a biosimilar is a clinically equivalent, safe and cost effective alternative to the reference product. I think this may be easier in an integrated delivery system where the payer has more visibility and can exert more influence on the patients and prescribers. I see tremendous difficulty in the Medicare patient population especially with continuing therapy as the member moves through the phases of their benefit unless the paradigm of how these drugs will process during the coverage gap phase of the benefit is changed. Not allowing the same 50% discount to be applied during the coverage gap phase of the Part D benefit to the biosimilar product will result in patients switching from the biosimilar to the reference product back to the biosimilar when their benefit resets. There is no way to know what clinical consequence this will have. Questions remain whether this could lead to the development of antibodies which will either require an increase dosage to produce the same therapeutic effect or if switching could render the drug ineffective causing the patient to lose disease control and require additional medical services to treat a condition that was previously under control. This would translate into decreased patient satisfaction, decreased quality and increased total costs.”

Sheila Arquette, R.Ph., Director, Pharmacy, Independent Health

How should manufacturers incorporate reimbursement hubs, patient assistance programs and other customer support services into biosimilar launch strategies?

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Sue Naeyaert, Global Head Pricing, Market Access and Policy, Biosimilars, Merck, a business of Merck, KGaA Darmstadt, Germany

“When designing the reimbursement hub and patient assistance components of their launch strategy, manufacturers will need to have a clear understanding of “who is the biosimilar patient”? If the biosimilar patient has already been exposed to branded biologics, the patient may have high expectations of the manufacturer’s assistance programs and this could influence the offering to patients. However, if the “biosimilar patient” is most likely to be branded biologic naïve, the manufacturer may be able to shape a more streamlined offering focused on the most critical needs of the patient.”

Dominic Robinson, Global Market Access, Specialty Franchise Partner, GSK

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"These types of services should be as robust as those currently available to patients on the innovator product. Any take away from the patient will result in complaints at the prescriber and/or pharmacy level and result in decreased support for moving away from branded versions of the molecule. The patient administration device should be as convenient as or more so than the innovator’s device."

Ambrose Carrejo, PharmD, Pharmaceutical Contracting, 
**Kaiser Permanente**

“I think it is extremely important to incorporate at a minimum, the same level of patient, prescriber and payer support services into their biosimilar launch strategy as the reference product is currently offering. As the biosimilar product attempts to displace the market leader, based on the available clinical evidence (i.e. documented vs extrapolated, cost effectiveness and safety), the biosimilar manufacturer will need to ensure as seamless a transition as possible not only clinically but with all wrap around services as well to gain acceptance.”

Sheila Arquette, R.Ph., Director, Pharmacy, 
**Independent Health**

“Given the fairly low rate of utilization (25-30%) of reimbursement hubs by providers, I do not feel that reimbursement hubs targeting prescribers will be important to biosimilar launches. Hub benefit investigations processes are typically identical to, and often duplicated by, specialty pharmacies (SPs) who perform these functions routinely in processing prescriptions. Physicians do not want to have to interface with additional hubs, portals and the like unless it is absolutely necessary (such as in the case of limited distribution products or strict REMS requirements). On the other hand, I feel that it will be important to provide support services to patients – including copay cards, ancillary supplies (e.g., sharps containers), and nursing support – as these will be essential to compete with reference products, which offer robust patient support programs. I feel that services should be tailored to patients’ needs in order for them to successfully establish and continue on therapy with a biosimilar with regard to financial, educational and safety needs. Though these support services are probably less relevant for patients who are switching off of a reference product, they will be important to attract and retain patients who are beginning biologic therapy with a biosimilar. Providers, in turn, will benefit from patient support services provided by biosimilar manufacturers that assist patients in starting and adhering to biologic therapies, leading to improved outcomes. I think patient assistance programs (PAPs) where free drug is provided to uninsured patients will be eschewed by pure-play biosimilar manufacturers, as they are playing a margins game in order to offer competitive prices. “

Noah Greenberg, Pharmacist, Specialty Medication Services, 
**UVA Health System**

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How would interchangeability designation affect promotional strategies for biosimilar products?

“Interchangeability would cause huge change for biosimilars. Physicians will likely not want to substitute a biosimilar for patients who are doing well with an innovator product, so this will be a difficulty. Companies will need to be very careful about promotion and commercial strategies to ensure they are complying with FDA guidance. This is a very important aspect of regulation that everyone is waiting for.”

Rakesh Dixit, Vice President, R&D, Global Head Biologics Safety Assessment, MedImmune

“Obviously a designation of interchangeable is going to enhance the uptake of these product. Lack of this designation is not an insurmountable obstacle. Depending on the sophistication or the willingness of a given organization, a move from the innovator product to a biosimilar version of the product can be as complete as desired. One must realize that biosimilars are not improvements on the current products. They are not safer or more efficacious. The use of these new versions are dependent on the financial incentives for both patient and payer. A significant savings over the current annual expenditure for the innovator product, when one compares the full cost of using a biosimilar (patient switch backs to brand), will support a rapid and complete uptake of the biosimilar product. Lack of this price delta will result in an anemic uptake as has been seen in Europe.”

Ambrose Carrejo, PharmD, Pharmaceutical Contracting, Kaiser Permanente

“Interchangeability will add an additional level of confidence especially for providers who are financially at risk and who are contemplating switching a difficult to manage and control patient from a therapy they are currently stable on.”

Sheila Arquette, R.Ph., Director, Pharmacy, Independent Health

“Around twenty percent of reference products are dispensed through a pharmacy. The other eighty percent are physician or hospital administered. Thus, interchangeability affects only a small percentage of biologics. However, currently there are no FDA guidelines for interchangeability. One question is whether payers will be willing to pay a premium for interchangeable biologics. Accordingly, is it worth the investment for a biosimilar company to seek interchangeability?”

Joseph P. Fuhr Jr., Lecturer, College of Population Health, Thomas Jefferson University

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How will the various state substitution policies affect access to biosimilars for patients?

“The state substitution policies enable pharmacists to substitute a biosimilar for the reference product if it has been deemed interchangeable by the FDA. Not all states have endorsed a substitution policy. Substitution will take the choice of a particular product away from the clinicians control, although in most states, notification must be sent to the physician. Such policies may increase access to biosimilars, but given the FDA had not produced even draft guidance for interchangeability, it may be a few years before we see an impact on what that means for biosimilars in practice.”

Sue Naeyaert, Global Head Pricing, Market Access and Policy, Biosimilars, Merck, a business of Merck, KGaA Darmstadt, Germany

“If substitution is not permitted by state law and based on the clinical data and cost savings, this could be a significant impediment to acceptance of the biosimilar products. Not being able to substitute may also convey the perception that the biosimilar products is not as good as the originator product and may make it a difficult sell to patients and prescribers.”

Sheila Arquette, R.Ph., Director, Pharmacy, Independent Health

“I think that, to a large extent, state substitution policies are made irrelevant by managed care. With the plans scrutinizing biologics so heavily (i.e., nearly all biologics require a prior authorization), there will be few opportunities for pharmacies to make such a switch. Payers and IDNs are going to make their own assessments about the clinical equivalency via pharmacy and therapeutics (P&T) committees and then, assuming no major clinical differences, craft formularies based on cost. Additionally, the payer’s formularies and step edits are not contingent on the agents being deemed interchangeable by FDA whereas the majority of state substitution laws require this designation. Unlike small molecule products, the opportunities for pharmacies to make a switch for uninsured or “cash” patients will be few and far between.”

Noah Greenberg, Pharmacist, Specialty Medication Services, UVA Health System

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How will the rapid expansion of pure-play biosimilar companies affect the U.S. biosimilars market?

“Pure-play biosimilar companies have both advantages and disadvantages. If major companies enter into biosimilar competition, they have the technical know how to make products cheaper. It will be difficult for pure-play companies to compete. In my opinion, pure-play companies will need to work with the larger companies or make some type of alliance to offer a lower price. We don’t yet know how this is going to play out.”

Rakesh Dixit, Vice President, R&D, Global Head Biologics Safety Assessment, MedImmune

How can manufacturers involve patient advocacy organizations and key opinion leaders in high-cost therapeutic areas in biosimilar launch strategies to assist with market entry?

One way is to make sure that they clearly understand what a biosimilar is. Biosimilars are highly similar to the reference product. Even the reference product will vary from batch to batch so that the biosimilar may be more similar to the reference product than a certain batch of the reference product.

Joseph P. Fuhr Jr., Lecturer, College of Population Health, Thomas Jefferson University

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Learn More About these Key Thought-Leaders...

About Ms. Naeyart...
Sue has more than eighteen years international experience working in academia, government and finally the pharmaceutical industry. She has worked and lived in Switzerland, Belgium, Australia, and Singapore, holding a variety of senior roles at the local, regional and global levels in pricing, health economics, market access and policy. During last year (2016), Sue added the United States as a country where she has lived and worked, being based in Washington DC, USA on assignment from Switzerland; EMD Serono’s home for their Biosimilar Unit. During the last three and a half years Sue has focused her energies in the biosimilars’ field, developing pricing and market access strategies for successful biosimilar launches, and influencing the development of biosimilar policies that can help sustain a viable biosimilar industry.

Prior to working in Switzerland as Global Head Pricing, Market Access and Policy Biosimilars, Sue was in Singapore with Merck Serono heading up Pricing and Market Access for the APAC region, and before that, was in Belgium working for Johnson & Johnson in their Global Pricing and Health Economics Unit. Sue started her career as a pharmacist, and then moved into the area of health economics and research with the University of Sydney, followed by being awarded a research fellowship with the EORTC (European Organisation for Treatment and Research in Cancer), based in Brussels. Sue has a bachelor of Pharmacy, a Graduate Diploma of Pharmacy (with a specialisation in health economics) and a Master of Commerce with an advanced specialisation in business economics and statistics. She is regularly a guest speaker at conferences and has numerous peer-reviewed publications.

About Mr. Robinson
Dominic has over twenty years of experience in the pharmaceutical industry, twelve of those in the area of market access at country, region and global level. Dominic was previously the UK Head of Market Access and Director of NHS Strategy for Servier Laboratories, where he was responsible for his company’s submissions and relationships with NICE and the Scottish Medicine Consortium.

In August 2010, Dominic relocated to the US, joining the dermatology division of GSK as their Global Director for Market Access. From 2014, he became a Therapy Area head within GSK’s Specialty franchise, and in 2016 became the Global Market Access Specialty Franchise Partner, sitting on the Franchise Executive team.

Dominic has specific responsibilities for defining and communicating payers’ evidence needs into GSK’s R&D organisation, as well as defining pricing and access strategies as a core partner in the global commercial team.
About Dr. Dixit

Dr. Dixit conducted extensive graduate and post-graduate training in Toxicology–Biochemistry with both Indian and US Institutions (Case Western Reserve University, Medical College of Ohio, University of Nebraska) and is board certified in Toxicology from the American Board of Toxicology, Inc. since 1992. Rakesh served as a Senior Toxicologist with Midwest Research Institute between 1987 and 1992.

In December 1992, Rakesh joined the Department of Safety Assessment, Merck and Co., Inc, West Point, PA where he served in various management positions. During his about fourteen years with Merck, Rakesh contributed to the successful filings of many blockbuster drugs. For about a year, Rakesh was associated with Johnson & Johnson PRD, La Jolla/Alza as Senior Director of Toxicology.

In Aug 2006, Rakesh joined MedImmune, Inc. (an AstraZeneca Biologics company) as Senior Director, R&D and Global Head of Biologics Safety Assessment, Experimental Pathology and Laboratory Animal Medicine. In his current position as a Vice President of R&D since 2010, Rakesh is responsible for providing guidance on research and development of biological products, including nonclinical toxicology/safety support for all AstraZeneca-MedImmune biologics products, including monoclonal antibodies and vaccines. Rakesh has published more than 60 papers in renowned international journals and has given over one hundred invited lectures/presentations/workshops in national and international meetings. Rakesh is one of the most invited speakers in the biotechnology industry.

Rakesh’s areas of expertise are mainly in the area of pharmaceuticals and biologics drug development, safety assessment of small molecule drugs, biologics, and vaccines and in exploring mechanisms of toxicity and biologics pharmacological activity. Rakesh has helped to bring several blockbuster pharmaceuticals to the market while working at Merck. Rakesh is a recognized expert in safety and pharmacology biomarkers and their applications. Rakesh is the Editor-in-Chief of Toxicology Mechanisms and Methods and Associate Editor for Toxicology Applied Pharmacology and Journal of Toxicology and Environmental Health. Rakesh was selected by his pharmaceutical peers as one of the 100 Most Inspiring People in Pharmaceutical Industry by PharmaVOICE in 2015. Rakesh also serves as an expert reviewer and in appointed committee for many programs managed by the prestigious U.S. National Academy of Sciences and US National Institutes of Health, including National Cancer Institute.

About Dr. Carrejo

Dr. Carrejo received his Doctor of Pharmacy degree from the University of California at San Francisco’s School of Pharmacy in 1986. He graduated with honors and received the Highest Academic Achievement award for his graduating class. He completed his clinical residency at Long Beach Memorial Hospital in June of 1987.

After completing schooling and residency, he began his professional career at the Pacific Presbyterian Medical Center in San Francisco, California. There he worked as a clinical pharmacist running the Total Parenteral Nutrition Service for Pharmacy and providing clinical services to the medical/surgical ward. He left this position in February of 1990 to begin working for Kaiser Foundation Hospitals.

Dr. Carrejo began his career with Kaiser as a Drug Education Coordinator (DEC) at Kaiser Richmond, and was soon given the additional responsibility of Kaiser Oakland Medical Center. He was then promoted to Clinical Operations Manager where he had oversight of the drug use management efforts and the ambulatory clinic pharmacists. In June of 1999 Ambrose was promoted to Drug Use Manager for Northern California. In this role he provided oversight and leadership for the Drug Education Coordinators of Northern California. In June of 2006, Dr. Carrejo was promoted to Assistant Director of Pharmaceutical Contracting. Finally in May, 2008 he was promoted to his current position: National Pharmaceutical
Contracting Leader, where he is responsible for the contracting of all pharmaceutical purchases for the entire Kaiser Permanente program.

Ambrose received The Vohs Award, the Kaiser Permanente’s highest quality award. This was in recognition of his contributions to a drug use management plan that both improved the quality of outcomes and the cost effectiveness of the drugs prescribed. He was invited to by the Institute of Health Economics to speak about aspects of innovative contracting at their Alberta Canada meeting. He was board member of the Pharmacy Foundation of California. During his career he has testified before the U.S. Senate, provided background information to Government agencies and private counsel on matters regarding the purchase and marketing of pharmaceuticals. Further he has provided testimony in several trials for the prosecution and defense. Today Ambrose continues his twenty-six year career at Kaiser Permanente as the National Pharmaceutical Contracting leader for Pharmacy.

About Ms. Arquette
Sheila Arquette is the Director of Pharmacy Services for Independent Health. She holds a Bachelor of Science in Pharmacy from the State University of New York at Buffalo School of Pharmacy. Sheila has extensive practical and leadership experience in retail and hospital pharmacy practice, LTC consulting and dispensing in addition to the managed care, PBM and specialty pharmacy space. She is a regular speaker and participant at national pharmacy conferences, roundtables and industry meetings. She is a current member of AMCP and NASP and serves as the Co-chair of the NASP Government Affairs Committee.

About Dr. Greenberg
Dr. Greenberg first became interested in biosimilars while researching the topic during an internship at The Dominion Group, a market research vendor. Since then, he has presented information on the scientific, clinical, legal, regulatory, and commercial considerations of biosimilars to associates at pharmaceutical companies such as Pfizer and Bayer. Dr. Greenberg completed a one-year fellowship through Rutgers University in the R&D Strategy and Analytics group at Bristol-Myers Squibb, where he focused on industry benchmarking and competitive intelligence. He joined University of Virginia Health System (UVA HS) Specialty Pharmacy Services as a pharmacist in July 2015 and is currently pursuing the Certified Specialty Pharmacist (CSP) designation.

About Dr. Fuhr Jr.
Dr. Joseph P. Fuhr Jr. is a professor of economics at Widener University and currently serves as a senior fellow with The American Consumer Institute. Dr. Fuhr received his M.A. and Ph.D. from Temple University and his B.A. from LaSalle University. His primary research areas are antitrust, health economics, pharmacoconomics, telecommunications, and sports economics. He has published over fifty articles and presents regularly on these areas of expertise. In pharmacoconomics, he has written on cost benefit analysis, predictive modeling and biosimilars. He has published six articles on biosimilars and has given various presentations. Professor Fuhr has been an expert witness on antitrust matters related to health economics and has worked on various consulting projects.