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Part 1
Biosimilars: Opportunity Knocks
– Building a Better Technology
Mousetrap

1 **Part 1:** Biosimilars: Opportunity Knocks – Building a Better Technology Mousetrap

By Brian Bamberger, Life Sciences Practice Lead

Biosimilars are officially approved subsequent versions of off-patent biopharmaceutical products, sometimes also called "follow-ons." Like the biologics they're following, these "large molecule" drugs are made from living organisms and used to treat complex diseases, including Alzheimer's and cancer. Examples of biologics include gene therapies, blood or blood components, vaccines, allergenics or recombinant therapeutic proteins.

Already in use in Europe, biosimilars are poised to enter the US market in 2015, with two such drugs already in the Food and Drug Administration's (FDA) approval pipeline.

Paving the way for their introduction was the Biologics Price Competition and Innovation Act passed in 2009. Market entry has been slow for many reasons, not the least of which is the challenge of integrating biosimilars into the current US drug supply, order, distribution and administration system.

Perhaps one of the biggest challenges is that biosimilars are not generics, which are FDA-defined bioequivalents of small molecule (traditional) drugs synthesized using chemical processes. Unlike generics, biosimilars are not integrated with pharmacy inventory and dispensing, ePrescribing, claims switching – all core infrastructure components built for pharmaceuticals marketed by chemical name and bioequivalent to a brand/reference drug product.

Biosimilars, on the other hand, are manufactured in or from biological sources and not always interchangeable, identical or bioequivalent. In fact, the FDA will give them four ratings: 1) not similar, 2) similar, 3) highly similar, and 4) highly similar with a fingerprint-like similarity. Clarity will be provided in the Purple Book, which is meant to be the equivalent for biologics profiled in the Orange Book, a statutorily required, FDA publication that links small-molecule drugs to approved therapeutic equivalents.

Regardless of the rating, biosimilars may perform very differently from the original branded version, thus posing a safety concern.

Whereas the chemical process used to synthesize small molecule generics is relatively straight-forward, that's not necessarily the case with large molecule biologics. One of the challenges with biosimilars is that their manufacturers do not have access to the innovator product's original molecular clone or cell bank, nor to the exact manufacturing processes or active drug substances. Furthermore, there are concerns that even within the same manufacturer, there may be variations by lot. All of this leads to the importance of tracking by manufacturer and lot number.

Like small molecule medications, prescriptions for biologics and biosimilars are written by physicians. Unlike traditional medications, biologics and biosimilars are dispensed via channels that are more limited and controlled, which makes them theoretically easier to track. However, they may be administered in a variety of clinical settings, or self-administered by the patient him or herself. Today the drug, manufacturer and lot numbers rarely reach the point of

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administration, making it a challenge to record specifically what was administered, particularly for cases of patient self-administration.

Further confounding the situation is that information about the administered biologic does not get communicated back to the prescribing physician. The reason is that there is no consensus on the rationale for doing so, and the supporting transactions either do not exist, are not being used or have yet to be standardized.

This is important because adverse events are most commonly reported by the patient to their physician. Without the knowledge of what biologic or biosimilar was dispensed, linking the adverse event to the manufacturer, drug and lot number is a real challenge and a missed opportunity.

It is suboptimal because, ideally, an adverse drug event would be traced back to the manufacturer, drug and lot number of the administered biologic or biosimilar, ensuring that impacted patients are alerted and situation addressed more efficiently. In addition, it would provide data to help justify non-impacted patients remaining on therapy, and provide critical information to the manufacturer and Federal government that will help address potential future challenges and decrease risks.

This is where electronic health records and health information technology can help. We will address these benefits and the potential high value of biosimilars in a future article.

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Part 2
Improved Prescription Information: The
Key to Closing the Medication
Adherence Gap

2 Part 2: Improved Prescription Information: The Key to Closing the Medication Adherence Gap

By Brian Bamberger, Life Science Practice Lead

Medication adherence is among the most costly challenges facing health care today. It's a very simple concept: patients should take their medications at the times, dosages and frequencies as directed by their physician. In reality, they do not.

Nonadherence to taking medications as prescribed has major economic consequences. The direct cost of medication nonadherence on the US health care system is estimated between $100 billion and $289 billion annually in lost wages, premature deaths and unnecessary hospital and doctor visits. On top of this, a recent study estimated that pharmaceutical manufacturers lose an additional $188 billion annually in revenues.

As a result, interventions to improve medication adherence should be a top priority of the pharmaceutical industry. Efforts to date largely have focused on free drugs, reminders, or lower co-pays. We believe that changes in health information technology (health IT) to provide more accurate and complete prescribing information within electronic health records (EHRs) can go a long way toward improving patients' compliance with their drug regimens. While this alone will not solve the problem of medication nonadherence, it is a step in the right direction— particularly with respect to improving formulary and benefit data, improving medication history information and alerting prescribers as to whether prescriptions have been filled.

Leveraging the power of EHRs to improve medication adherence. Existing transactions and standards could be extended and enhanced in EHRs to provide significantly more high-quality data at the point of prescribing. However, work remains to make these transactions more

accurate and useful in improving medication adherence. For example:

• **Formulary and benefit information.** In an EHR or electronic prescribing (ePrescribing) system, formulary and benefit data are used to enable formulary validation at the point of prescribing. This information is made available through a formulary and benefit standard, which has been available for nearly a decade.

Despite the promise of formulary validation to increase formulary compliance and cut costs for prescribers and patients, this transaction is significantly underused. That is because the data underlying the transaction— including co-payments, prior authorization flags, formulary tier levels and quantity limits—are either not provided, inaccurate, or too complex to be interpreted easily by a prescriber. This creates confusion and distrust of the information among physicians. The data provided in the ePrescribing system may be insufficient to meet the needs of the prescriber and patient. Conversely, too much information may be entered, creating data overload. The result: prescribers often ignore this valuable resource when ePrescribing or rely on the pharmacist to navigate the patient's formulary requirements after the prescription is sent to the pharmacy.

• **Medication history.** Similarly, the medication history transaction could be leveraged for purposes of medication monitoring. Medication history shows all prescriptions for patients paid by a particular insurer.

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While relatively comprehensive, there are still gaps. Not all payers—such as state Medicaid programs—provide such data. In addition, information about drugs paid for in cash is not captured. Generally, EHRs are only programmed to request medication history information in advance of a scheduled visit, in most cases based upon the next day's appointment schedule. This means the medication history information in EHRs cannot be used to proactively monitor a patient's adherence unless the patient is scheduled to visit.

• **Electronic fill status.** Although rarely used thus far, RxFill is a tool that can help flag patient nonadherence to medication therapies before a patient's next scheduled visit when medication reconciliation will be performed. Using this functionality, a pharmacy system can send a real-time message to an ePrescribing or EHR system indicating the fill status (dispensed, partially dispensed, not dispensed) of new and refill prescriptions. Such feedback can help providers identify noncompliant patients. RxFill information is also sent to the prescriber in real time, eliminating the need to initiate a query to access this information outside of a scheduled appointment. However, providers are not embracing this opportunity because, in large part, they are not compensated directly for contacting patients when an adherence issue is identified between office visits. Moreover, they are reluctant to receive adherence alerts due to liability fears. Pharmacies and other industry stakeholders do not see a value proposition for investing in software development and/or ongoing transaction costs to send fill status alerts back to the prescriber because they already contact patients when prescriptions are ready and not picked up.

Closing the gap. Policies to improve medication adherence using health IT must leverage existing standards to improve the quality of prescription information available within EHRs. That said, what can be done to improve medication adherence through better information and medication management in EHRs? For example:

• To improve the consistency, accuracy and completeness of formulary and benefit information at the point of prescribing, how can we establish consistent standards for formulary information provided to ambulatory EHRs that include available medications and patient cost-sharing information? What best practices can help EHR vendors create more effective displays of formulary information?

• To provide EHRs with more timely and accurate medication history, how can we encourage all payers to contribute medication history information? How can we better capture data on over-the-counter purchases? Could EHRs be enabled to easily link written and filled prescriptions by carrying prescription serial numbers through on claims and pharmacy systems?

• To encourage wider adoption of electronic prescription fill status, what can be done to determine the return on investment to pharmacies for the cost of sending these transactions through an intermediary or directly to the provider? What is the "sweet spot" for getting prescribers to use this transaction to improve patient outcomes and medication adherence without sending them into information overload and alert fatigue?

Point-of-Care Partners is exploring such opportunities with standards development organizations, payers and other stakeholders to help improve medication adherence through health IT. Let us put our ideas to work for you.

3 **Part 3:** Drug Databases: A Growing Resource for Patient Care and Safety

By Brian Bamberger, Life Science Practice Lead

Drug databases are integral to patient care and safety. They provide clinicians, pharmacists, payers, wholesalers, hospitals and others with a wealth of such valuable information as drug name, related generics, therapeutic class, National Drug Code (NDC) number and prices. They also include information about allergies and possible drug interactions with other medications, thus helping to prevent medication errors. Commercial database vendors may offer additional data covering a variety of topics, including immunization history, patient education, herbal medications and Medicaid drug rebates. In short, drug databases are becoming even more useful in supporting cost-effective patient care and safety.

Providing users the most up-to-date information is challenging. Updates to commercial and proprietary databases vary; some are updated weekly while others may be refreshed monthly or even quarterly. Vendors have come a long way since the early days of electronic prescribing (ePrescribing) in transmitting updates to clients. While updates were once available only through CDs, the industry has kept pace with technology to provide varied electronic access databases. We can envision a time in the near future when users will access a database directly at its source without a local copy.

Availability of current drug data is important to all stakeholders, who need to know about newly launched products and pricing changes. Affordability is a key factor in determining whether patients continue to take their medications as prescribed, switch to another drug or abandon their treatment altogether. Cost data are vital to payers with regard to formulary management, as well as purchasers in hospitals and clinics. Information regarding allergies and possible drug interactions support drug utilization review, which is key to improving patient safety and quality of care.

However, syncing users with database updates is easier said than done. This has been a low priority for electronic health record (EHR) vendors, who have been concentrating on meeting meaningful use requirements. In fact, recent data compiled by Point-of-Care Partners (POCP) show degradation in how often EHR vendors make updates available—especially when using a home-grown database. Latency of medication information can delay the development and use of alerts related to patient safety concerns about particular products.

Lack of timely product updates can frustrate prescribers when they can't find a recently launched branded drug in their EHR system. Varying update schedules can have additional negative consequences for the pharmaceutical industry. Until updates occur, brand managers sometimes find that prescriptions are being written for competitive brands and the sales force may encounter problems finding their branded drugs in EHRs, which undermines their credibility and that of their products among providers.

To be sure, these problems have always existed, but have become more apparent with the recent surge in EHR adoption over the past few years. The problems of missing drug data or data latency have not been lost on drug database companies. POCP works regularly with several, which are diligently endeavoring to issue more frequent new-drug updates to clients and reconcile their databases in light of the complexities of differing release schedules and constantly changing technologies.

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