FDA Faced with Biosimilar Naming Challenge

A group of drug policy experts from the FDA met with members of the National Council for Prescription Drug Programs (NCPDP) in early May to hear concerns regarding the use of non-traditional drug names for biosimilars. NCPDP requested the meeting after two biosimilar products were approved for marketing using names different from their reference products: trastuzumab and ado-trastuzumab, and filgrastim and tbo-filgrastim. Drug use and patient safety were among the chief concerns presented to the FDA in this closed-door “listening” session where the speakers advised the FDA to use the same non-proprietary names for biosimilars and their reference products.

Others in the industry, including the Biotechnology Industry Organization (BIO), believe adding a suffix or prefix to a non-proprietary drug name is an easy solution to the problem resulting from the belief that biologics deemed interchangeable are not like “conventional generic medications”. BIO says “interchangeable biologics are not the same as the drugs they seek to substitute. In fact, two biologics made using different cell lines and differing manufacturing processes will rarely, if ever, be exactly the same. Those suggesting interchangeable biologics and generics are the same are wrong.” It is this rationale that led the FDA to the use of 7-character prefixes or suffixes being added to the non-proprietary drug name to distinguish a biosimilar from an innovator product. Proponents have also argued that distinct names are needed to track post-market safety events.

The NCPDP group presenting to the FDA, which included representatives from the drug compendia, pharmacy professional organizations and claims processors, feel the opposite is true. They are worried that a change in the traditional drug naming process would necessitate numerous modifications to the integrated systems that utilize the drug databases and the associated “intelligence” supported by the compendia. Such a change is not trivial and will disrupt systems as they currently exist unless the associated software is also changed. Those systems are already programmed to use current drug database structures, which help to ensure proper drug usage and patient safety. While modifying those systems to support a new drug naming process for biosimilars is possible, it will be difficult and require time to design, program, test and implement across the platforms that use the drug databases.

If a different drug naming system is used by the FDA for biosimilars, the presenters feel this will not resolve, but create a safety issue by introducing unneeded complexity and confusion. The compendia data in question are the basis for a variety of clinical processes executed in pharmacy and claims processing systems to provide various warnings to pharmacists when clinical exceptions or issues exist. The group warned these processes will be disrupted “if standard nonproprietary naming conventions for determining acceptable ‘established names’ are violated.” In addition, “each process will have to be individually rebuilt to ensure patient safety and restore functionality to the system. While that can be done, there is a danger in disruption.”

In an effort to reduce any FDA confusion regarding the complexity of the systems using the compendia drug databases, NCPDP members shared their experiences of how small changes in product descriptions and the associated data can have major consequences. Issues discussed included inconsistent nomenclature used in various private and government databases for trastuzumab and ado-trastuzumab and how similar issues are anticipated with filgrastim and tbo-filgrastim. NCPDP offered to collaborate with the FDA to create “practical but standardized ways to ensure the safety and proper product identification of medications” and “to ensure that the data made available to downstream users, including physicians, pharmacists, and patients, are not only accurate, but also the most informative and least confusing they can be.”

In July the FDA received a letter from a coalition of chain pharmacies, PBMs, insurers, unions, and pension funds. This group told the FDA they believe biologics and biosimilars “should be required to have the same International Nonproprietary Name (INN),” citing patient and prescriber confusion and medication errors as possible safety issues. This group included AMCP, NACDS and PCMA, as well as CVS Caremark, Express Scripts, and Walgreens.

It is not likely that a middle ground will provide a sufficient resolution to either side of the argument. The FDA will continue to ponder the biosimilar naming dilemma, and PHSI will continue to monitor this key issue and keep you up to date on future developments.
Prescription Compounds Causing Grief

In the past few years, the number and price of compounded prescriptions seen by PBMs and health plans has skyrocketed. Worker’s compensation PBMs have reported a five-fold increase in the use of compounded drugs in the past five years. In part due to the rising prices for compounded products, many payers have hit a breaking point and are now taking aggressive steps to limit the use of compounded drugs.

In 2012, the National Council for Prescription Drug Programs (NCPDP) launched their new Telecommunication Standard Version D.0 that supports the transmission of multiple ingredients for a single prescription. Prior to this, pharmacies usually billed for the most expensive ingredient used in the compound, and this often lead to inaccurate reimbursement. Now, for better or worse, the reimbursement costs can be based on all ingredients used in the compounds. Another benefit of D.0 is the ability of the computer system to check for drug interactions affecting all components, thus adding a safety benefit as well. D.0 also allows insurers to see the use of non-FDA approved agents being used in the compounds and enables insurers to deny claims for compounds in a more systematic manner.

Compounds are necessary for many patients who need a specific agent that is not commercially available. Compound costs are usually higher than commercial product costs due to the amount of preparation time. Patients and payers have seen costs rise more than 10-fold in the past few years. While the average price of a compound was $90 in 2012, the average compound price in 2014 has risen to $1,100 according to Express Scripts. Although most pharmaceutical prices have risen in the past few years, this increase far outpaces any reasonable explanation.

In response, several insurers and PBMs, including OptumRx, Express Scripts, and Harvard Pilgrim, have either severely limited the number of compounding agents that are reimbursable or restricted their use to only children and adults with a medical necessity. Since many patients rely on these medications, some compromise must be reached. With prices rising at this fast pace, it is not surprising that many PBMs have started requiring prior authorizations for compounded products to determine if they are medically necessary. With the escalating prices, some sort of change seemed inevitable, but to completely remove coverage for compounds would be extreme. PBMs acknowledge that pharmacists spend a great deal of time and effort compounding medications and should be reimbursed for this beyond the ingredient cost of the compound components.

From a pharmacy perspective, pharmacies have adapted to lower reimbursement rates and maintained profitability through the improved use of technology, implementation of cost control measures, and increase in operational efficiency. We anticipate that the same would prove true with compounds. We believe that most compounding pharmacists work to serve patients’ needs and do not create a false demand for compounds through direct physician marketing of only high-cost compounded products. With compromise on both sides and a moderation in pricing, it would seem that a solution should be able to be reached that would keep both parties happy and keep patients out of the crossfire. Without compromise, patients may be forced to go without needed medications, and pharmacy sales could suffer.