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...leadership will be needed to address the regulation, legislation and formulary decisions with these new biosimilars.6

Discussing the Future of Drug Development and the Pharmaceutical Marketplace

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Introducing the Issues

Based on the ASHP Pharmacy Forecast, Kaczor introduced predictions for the pharmacy profession regarding how specialty pharmaceuticals, pharmacogenomics, limited distribution systems, cost management of generic drugs and vertical integration of pharmaceutical manufacturers will look in the next five years. These topics are very important in the pharmaceutical industry, and pharmacists should be proactively thinking about challenges and corresponding solutions that may eventually arise in these areas.¹

In order to provide a framework for discussion among the Summit’s participants, Kaczor first provided an overview of current issues. After the summary, the Summit attendees, with a wide variety of pharmacy experiences and expertise, could then offer their thoughts and leadership experiences to strategically plan and form future goals for these various issues. To achieve approval for a new drug in the marketplace, the U. S. Food and Drug Administration (FDA) examines various characteristics of a drug such as its absorption, distribution, metabolism, excretion, mechanism of action, dosage form, side effects, drug-drug interactions and effectiveness in comparison to similar drugs.² Kaczor provided some statistics on new drug approvals over the last couple years and noted that there were 41 new drug approvals in 2014 and 45 in 2015. Out of all these approvals, Kaczor emphasized that over 20 percent were oncology medications. The cost of cancer treatment is also predicted to increase approximately 166 percent from 2006 to 2020.³ Additionally, there has been an increased trend for cancer drugs to have indications for a specific cancer type, formulations to target specific biological markers for a more personalized treatment approach and chemotherapy by oral administration instead of traditional intravenous methods. The advancement of oral cancer therapy can now allow patients to receive cancer therapy while at home, although similar side effects to that of intravenous therapy may be present.⁴

Regarding specialty pharmacy, Kaczor mentioned that there has been a 67 percent increase in the cost of specialty medications to treat chronic diseases. Although there is not a standard definition for specialty medications, common characteristics include medications that cost greater than $600 which have a complexity component including, but not limited to, chronic disease states, limited distribution systems, special storage conditions and ongoing safety and efficacy monitoring. Some disease states that require specialty pharmacy services include oncology, multiple sclerosis, rheumatoid arthritis, Crohn’s disease, human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS), hepatitis C and growth hormone disorders.⁵ When analyzing the overall medication costs in 2014, Kaczor noted that around 32 percent of this cost was attributed to specialty medicines. Over the next few years, this amount is expected to further increase to around 50 percent.

To further provide a framework to generate discussion, Kaczor asked for thoughts on how pharmacists can take a leadership role within pharmacogenomics. To emphasize the need to use a pharmacist’s knowledge with pharmacogenomics, Kaczor focused on the pharmacogenomic effects with the antiplatelet drug clopidogrel. Regarding clopidogrel’s metabolism, Kaczor explained that patients may be a slow, regular or rapid metabolizer of the CYP2C19 enzyme. Without proper education on pharmacogenomic data, Kaczor noted that some may assume a poor metabolizer for clopidogrel may cause increased levels of the drug; however, a poor metabolizer of this particular medication will actually cause less prodrug form to convert into its active form, likely contributing to subtherapeutic effects. To further observe the complexity of pharmacogenomics, Kaczor then mentioned other factors that must also be included in making therapeutic decisions such as a patient’s other medications that may either induce or inhibit the CYP2C19 enzyme. Kaczor also brought to attention legal implications that affect the management of a patient’s pharmacogenomic data. Since only a small portion of pharmacogenomic data is needed for drug interventions, Kaczor challenged how the remaining portion of pharmacogenomic data should be handled.

Kaczor asked for thoughts on the incorporation of biosimilars into pharmacy practice since drugs such as Neupogen® (filgrastim) and Remicade® (infliximab) are not considered bioequivalent like many generics. To provide an overview of the emergence of biosimilars to the pharmaceutical marketplace, their approval process is somewhat similar to that of a generic small-molecule drug with its respective
To further expand on the discussion of ACOs, Kaczor provided an example of an ACO by describing Partners For Kids (PFK) at Nationwide Children's Hospital. Kaczor explained that PFK is fully capitated and responsible for approximately 330,000 covered lives in central and southeastern Ohio through arrangements with Medicaid Managed Care Organizations. Partners For Kids works with providers to improve the quality of care while limiting expenses wherever possible, including drug expense. As ACOs expand, Kaczor asked for thoughts on eliminating risks from limited distribution systems and improving pharmacist leadership to advocate against these systems.

The last topic explored was the increased trend in both horizontal and vertical integration of pharmaceutical manufacturers. He defined horizontal integration as the merging of multiple manufacturer companies and explained that vertical integration observes the entire drug process from management of raw materials to distribution to hospitals.

Engaging the Audience: What are Goals and Strategies Associated with These Issues?
To initiate the group discussion of the Summit's participants, Kaczor first asked for thoughts to address limited distribution systems and specialty pharmacy. One participant brought up the point that around 50 percent of all FDA drug approvals are currently being approved as specialty pharmacy. Then, the participants questioned if all new drug approvals or even generics may eventually become classified as specialty pharmacy since there is no industry standard to classify them. One Ohio Northern University alumnus offered some remarks from a payer perspective regarding specialty pharmacy by mentioning that distribution systems are moving from fee-for-service to value-based medicine. Currently, specialty pharmacies are based on a fee-for-service model more commonly than a value-based model. One attendee remarked that over time he has been noticing a shift for limited distribution systems to follow Accountable Care Organizations (ACOs). This will help pharmaceuticals to further transition into a value-based model in the future. To understand the purpose of an ACO, it can be defined as a network of healthcare professionals and hospitals who work together to provide a better continuum and quality of care for patients while sharing medical and financial responsibilities. The ACOs operate to provide the right services to the right patient at the right time while reducing duplication in medical tests and other services.

Some ACOs still operate by a fee-for-service method; however, incentives will be offered if the ACO can keep costs low. They also must accept the risk of losing money or being required to hire additional staff or take certain measures if quality and outcome benchmarks are not met. It was then noted that smaller systems may have a harder time than larger systems to enter an ACO due to factors including pricing and access to the drug and its volume. When observing the increased entrance of oncology drugs into the marketplace, one pharmacist mentioned that value-based medicine has not yet been applied to these medications, but that we are doing it in other cases as Entresto® (sacubitril/valsartan) has recently been contracted by a value-based model. To summarize the remarks, pharmacy leadership needs to make the case for pharmacists' engagement within ACOs in the future as the health system continues to transition into value-based medicine models.

To further expand on the discussion of ACOs, Kaczor provided an example of an ACO by describing Partners For Kids (PFK) at Nationwide Children's Hospital. Kaczor explained that PFK is fully capitated and responsible for approximately 330,000 covered lives in central and southeastern Ohio through arrangements with Medicaid Managed Care Organizations. Partners For Kids works with providers to improve the quality of care while limiting expenses wherever possible, including drug expense. As ACOs expand, Kaczor thinks that the ACOs which are assuming these risks will need to have a larger voice regarding the payment of high cost drugs. One participant added to this discussion that it could be frustrating to work with certain specialty drugs, like Herceptin® (trastuzumab) and Lunesta® (eszopiclone), with the limited distribution systems. Another participant offered some advice that it will take time and persistence to work with limited distribution systems. To summarize the discussion on payment models on pharmaceuticals, pharmacist leadership will need to diligently voice their opinions on ACO regulations and value-based medicine to better manage the expenses of specialty pharmacy.

Next, a pharmacist who works to build specialty pharmacies brought to attention that pharmacists need to take a leadership role to redefine the medications that are entering the specialty pharmacy category. For example, he reminded everyone that medications used to be identified by their mechanism of action; however, anything that costs over $600 is now considered specialty pharmacy. As one positive viewpoint on specialty pharmacy, Kaczor suggested that specialty medicines are commonly perceived as high-touch; therefore, pharmacists could justify their clinical services to be reimbursed with the profit earned from these drugs. Overall, specialty pharmacies can be very successful if pharmacy leadership plans appropriately.

To focus the specialty pharmacy discussion again with a pharmacogenomics perspective, one participant, a previous United States Pharmacopeia expert committee member, mentioned that by the year 2020 there could be a small machine the size of a desktop printer to print medications personalized to each patient according to their genome. Another participant noted that as one small step toward this
goal, the first FDA approved printed drug was made in 2015. It was also discussed that in 20 or 30 years, there could be a possibility that hundreds of medications may be made like this.

As the Summit discussion continued, participants explained that specialty pharmacy was initially designed for clinical care; however, its utilization may have transitioned due to financial motives over time. Another of the Summit’s speakers stressed the need of leadership to shift the financial focus of specialty pharmacy back to a clinical focus. She noted that this can be achieved by hiring specific clinical pharmacists to develop these new programs since specialty pharmacy requires complex accreditation and reimbursement protocols and a need for patients to receive appropriate education on those medications.

The discussion on specialty pharmacies eventually moved to the issue of poor integration of information from electronic medical records (EMR) among health systems. Kaczor spoke of a specialty pharmacy recently started at Nationwide Children’s Hospital which services the cystic fibrosis clinic and agreed that healthcare professionals could experience collective benefits by reporting individual data from various clinics into an Integrated system such as an EMR to comprehensively track patient outcomes. Two individuals guided this conversation to also address partnerships between providers and payers with pharmacy. Another participant answered that the ACO model’s ultimate goal is to improve quality and communication and to reduce costs and asked of the role of manufacturers with the negotiations of contracts. It was discussed how manufacturers need to be involved in these sorts of discussions such as where rebates fit in with outcome-based contracts. To summarize this conversation, pharmacists need to take leadership roles with ACOs, EMRs, payers and manufacturers to provide better integration of data and quality with value-based medicine.

Looking at the utilization of EMRs in the future, one attendee suggested that EMRs should be owned by the patient instead of the health system. Another individual added that it would not be valuable for the patient to own the record until it can be used wherever they go. A discussion was generated on how professional societies, state boards and colleges could be involved with these decisions. Although the Summit’s participants understand these issues being discussed, the participants were reminded that the average pharmacist may not understand the details of such complex issues. Solutions will come from advocacy together as a profession.

Lastly, the discussion moved to address drug shortages and drug price increases. One participant posed a specific question on what would happen if a manufacturer of a certain drug did not receive the contract from a group purchasing organization (GPO) that had 60 percent of the market. The participant explained his concerns of drug shortages and price increases that may result when only one or two manufacturers for a certain drug face an issue on supplying that drug. To address the issue on drug costs, it was stated that drug costs had been increasing in a controlled fashion for much of the last decade but, more recently, some drug prices have jumped around threefold. To address one area of drug shortage management, it was suggested that a professional protocol should be made in regard to the gray market. To understand these issues better, another participant expanded this discussion offering advice on how pharmacy associations can address one area of drug shortage management, it was suggested that a professional protocol should be made in regard to the gray market. To understand these issues better, another participant expanded this discussion offering advice on how pharmacy associations can help, including both at the national and international levels. As an example, she referenced how European pharmacy programs have already implemented value-based medicine programs due to their innovation when facing drug price issues. In the future, pharmacists are continuously needed in protocol development and pharmacy association involvement.

Reviewing the Key Points

In conclusion, the discussion opened the door for various leaders in pharmacy to address and discuss some of the current issues, goals and visions within these topics. Specifically, several areas of discussion that were addressed included the management of limited distribution systems; generic drug price escalation; communication between manufacturers, insurance companies and healthcare professionals; fee-for-service versus value-based medicine; the definition of specialty pharmacy; future use of pharmacogenomic data with pharmaceutically; improved incorporation of data in EMRs; new clinical roles for pharmacists within specialty pharmacy; and involvement of local, state and national pharmacy organizations. With discussions among pharmacists at events such as Ohio Northern University’s Health Systems Leadership Summit, the profession of pharmacy will continue to experience beneficial changes in the areas of drug development, therapeutics and the pharmaceutical marketplace in the future.

References


