Consistent Cost Savings From Pharmacists’ Help with Medication Adherence

by Jennifer Kim, P3

These days, it may seem like the cost savings of pharmacist-guided pharmacotherapy is common knowledge, but pharmacists still have a difficult time earning recognition for that fact. In reality, not only do pharmacists contribute to millions of dollars in healthcare savings for states and patients, but they also encourage medication adherence to help patients better manage their diseases.

In several recent studies, a few key facts were established: due to treatment nonadherence, an excess $200 billion were added to healthcare costs in 2012, and people over the age of 40 and those with chronic conditions all had poor compliance with their drugs. With this evidence, one would think that third party payors would be recognizing the value of the work of pharmacists. Remarkably enough, CVS Caremark recently released a report on medication adherence, pointing to the significant cost savings that pharmacists can contribute. For pharmacists, the support of a fairly large pharmacy benefits manager is crucial.

CVS Caremark’s 2013 State of the States Adherence Report detailed variations of medication adherence and use of generics in different states and different patient populations. According to Troyen A. Brennan, MD, MPH, Executive Vice President and Chief Medical Officer of CVS Caremark, the report offered data to show policymakers and healthcare professionals the potential of “interventions that can improve medication adherence in order to advance health outcomes for patients and lessen the cost burden for the health care system.”

Dr. Brennan explained that CVS Caremark uses this data to develop programs such as the CVS Caremark Pharmacy Advisor® counseling program, which can increase adherence rates up to 3.9 percent and return $3 in savings for every $1 spent on counseling.

With this acknowledgement by a major player in the world of pharmacy benefits management, pharmacists can hopefully see more cooperation with legislators and other healthcare professionals to aid patients in managing both ailments and costs.

References:

Consumers Win in Supreme Court’s Pay-For-Delay Resolution, Antitrust Laws Beat Patent Laws

by Melanie Chen, PP2

Pharmaceutical companies that engage in pay-for-delay, a practice in which brand-name drug manufacturers pay generic drug companies to keep their cheaper generic drug versions off the market, can now expect stricter federal scrutiny. In a Supreme Court ruling on June 17th, 2013, the justices declared in a 5-3 vote that the Federal Trade Commission can sue pharmaceutical companies for pay-for-delay collaborations on the grounds that they violate antitrust laws designed to protect free trade.

The facts of the case are the following. Solvay Pharmaceuticals is the brand-name manufacturer of the drug AndroGel, a gel that raises low testosterone levels. In 2000, Actavis Inc. filed an application with the Food and Drug Administration to make a generic version of AndroGel. Two other generic drug makers, Par Pharmaceutical and Paddock Laboratories, also applied shortly afterwards. Solvay responded by filing a suit against Actavis and the other two drug makers claiming patent infringement. To settle the suit, Actavis agreed to withhold its generic version

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Innovations in Pediatric Formulations

by Jennifer Kim, P3

Most children are finicky about the taste and texture of their medications. For a child to tolerate taking some medicine, the drug has to be smooth, candy-colored, and palatable. Most adult medications usually have various dosage preparations – tablets, capsules, suspensions, and syrups – but pediatric formulations tend to be limited or are simply rendered from the adult forms. Knowing these obstacles, the Eunice Kennedy Shriver National Institute of Child Health and Human Development: Pediatric Formulation Initiative (PFI) was developed back in 2005 to promote and advocate a separate and necessary market for pediatric formulations of drugs.

Statistics show that children over six years of age are capable of mastering the skill to swallow a pill, but studies also show that most adolescents are hesitant about swallowing pills until 11 years of age. This presents a problem for physicians and pharmacists to properly care for their younger patients. There are some methods to altering solid dosage forms to help administer drugs to a pediatric patient. For example, pharmacists could crush tablets, cut pills, or prepare oral suspensions and solutions. However, these methods may reduce bioavailability, stability, and variable therapeutic indexes. By utilizing such methods, a medication that was once acceptable to be used in an adult patient may become extremely problematic for a pediatric subject.

After the PFI was established, the World Health Organization also launched the “Make Medicines Child Size” worldwide initiative. In addition, a European counterpart by the European Medication Agency was developed to help stimulate the pharmaceutical industry to develop more pediatric dosage forms. The efforts of these three organizations were successful, and today, several new dosage are formulations available to children. Infants and adolescents have may have the choice of oral liquids, orally disintegrating tablets, and orodispersible films.

With the recent innovations in pediatric formulations, medications that were originally not accessible to children can now be created specially for them. Due to the work of these institutes, children all over the world have access to the medicine they need.

References:
Ciclopirox for the Treatment of HIV

by Yingzhi “G” Zhang, P3

According to a study by Rutgers New Jersey Medical School researchers, ciclopirox has demonstrated efficacy in eradicating HIV infection from cell cultures, without viral rebound once the drug has been stopped.

Cells that become infected with viruses have a mechanism to self-destruct, destroying their own mitochondria via a process called apoptosis, preventing viral proliferation and further infection of healthy tissue. HIV-1 has the ability to shut off the cell’s apoptosis pathways, preventing them from committing suicide upon infection.

Although anti-retroviral medications are extremely effective in keeping the virus at bay, they cannot cure the infection and must be taken by patients for the rest of their lives to remain effective. Missing doses of anti-retroviral medications greatly decreases their effectiveness, and non-compliance remains one of the top reasons for therapeutic failure in HIV positive patients.

Ciclopirox, a medication typically used topically to treat fungal infections, has been shown by researchers to inhibit the expression of HIV genes. The drug also appears to block the function of mitochondria in infected cells, thereby reactivating their apoptosis pathways and further preventing the virus from spreading. Additionally, discontinuing the drug did not result in a rebound infection, as is common in anti-retroviral medications.

Further clinical trials are needed to evaluate the efficacy of ciclopirox as an anti-HIV medication. The drug, however, is already approved for HIV treatment by the FDA and the EMA, indicating that it is safe for human use. The speedy approval of such a drug, well-tolerated in clinical trials, may indicate the approach of an end to the era of HIV as the predominant pandemic the world faces.

Pay-For-Delay Resolution

Continued from the front page

from the market until 2015 and to promote AndroGel to certain doctors. In return, Solvay will pay Actavis a sum estimated to fall between $19 million and $30 million each year for nine years. Solvay made similar deals with the other two companies. Such “pay-for-delay” agreements, also called reverse-payment settlements, are a way for drug companies to dissolve patent litigations that arise when a generic drug maker challenges the validity of a brand-name maker’s drug patent.

The Federal Trade Commission, with the mission of protecting consumers against monopolistic business operations, views these actions as anticompetitive because they deny consumers access to less expensive generic drugs. The Supreme Court took the side of consumers putting the FTC in a stronger position to investigate potentially anticompetitive pay-for-delay court settlements.

However, the Court did not definitively say that these kinds of agreements were illegal, a stance that the FTC was hoping the Court would lean towards. Instead, the Court has stated that the legality of each agreement will be determined by a “rule of reason,” a fact-based evaluation commonly used to assess antitrust claims. This means that lower courts must analyze every pay-for-delay compensation for latent anticompetitive activity on a case-by-case basis.

“No other decision this term will have as much impact on consumer’s pocketbooks,” said David A. Balto, an antitrust lawyer and former FTC policy director who applauds the Court’s decision.

Americans spent $320 billion on drugs in 2011 according to IMS Health, a healthcare research company.

The FTC maintains that reverse payment deals cost US consumers about $3.5 billion annually. Generic drugs can be as much as 90% cheaper than their brand-name counterparts. Since 70% of all prescriptions are filled with generics, the Court’s decision in Federal Trade Commission vs. Actavis, Inc., could lend a hand in increasing generic drug availability and lowering healthcare costs.

The upcoming consequences of the ruling are difficult to pinpoint. Generic drug makers are likely to benefit from a crucial shift in power, which may lead to more aggressive patent confrontations now that brand-name companies have to think hard about their options before buying out their competitors. On the other hand, some generics may be discouraged from challenging brand-name drug patents and entering the market, since the extra scrutiny will likely mean lengthier and costlier FTC examinations.

One troubling aspect of the verdict is how little guidance the Supreme Court has given lower courts with regards to exercising “rule of reason.” Though a large payment generally suggests anticompetitive conduct, there is bound to be confusion amidst lower court circuits over how to spot anticompetitive intentions within the context of each particular pay-for-delay case.

For medication prescribers, drug availability and prices may be fated to change as a direct result of the resolution.

One consequence will surely arise in the aftermath, though: pharmaceutical companies can expect the FTC to take down names for any lucrative, and therefore suspicious, pay-for-delay packages.

Key Takeaways:

- Pay-for-delay agreements are not presumptively illegal, but parties seeking to resolve patent conflicts using pay-for-delay will be subject to increased risk of antitrust violation
- The FTC will continue to rigorously inspect pay-for-delay deals
- Court ruling provides little guidance on how to evaluate competitive effects using “rule of reason”
- Prescription medication availability and prices may be severely affected

References:

by Christina Zikos, P2

A Global Perspective in Health:
Access to Essential Medicines

A new report released by the United Nations on September 19 states that essential medicines are not sufficiently available in developing countries, with only 57% of public and 65% of private health facilities in 2012 being adequately stocked. While local production of some medicines has increased access in some areas, and some HIV/AIDS drugs have become more accessible and affordable in some regions, on the whole, prices for essential medicines in developing countries are too high. According to the report, prices can be more than three times higher than international reference prices in public sector facilities and more than five times higher in private sector facilities. The report urges the pharmaceutical companies to make essential medicines more affordable and to develop new pharmaceuticals.

These shortcomings equate to about one third of the world’s population not having regular access to essential medicines. Many of these people live in sub-Saharan Africa, though a sizable amount are the poor left behind in emerging economies.

Unequal access to essential medications can be due to a number of issues. Scarcity of drugs in the public sector can be due to underfunding, inaccurate demand predictions, and inefficient infrastructure to acquire and distribute the medicines. When patients turn to the private sector, they may find drugs more readily but at a higher price. Medicine quality is also problematic when resorting to cross border importation of essential medications; medications of low quality and stability are often encountered.

Scaling back, we can also examine the supply of essential medicines from their source. A lack of research may mean that medications for certain conditions do not exist. Such is the case for safe drugs for sleeping sickness or heat-stable insulin for diabetics in the tropics. There is also a lack of suitable formulation, such as the scarcity of fixed-dose combination syrups of antiretrovirals for children with AIDS.

Therefore, it is arguable that some of the responsibility for increasing access to essential medications falls on the pharmaceutical industry.

To this end, an independent initiative has been in existence since 2008 to monitor the world’s 20 largest research-based pharmaceutical companies. Access to Medicine Index is published every two years to rank the companies on their efforts to make their products more available, affordable, and accessible in developing countries. The ultimate goal is to encourage the companies to do more by providing insight on company policies and practices that improve access to medicine.

The index considers the companies’ drugs for top ten communicable diseases and top ten noncommunicable diseases that cause the highest disease burden in developing countries, fourteen neglected tropical diseases, and a number of maternal and neonatal conditions.

Evaluations are made on 101 indicators in seven areas:

1. organization and management of access programs (10% of the score)
2. conduct of relationships with policymakers, competitors, customers, and the public (10%)
3. R&D of relevant products (20%)
4. pricing policies and distribution (25%)
5. patent and licensing policies (15%)
6. capability advancement in developing countries (10%)
7. product donation and philanthropic activities (10%)

Overall, the pharmaceutical industry is making some progress in improving global access in that seventeen companies improved their scores in the newest 2012 report. GlaxoSmithKline retained its lead and Johnson & Johnson and Sanofi advanced into the top three.

Some of the success of the top three companies, Gilead, and Eisai may be attributable to a Developing Countries and Market Access unit that they each have set up that operates under a lower price/higher volume model. This new department oversees business in all “Least Developed Countries” and management is rewarded by volume growth rather than profit growth.

Furthermore, a number of companies are now allocating as much as 20% of their R&D to new products to address the needs of the poor – an area that has been stagnant due to poor economic return. Sanofi is creating a leishmaniasis product that can be applied to the skin in lieu of repeated injections that require administration by health care workers. J&J is developing a portable tuberculosis diagnostic that will yield results within minutes.

Another increasingly common tactic is tiered pricing schemes for a broader range of products. The impact on affordability of this method is to be determined.

Interestingly enough, many companies are working together and exchanging information to aid in R&D. The primary focus of research is for lower respiratory infections, diarrheal diseases, HIV/AIDS, malaria and tuberculosis. Neglected tropical diseases are still decidedly underfunded, but funding has been boosted by the private sector in 2012. African trypanosomiasis, leishmaniasis and Chagas disease received the most investment, with leprosy, soil-transmitted helminths, yaws, Buruli ulcer, dracunculiasis or fascioliasis lagging far behind.

References:
9 Questions with Dean Barone

by Emile Zhang, P1

How did you start out in the field of pharmacy? What made you fall in love with the profession?

I became interested in the field of pharmacy because of my uncle; he was an army pharmacist. I was excited to have the opportunity to go to St. John’s University. While at St. John’s, I was working in community pharmacy. I really enjoyed the community setting: working with patients, pharmacists, and physicians. It was my experience in community pharmacy that made me fall in love with this field. I was ready to graduate when I found out about St John’s new Pharm.D. program. I joined on the advice of a Pharm.D. I met on rotations. I fell in love with emergency medicine pharmacy during my rotations at Bellevue Hospital in NYC. From there I went to the University of Illinois to do my post-doc residency, then to Rutgers for my first real professional job.

You have been a pharmacist for 32 years, since 1981. Are there any mistakes that young pharmacists should watch out for?

One of the mistakes I would say not to make is to have a plan that is too inflexible. When I was a student I had planned to work in community, but my career totally changed when I met that Pharm.D. I met on rotations. I fell in love with emergency medicine pharmacy during my rotations at Bellevue Hospital in NYC. From there I went to the University of Illinois to do my post-doc residency, then to Rutgers for my first real professional job.

What, in your opinion, is your greatest accomplishment of your career? How did you accomplish this?

I think two significant contributions we’ve made are creating our industry fellowship program and emergency resident medicine program. I’ve had a hand in starting these two programs, along with a very supportive Dr. Colaizzi. Though I feel that creating a strong clinical program in emergency medicine was a major accomplishment, I would call the industry fellowship program my biggest contribution. 700 people have now gone through the program, a lot of them Rutgers graduates. Prior to that, there were jobs in some small select areas but we made a big impact in creating jobs for pharmacists in the industry.

What would you say is your style of leadership?

My leadership style is very inclusive. I value everybody’s opinion and don’t like to make decisions unilaterally. I like to be well-informed when making decisions. I also try to get people involved. I try to create an environment where people feel that they can try different things, and it’s ok if someone fails as long as they try their best. My management style is leading by example and making sure that everyone feels included as part of the leadership team.

You’ve recently been awarded money from Merck for a project. Can you tell us about it?

There are many companies that give us funding for our fellowship program. The funding level now is over $6 million – that’s money companies give us to create these fellowships. Our post-doc fellows study with us for two years. Some will be at Bristol-Myers Squibb, some will be at Merck, and some will be at J&J. The program now is approaching 30 years; more information can be found on our website.

Is there a way and manner that you prefer to be approached by students?

I try to be as accessible as possible. It’s easiest for students to just send me a quick email; I’ll connect you to Lisa, my associate, who prepares and manages my encounters. If a student wants to see me, I definitely want to make time in my schedule for him or her.

What would you recommend to students who are interested in pursuing similar career paths to you?

Keep your options open. Keep an open mind. Always look for opportunities. And say yes to different things, even though they may lead to kind of a strange career path. It’s also a lot of luck and perseverance. But I think the key thing is keeping an open mind and doing the best you can.

Do you have any hobbies or interests?

I like to do two things: travel and read. I like traveling: seeing different things and different cultures. I also like to read general fiction novels – nothing too complicated. I don’t know why but I love the Harry Potter books. They’re fun books to read.
Questions with Dean Barone

In closing, is there anything you’d like to say to your students?

I want to tell the students how proud I am of them. I do honestly believe that we have some of the most talented students in the country. When I see the different things that our students are involved with, such as all the various organizations and community projects, it makes me very proud of them. They are the ones that make our school good. Anything I can do to make them more competitive and have a better experience, I will. The better they look, the better the school looks. I want to be proud of them and I want them to be proud of Rutgers. I think the strength of our school comes from everybody: our students, faculty, administration…everyone.

Reference:

On October 3rd, over 30 Rx organizations across the globe used Twitter to disseminate tweets tagged with #pharmacist to describe the impact that pharmacists have on patients, communities, and the health care industry.
by Jazmin Turner, P3

Sixth year pharmacy students have the unique opportunity to choose rotations that go beyond hospital and community settings. The Indian Health Service in Kayenta, Arizona is one such opportunity. In order to be chosen for this rotation, interested students must write an essay about why they want to do an IHS rotation, how the rotation can help them as future healthcare professionals, and what characteristics would make them successful on the rotation as a P3 student. The essay deadline is in December. In the spring, students find out if they were selected, and they rank their top three cycle preferences. When everything has been made official, the preceptor sends an email about the rotation detailing things such as exit interviews from past IHS rotation students and recommendations for things to bring (your own sheets, cash, sneakers, ear plugs for dogs barking at night). The preceptor also sends forms to fill out to get cleared to work there, which are necessary for a government job.

Current P4 student, Efe Johnson, completed her IHS rotation over the summer during her third cycle. She was interested in going to another part of the country and working with a unique and underserved patient population. Johnson worked at Novo Nordisk for three years and developed an interest in diabetes, a disease state that is prevalent among Native Americans. When she first arrived in Arizona, it was midnight and she had to pick up her keys from the emergency room of the clinic because everything else was closed. She lived in a three bedroom trailer with two other Rutgers students. There were dirt roads and the closest cities were hours away. They had no internet, poor phone reception, and a TV that did not work, so it took some time to adjust and she had to find alternate pastimes to enjoy in her spare time.

Every day of rotations was different for Johnson. Her preceptor let her shadow different practitioners such as pediatricians, emergency room physicians, and nurses. She was able to speak to a psychologist who was a commissioned officer in the United States Public Health Service.Commissioned officers are sent to different locations during times of disaster. This particular psychologist had been deployed to Newtown, CT after the shooting and to Boston after the marathon bombing. Johnson went on home visits with nurses who went to check on mothers and their newborns and she was able to utilize certain techniques that she learned in Physical Assessment, such as taking pulse and checking temperature. Johnson was also able to speak with an infection control nurse and she learned about different infectious diseases that were endemic to the area, such as the hanta virus which is transmitted through mouse droppings.

Pharmacists at the IHS ran diabetes and Coumadin clinics. For the diabetes clinic, Johnson watched nurses educate patients about how to inject themselves with insulin and helped stress the importance of taking medicine every day and eating healthy. There was one situation where a patient was getting insulin for the first time and he did not understand how to use it. Johnson was not comfortable dispensing the insulin at that point. Then she also realized that the dosing was not appropriate, so she brought it to the attention of the physician. It turned out that the physician had not been trained by the diabetes specialist and made a mistake with a dosing. This situation helped to illustrate the importance of pharmacist interventions in patient care. With the Coumadin clinic, Johnson counseled patients and checked to see if their therapy was correct. She pricked patients’ fingers to get the International Normalized Ratio (INR), which is a measure of anticoagulation. Johnson was able to utilize much of the knowledge she had learned in Pharmacy Communications to counsel patients, especially how to use inhalers.

In addition, Johnson and the other students were required to create a Continuing Medical Education presentation for physicians on osteoarthritis as well as report adverse drug reactions. She even was able to go to a local elementary school and teach children and their families about poison prevention.

One of the most appealing aspects of the IHS rotation is the opportunity to learn about a new culture and explore an exciting area of the country. Johnson traveled to places such as Zion National Park, Bryce, Sedona, and Las Vegas. She was able to learn Navajo phrases and she even got addicted to some Navajo food. Every Wednesday a flea market was held and she was able to see some of the beautiful items the people there made. Johnson would recommend this rotation to people who want to have a more clinical, hands-on experience with patients. It would be ideal for those who really want to help underserved populations, but one must be sensitive, understanding, and willing to learn about the Navajo culture.
The Importance of Being Ernest
Exploring the EMSOP Network: Where can a Pharm.D. from EMSOP lead you?

An Interview with Dr. Thea Golden, PharmD/PhD Candidate

by Smita Jaggernauth, P1

With a bounty of career options to explore during rotations, pharmacy students are fortunate enough to get experience in multiple settings. One pathway, however, that is chronically overlooked is academic research. This is gradually changing at the Ernest Mario School of Pharmacy with the recent addition of the PharmD/PhD program, which provides students interested in basic science the opportunity to smoothly transition into a PhD program after receiving their PharmD.

One of the students in this pioneering program is Dr. Thea Golden, a 2011 pharmacy graduate who has been in the program working in Dr. Gow’s lab for two-and-a-half years. Although the program is structured such that students begin coursework during their P4 year, Dr. Golden completed her fourth-year rotations before ultimately deciding to enter the program to pursue a PhD.

Dr. Golden started her endeavors in research by working in Dr. Gow’s lab during her P3 year. Dr. Gow’s lab in the Pharmacology and Toxicology department focuses on the role of nitric oxide on immune cell function and the pathophysiology of cardiopulmonary diseases. Dr. Golden approached Dr. Gow specifically after a positive experience in his Pharmacology class and because of her interest in lung pathology, stemming from a childhood case of asthma.

During this time, she realized that she enjoyed the inquisitive nature of research, with its continuous quest to ask questions and expand upon scientific knowledge. This appreciation, coupled with her desire to teach students and head her own laboratory, lead her to pursue a PhD.

Her initial project in Dr. Gow’s laboratory examined the role of macrophages in a bleomycin-induced acute lung injury model. Currently, her work focuses on characterizing the recruitment and activation of monocytes in lung inflammation models.

Dr. Golden’s hard work has paid off in several respects. She became published in the journal *Nitric Oxide*. In addition, her work has spurred collaborations with other institutions such as the University of Pennsylvania and the Cleveland Clinic. Dr. Golden’s most impressive accomplishment, though, is being awarded the prestigious F31 Predoctoral Fellowship from the National Institute of General Medical Sciences (NIGMS), a subset of the National Institutes of Health (NIH). This fellowship is awarded to PharmD/PhD students who have demonstrated excellence within their field. Dr. Golden feels that this recognition from the NIH encourages her and justifies the growing trend of pharmacists dually trained in clinical and basic sciences.

Dr. Golden’s advice to pharmacy students interested in research is to get as much laboratory experience as possible. Students should reach out to professors through email and class about research. Although it may take multiple attempts, persistence and patience with professors will eventually open doors for opportunity. Schoolwork, extracurriculars, and work commitments might make setting aside time for research difficult. Therefore, Dr. Golden recommends prioritizing commitments, a task she personally achieved by working a minimal amount of hours in a community pharmacy each week.