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U.S. Pharmacist®

Generic Pharmaceuticals 2009:
The Road Ahead

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Participants in *The Road Ahead*

Robert W. Pollock, RPh, MS (Moderator)

Bob received his BS degree in Pharmacy and his MS degree in Pharmacy Administration from the University of Rhode Island where he studied as a Fellow of the American Foundation for Pharmaceutical Education. He is Senior Vice President of Lachman Consultant Services, Inc., which provides consulting and regulatory services for the pharmaceutical and allied health industry. Formerly, Bob was Acting Deputy Director for the Office of Generic Drugs (OGD), Center for Drug Evaluation and Research, Food and Drug Administration.

Doug Long (Presenter)

Doug is Vice President of Industry Relations at IMS Health Inc., the world's largest pharmaceutical information company, serving over 101 countries. He has been with IMS since 1989. Previously Doug was at Nielsen Market Research for sixteen years. Doug received a BA degree from DePauw University, and an MBA in Management from Fairleigh Dickinson University.

Chris Kidd, RPh (Presenter)

Chris received her BS degree in Pharmacy from Purdue University. She is Pharmacy Supervisor for Marsh Supermarkets. Chris is responsible for managing the annual pharmacy budget, purchasing and procurement planning for the supermarket pharmacy department.

David Badeen

David received a BS in Pharmacy from Southwestern Oklahoma State University. He is Senior Buyer at Wal-Mart Pharmacy Division. David is responsible for strategic planning for pharmacy merchandising and procurement of brand and generic pharmaceutical products.

J. Mark Bover

J. Mark received a BS in Pharmacy from the Albany College of Pharmacy. He is the Senior Director of Generic Pharmaceutical Purchasing for Rite Aid. J. Mark is responsible for annual purchases of generic pharmaceuticals, maximizing impact of new generic launches, contracting agreements and, promotion of market initiatives available to manufacturers.

Charles Burnett

Charles is Senior Vice President of Costco Wholesale Corporation and is responsible for overall pharmacy operations. Back in 1986, he started the pharmacy division, which has now grown to 348 pharmacies in the U.S., 46 in Canada, and 27 in Mexico.

Bill Ladwig

Bill received his BS degree from South Dakota State College of Pharmacy. He is Vice President of Professional Services for Lewis Drugs Inc. Bill is responsible for the overall operation of Lewis Drug, Inc.'s retail and institutional pharmacies.

Ted Lingerfeldt, RPh

Ted graduated from the University of North Carolina School of Pharmacy. He is the Director of Pharmacy Procurement and Analysis for Kerr Drug. Ted is responsible for all pharmaceutical purchases for Kerr Drug, both brand and generic.

Kristen N. Reabe, PharmD

Kristen received her PharmD from the University of Wisconsin, School of Pharmacy. She is Vice President of Contracts for Pharmacy Select, a contract entity representing over 6,000 community pharmacies across the U.S. Her responsibilities include contract negotiation, program development, and market analysis.

Thomas E. Scono, RPh

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Generic Pharmaceuticals 2009:
The Road Ahead

While the summer of 2008 may have been coming to an end on August 22nd, a discussion on the current and future state of the generic drug industry was just beginning. In a conference room at the San Diego Marriott Hotel, ten prominent pharmacy executives participated in U.S. Pharmacist's *third annual* Dialogs in Generics *meeting. This year's theme, "Generic Pharmaceuticals: The Road Ahead," supported by Greenstone LLC., focused on what challenges and opportunities the generic pharmaceutical marketplace are tackling today and are likely to face in years to come. Panelists this year included: Moderator: Bob Pollock, RPh, Senior Vice President, Lachman Consultant Services, Inc.; Presenters and Participants: Doug Long, Vice President, Industry Relations, IMS Health Inc.; Chris Kidd, RPh, a practicing pharmacist at Marsh Pharmacy; Panelists: J. Mark Bover, Senior Director, Generic Pharmaceutical Purchasing, Rite Aid; Tom Scono, RPh, Vice President of Contracts, EPIC Pharmacies, Inc.; Kristen Reabe, PharmD, Vice President, Contracts, Pharmacy Select; Charles Burnett, Senior Vice President, Costco; Bill Ladwig, Vice President of Professional Services, Lewis Drugs; Ted Lingerfeldt, Director of Pharmacy Procurement and Analysis, Kerr Drug, Inc.; and David Badeen, Pharmacy Regional Manager, Wal-Mart.*

In *U.S. Pharmacist's* continuing effort to keep pharmacists current on events affecting the generic drug marketplace, this year's roundtable discussion followed a natural progression from its two predecessors. In 2006, *U.S. Pharmacist's* panel of experts tackled some of the biggest issues facing pharmacy and generic drugs at the time, many of which are still confronting the industry. Interestingly, one of the hot topics two years ago centered on the then pending implementation of the controversial average manufacturer's price (AMP), which has still not seen the light of day.

Another issue discussed at that meeting that is still of major concern was the backlog of generic approvals at the U.S. Food and Drug Administration (FDA). With the influx of new competitors, choking government regulations, and increased mergers and acquisitions, it became clear that a "perfect storm" was brewing on the horizon that could have had serious and long-term consequences for the generic industry. However, as dire as the situation appeared then, a year later in 2007, panelists participating in *U.S. Pharmacist's* second annual generics roundtable generally agreed that the industry weathered the impending storm of the year before, but cautioned that the industry was still evolving and was indeed at a "critical crossroads" facing even greater challenges that were once again threatening the growth of generic pharmaceuticals. Some of these issues included the new Deficit Reduction Act (DRA) with its unwieldy provision of using AMP in the industry's pricing structures, the FDA's backlog of drug approvals, issues dealing with the safety and efficacy of drugs already in the marketplace, and the beginning of a new administration in the White House.

Fast forward to August 22, 2008, in San Diego, where the panel of key opinion leaders took their seats at the table to take a focused look at the future of the generic industry formed partly by two keynote presentations-an industry overview presented by Doug Long, Vice President of Industry Relations, IMS Health, and an analysis of an exclusive *U.S. Pharmacist* generic survey to practicing pharmacists by Chris Kidd.

Tackling the Difficult Issues

This year's authoritative panel set out to answer many of the perennial questions being asked of generic manufacturers, distributors, retailers, and drug wholesalers. What is the effect of the recent influx of competition and the drive for value priced generics from unknown or foreign generic competitors? How has the rush to be the first out with a generic played into today's competitive climate? Given the number of patent expirations expected over the next

few years, what will brand companies do next? What strategies might brand companies employ to position themselves competitively, and is the time right to partner with a generic company?

In the mix of concerns is the perceived stifling of brand innovation and patent invalidity, as well as the impact of "at risk" generic launches. The roundtable attendees also tackled the effects on the industry of the growing number of discount generic prescription programs and the impact that mergers and acquisitions may play in shaping the industry's future.

Since this roundtable took place in August, just over ten weeks before the presidential election, many of the participants expressed their concern about who will be in the White House and what effects future legislation will have on generics. Many industry observers are anxious to see how the new administration handles many of the issues that were put on hold once the political posturing is behind us. Front and center are issues like AMP, universal health care, the future of Medicare Part D, and a revamping of the Hatch-Waxman Act.

While all of these concerns weighed heavily during the day-long discussion, the big question on everyone's mind was what the generic industry would look like in the future. There was general consensus that while there may be a few potholes along the way, the "road ahead" still looks very promising.

"With an aging population and chronic diseases becoming more prevalent, medications are helping people to live longer while also delivering a better quality of life, helping to fuel industry growth."

Doug Long

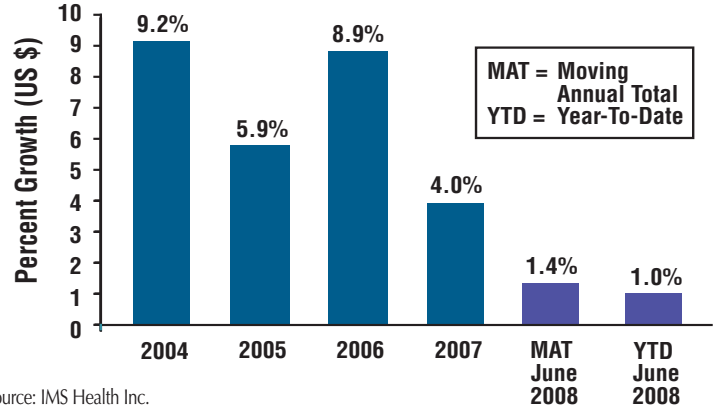
The State of the Overall Pharmaceutical and Generic Industries

All the participants agreed that the success of the generic industry's future was primarily dependent on innovator companies moving branded products through their pipelines and getting the FDA to approve them in a timely manner. To better understand the dynamics of today's pharmaceutical marketplace and what effect that may have for the future of branded and generic drugs, Doug Long, Vice President of Industry Relations for IMS Health, kicked off the meeting by offering the attendees a comprehensive overview and analysis of both the branded and generic pharmaceutical industries.

"What a difference a year makes from where we were last August," said Long. He reminded the participants that during the same time last year everyone was feeling very optimistic over sales fueled primarily by Medicare Part D. He said that few people really expected the market to end up as soft as it did in 2007, and even fewer believed it would remain that way well into 2008. In trying to explain the downturn in the market, Long noted, "I wish I could say there was one reason, but there's a multiplicity of reasons, and the softness is not only in dollars, but it's also on prescriptions or units, depending on how you want to look at it."

On a more positive note, Long said, "generics have really charged ahead." He explained that generic's now account for over 67% of the prescriptions dispensed and could reach 70% in the not too distant future. Long believes that one of the reasons for the increase in generics' market share is the FDA's cautiousness in approving innovative drugs. "The FDA has become much more risk averse than we've ever seen in the past. I think the pendulum right now is on risk, risk, risk, and it will swing back at some point when somebody complains why drugs are not getting approved."

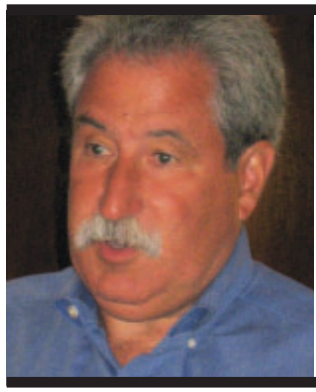
Graph 1. U.S. Pharmaceutical Market Growth Slows in YTD June 2008



Source: IMS Health Inc.

Long pointed out that mega-mergers are producing extremes in market share. He also noted that some companies are buying shares of generic companies to give them exposure to the emerging markets, such as China, India, Turkey, Russia, and Brazil.

"Things are not what they used to be," Long said. As an example, he said that the growth rate for the entire pharmaceutical industry for twelve months ending in June 2008 was 1.4% on a dollar basis; ironically that's exactly what the growth rate was for prescriptions **(Graph 1)**. "So there is no difference in prescription increases and dollar increases," he concluded. Long offered the panelists a bit of a historical perspective concerning the prescription marketplace. He explained the very productive period from the 1990s to the early 2000s was primarily fueled by innovation. "You saw the uptake of the number of prescriptions per person going up almost two to one in a five-year period of time. The downturn [of the early 2000s] was briefly interrupted because of Medicare Part D," said Long. "When Medicare Part D enrollment closed, you saw a very different picture during the last half of 2007, culminating with an actual prescription decline in the month of December." Long adds that "the worrisome trend continued into 2008 with steady monthly declines in number of prescriptions dispensed.



"I think that the brand name companies are getting back to basics and looking at their pipeline as their primary source for growth in the future."

Bob Pollock

He pointed out that in the second quarter of 2008 the number of prescriptions dispense were even below what they were in 2007. To put this into perspective, Long commented that last year was "the lowest growth since 1961 on a dollar basis."

According to Long, pharmaceutical manufacturers were historically able to count on 20 billion dollars of incremental opportunity every year, and now they are only up about 4 billion dollars over the last 12 months.

What Happened?

While industry pundits will point to any number of external forces on the market that caused the downturn, Long pares it down to three basic factors: lack of innovation, a risk adverse FDA resulting in a lower rate of approvals, and the concerns about safety of already approved drugs in the marketplace.

"Not only are we getting fewer approvals, we're getting more delays, more nonapprovals, and more products getting pulled from the market for safety concerns," said Long.

He also reminded the panelists that pharmaceutical sales tend to rise and fall over the years. "This is a cyclical business, always has been, always will be," said Long. With an aging population not in great health with chronic diseases, many industry observers thought the pharmaceutical industry was bulletproof. As it turns out, that was not true. "Sometimes, the bigger the mountain, the lower the valley," stated Long. "We are coming off the most productive cycle and now we're in a low cycle."

Long said that the business model of the 90s was much different than today. "Back in the 90s, all the pressure was on the pharmacist shortage and prescription volume going up, up, up. Largely it went up because there were more innovative products coming to the marketplace, which was driving prescription demand," said Long. "Some people would say that this market grew because of price increases. The market actually grew because of more people taking a greater number of prescriptions." In the face of a plethora of discount and free prescription programs that have dotted the retail landscape over the past couple of years, Long said "you would think that the industry would have witnessed a growth in prescriptions,

"I think today's economic situation is driving retailers to look for more innovative means to secure that extra refill."

Ted Lingerfeldt

"History has proven, through the greatest periods of stress you see the most innovation. If you're not innovative, you may not be here."

Bill Ladwig

not a decline. "That's one of the biggest mysteries to me in this marketplace."

He pointed to prescription refills as one of the biggest reasons for the overall drop in prescriptions, and that speaks volumes to the issues of compliance and persistency. People who are taking medications for chronic conditions are stopping their medications for any number of reasons, including higher co-pays and the ongoing concerns of the safety and efficacy of many newer drugs. Other possible explanations for the slowdown in prescription growth are the increased number of drugs switched from Rx to OTC status in recent years and a declining number of physician office visits, which are directly related to the deteriorating economy.

Biotechnology and Generics

Another important issue plaguing the industry is the need for manufacturers to prove the value of their medications. While not making much of an impact today, Long recommended to keep an eye on biosimilars, biochemical drugs that are not identical to the innovative product but close enough to encourage some physicians to prescribe them. Although some lawmakers may have taken a positive stance on biosimilars, this is still a controversial issue. Long believes it is not likely the generic industry will see substitutable biochemical products anytime soon.

Reaction by Panelists

Many of the roundtable participants echoed Long's concerns. Moderator Bob Pollock, Senor Vice President, Lachman Consulting, and Past Acting Deputy Director of the Office of Generic Drugs, suggested that the litigious environment created by Hatch-Waxman may be subsiding as more innovator companies are focusing on "creating new molecular entities instead of trying to protect their franchise products." He predicts that over the next decade, the innovator pipeline will once again be robust. "I think that the brand name companies are getting back to basics and looking at their pipeline as their primary source for growth in the future," said Pollock. "I think we are going to see a turnaround." Bill Ladwig, Vice President of Professional Services, Lewis Drugs, agrees with Pollock. "History has proven, through the greatest periods of stress you see the most innovation. If you're not innovative, you may not be here."

Pollock also suggested that the sagging economy with its increase in energy and gasoline prices was a reason for the slow growth. "Some people have to make a decision to get their prescription refilled or pay their electric bill."

For panelist Chris Kidd, an independent pharmacist who works for Marsh Pharmacy, a supermarket chain headquartered in Indiana, one of her big issues is dealing with patients who have reached the "donut hole" in the Medicare Part D program. The so-called "donut hole" is that threshold of the Medicare Part D program where there is no reimbursement until you reach the next threshold, some $2,000 away. Her pharmacy is also actively engaging patients in getting their prescriptions renewed. "I think that has driven up my business drastically," said Kidd.

Ted Lingerfeldt, Director of Pharmacy Procurement and Analysis at Kerr Drug, headquartered in North Carolina, basically agrees that

Chris Kidd

"Prescriptions are being treated as a commodity. Once the $4 [generic] prescriptions started, I believe mail order pharmacy companies were hurt immediately. I had a lot of my patients call their doctors to change their prescription to one that was on a four-dollar plan."

David Badeen

"From the stories I've heard from patients, many had to choose between buying food and paying for their prescriptions. I'd do it over and over every single day because it made health care accessible to those patients. That's the key behind this whole thing. That's what drove it and that's what made it so successful."

the economy is a big part of today's downturn. "I think today's economic situation is driving retailers to look for more innovative means to secure that extra refill," said Lingerfeldt. He added that Kerr Drug has been very proactive by operating their own call center to remind patients to refill their prescriptions.

Tom Scono, Vice President of Contracts, EPIC Pharmacies, took a different approach. "I think the disturbing trend I see is prescriptions that aren't actually making it to the pharmacy."

Government's Influence

It is generally believed that while the introduction of the AMP will add more transparency and fuel expansion of regulated drug pricing by the government for all pharmaceutical manufacturers, it will have a particularly negative impact on generics since many pharmacies today look to reimbursements based on the current average wholesale price (AWP) to return a better profit to their bottom lines.

The roundtable participants again discussed the controversial topic of the AMP, and whether or not it would ever become a reality in the near term.

The AMP is generally defined as the average unit price paid to the manufacturer for a drug in the U.S. by wholesalers that are distributed to the retail pharmacy class of trade. It was created because the federal government felt that the current AWP was a poor metric to use in estimating drug cost for reimbursement purposes.

However, how this played out has become extremely controversial, leading to inconsistencies across manufacturers, a number of highly critical studies by the Office of the Inspector General (OIG) and Government Accountability Office (GAO), allegations of gaming, and countless law suits against drug makers by U.S. attorneys and state attorney generals. Following the statutory changes made by the Deficit Reduction Act (DRA), the final rule changes to AMP included: an exclusion of customary prompt pay discounts to wholesalers from the calculation of AMP; clarify the definition of retail and wholesaler class of trade and how to treat sales reimbursed by third party payers; define what prices should be included in or excluded from the determination of a drug's AMP; exclude sales to nursing homes and discounts, rebates, or prices to Pharmacy Benefit Managers (PBMs) (except when PBMs act as mail order pharmacies; an exception that is very controversial with retail pharmacies), define many key terms for purposes of the Medicaid drug rebate program; and clarify how manufacturers should account for price reductions and other pricing arrangements in calculating AMP.

Financial Challenges

Major changes are being made to the DRA, and the AMP structure being proposed by Congress is currently on hold. It has been generally agreed that the new policies pose significant financial challenges for both branded and generic manufacturers.

Across the health care system, many industry observers believe that changes to the DRA are further evidence of the increasing power of government policy on the pharmaceutical supply chain. The majority of the panelists believe that AMP will be back, but in a different form than originally proposed.

"I think AMP will come back. It's

"It's pretty well known in the industry. You cannot economically fill a generic prescription for $4. So whoever fills one for $4 is automatically losing money, whether they claim it or not."

Charles Burnett

got to. The government has decided that it needs to do something more…however, I think it will be something a little more amicable," said J. Mark Bover, Senior Director, Generic Pharmaceutical Purchasing for Rite Aid. "Although, I think it's still going to cause an awful lot of stress for those that don't have the equivalent buying power of large organizations or consortiums."

Kristen Reabe, Vice President of contracts at Pharmacy Select, agrees. "I believe the independent pharmacy is the most at risk in regards to AMP. They will be looking to their wholesaler to provide pricing that allows them to be competitive with other classes of trade." She added that the wholesaler in turn will most likely put more pressure on the manufacturer. "It's all about getting the lowest price," she said.

Scono believes that AMP will have a major effect on the consumer and that it will eventually have the government rethinking its legislation.

Wal-Mart's David Badeen agrees that the market will probably see a resurgence of the AMP, "but it's not going to come back like it was originally proposed. Whether it's called AMP or something else, it will have some controls attached to it and will not be as onerous as it was originally proposed."

Kristen Reabe

"The average independent pharmacy owner is a 55-year-old male, [with] very little in line for a succession plan. When Medicare Part D rolled out and became an additional burden, many owners made the difficult decision to either close or sell to a chain."

Universal Health Care and the Impact of Medicare Part D

With a new administration moving into the White House, it is still too early to tell what direction it will take with regards to universal health care, or a modified version of it. The topic drew mixed emotions from the panelists. Some took the position it was good idea but too costly, while others believed that cost wasn't necessarily the major issue; it was really the level of health care that would be provided under such a system. They said that citizens in countries that have universal health care are opting for private care because of poor government service.

The conversation quickly turned to something that is already a reality, Medicare Part D. With some metrics now behind the government health plan, Bob Pollock asked the group how it has affected their business. Tom Scono and Kristen Reabe agreed that Medicare Part D's most negative influence was on independent pharmacies.

Reabe said the number of independent pharmacies declined by approximately 5% after the implementation of Medicare Part D.

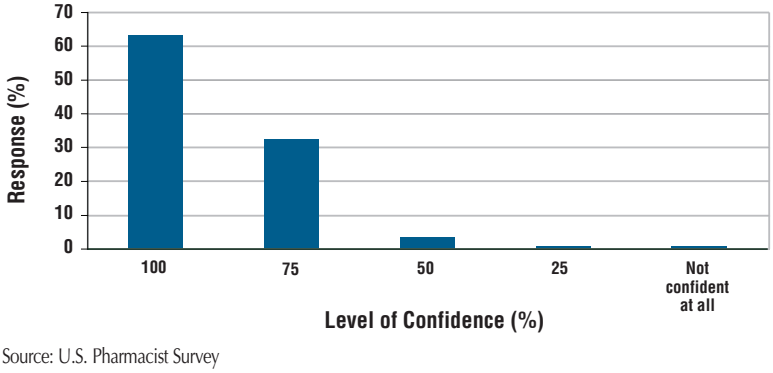
"Our pharmacies weren't prepared for the challenges of the program," said Scono. "While the script volume was a bonus that was much needed, the program and its late payments put a tremendous burden on the independent pharmacist."

Reabe summed it up when she said "the average independent pharmacy owner is a 55-year-old male, [with] very little in line for a succession plan. When Medicare Part D rolled out and became an additional burden, many owners made the difficult decision to either close or sell to a chain."

Exclusive Survey on Attitudes Toward Generics

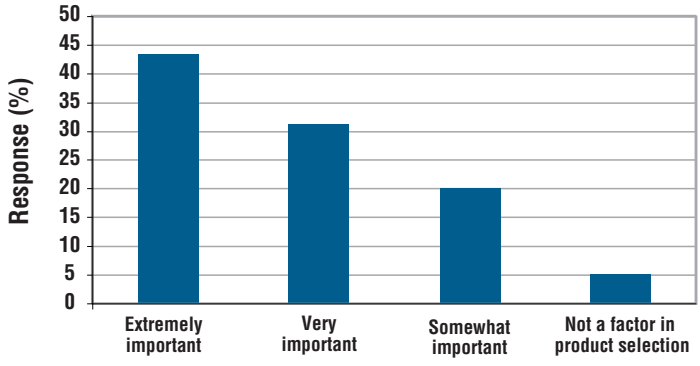
A highlight of this year's program was a keynote presentation of an exclusive pharmacist survey conducted by *U.S. Pharmacist*. The survey centered on pharmacists' personal perception of

Graph 2. Pharmacist's Confidence that Generic Drug is Equivalent to Brand Drug



Source: U.S. Pharmacist Survey

Graph 3. The Importance of Country of Origin and Confidence in Pharmaceutical Product Safety



Source: U.S. Pharmacist Survey

today's generics, the industry that manufactures them, and the distribution system that gets them into retail and institutional pharmacies. Chris Kidd presented the analyzed results.

The survey was e-mailed to pharmacists that represented a cross-section of all practicing pharmacists in the U.S., 60% of which were male and 40% female. The results were split evenly between chain, independent, and health-system pharmacists.

The questions concentrated on five major areas: confidence levels and personal attitudes towards generic drugs; satisfaction with their current generic drug supplier; knowledge and attitude of authorized generics and at-risk generics; perception of generic discount programs; and a view on prescriptive authority.

Confidence Levels and Personal Attitudes

The survey revealed that generics are well entrenched and respected in the marketplace. This was evident when 90% of the pharmacists said they were confident that the generic product equaled the brand in safety and efficacy **(Graph 2)**. In fact, the same percentage said they would take generics over the branded product themselves. They also indicated that 85% of their patients readily accept generics when they are dispensed.

"I think what the insurance company reimburses your customer base for prescriptions will affect [the confidence level] drastically," said Kidd.

The survey showed that just over half (55%) of the pharmacists felt they have control over which generic company's product to stock. Interestingly, half said they did not agree with mandatory substitution. Bob Pollock noted that the number could be higher because his home state of California does not have mandatory substitution and that may apply to other states as well, since it is a state issue and not federally mandated.

Country of Origin

There has been much publicity about counterfeit drugs and other issues related to imported drugs. Perhaps that is why nearly all the pharmacists who took the survey (95%) felt the drug's country of origin affects the safety of a product; 75% designated the level of that importance as "extremely important **(Graph 3)**."

Kidd noted that in her pharmacy there have been a number of customers that ask where their prescriptions come from now. "This is really a big issue and a lot of people are asking where these companies are based; where are these products coming from?" Kidd feels that until more people become educated on generic companies, or the pharmacist can explain who or where the generic drug is coming from, the issue may become more important.

Kristen Reabe commented that while there may be concern, many patients do not realize that the raw materials for a generic drug may be coming from overseas even though the product is actually manufactured domestically.

Rite Aid's Bover said that it is not just the pharmacist who is questioning the country of origin; many patients are beginning to inquire as to where the product originated. But he said that was nothing new. "We had patients as far back as fifteen years who didn't want to take a product that was made in certain foreign countries," said Bover. "Some people have prejudices. It's not just because of the current explosion of products originating in India. There are some

"The time a brand really loses its exclusivity in terms of how and when generic companies start to produce drugs will vary by product. You may get 24 hours or you get 24 months advance notice."

J. Mark Bover

patients that just don't want to take something that's originating from certain areas of the world."

Kidd agreed. She believes that kind of behavior is more prevalent among generics. "A brand name product to a customer is a brand name product. They don't really care where it comes from. But once you get a generic, they do want to know."

Pollock said private label distributors have made it even more difficult to trace the origin of the drug. For example, "an Indian company could hold an [approved] application [on a drug] and another company wants to private label it for distribution in the U.S.; it gets labeled with the distributor's name only. Some states mandate that the manufacturer's name be listed as well, but there are many states where it is not mandated. So the patient really has no idea where the product was actually made."

Authorized Generics and At-Risk Generics

Not surprisingly, 99% of the pharmacists surveyed felt that a generic product's consistency in color and shape was of paramount importance. "Explaining to an elderly person that they're getting the same medication even though it may look different can be very confusing," said Kidd.

She also admitted that she was "surprised" that 86% of the pharmacists surveyed felt they understood the definition of an "authorized generic," but was not surprised that 70% would prefer to dispense them **(Table 1)**.

Reabe agreed. "I think a lot of them think they understand what [authorized generic] means, but I think if we really asked them to define it, I don't think they could."

Despite the fact that an authorized generic is manufactured by the innovator company and is comparable to the innovator drug, Kidd said that in her experience "people come back after receiving the drug to tell me it didn't work."

When asked about "at-risk" generics, half of those surveyed felt they understood what it meant. More specifically, 17% of the pharmacists said at-risk generics were not a problem at all; 27% said it was only a small problem that can be handled with consultation; and 56% didn't like the idea of dispensing at-risk generics at all.

"This is a very hot topic as a result of the Medicare Modernization Act. To trigger the 180-day exclusivity period, it used to be first to commercially market the product or a court case. Now there are a series of forfeiture provisions under the new law where a firm may only have 75 days for the first generic applicant to begin commercial marketing, otherwise eligibility for exclusivity could be lost said Pollock. "So we're likely going to see a lot more periods of at-risk launches."

Rite Aid's Bover said that when it comes to at-risk generics, full disclosure is his company's preference. "When an at-risk generic is launched that could potentially go away, we let our pharmacists and they let their patients know."

The Impact of Generic Discount Programs

Forty-seven percent of the pharmacists surveyed said that generic discount programs had relatively no impact on their practice and there was only a modest loss of business. "Prescriptions are being treated as a commodity," commented Kidd. "Once the $4 generic prescriptions started, I believe mail order pharmacy companies were hurt immediately. I had a lot of my patients call their doctors to change their prescription to one that was on a four-dollar plan." This has created a situation where patients are getting their prescriptions filled at multiple pharmacies that may not be talking to one another, thus putting the patient's health at risk due to possible drug to drug interactions. Another concern is that people are coming into the pharmacy with four-dollar prescriptions and a $15 to $25 coupon. They are transferring their prescriptions from pharmacy to pharmacy for a gift card and then complain that the quality of health care has dropped drastically. There is no money made on that medication and some pharmacists feel that the discount programs are undermining their professional services.

Ted Lingerfeldt from Kerr Drug disagreed. He feels that prescriptions *are* a commodity and if generics are going to survive, we have to move away from a product-based reimbursement. "We as retail pharmacy have allowed generic prescriptions to become a commodity and we have to sell the other services we provide and be reimbursed for these services."

Table 1. What Is Your Level of Understanding as to What an "Authorized Generic" Is?

I completely understand	41.0%
I am pretty sure I understand the concept	45.3%
I'm not so sure of the concept	7.1%
I think I understand the concept	1.1%
I have no idea	5.5%

"I think the disturbing trend I see is prescriptions that aren't actually making it to the pharmacy."

Tom Scono

"It's pretty well known in the industry. You cannot economically fill a [generic] prescription for $4. Even if the drug was acquired for free, the cost of dispensing is more than $4. So whoever fills one for $4 is automatically losing money, whether they claim it or not," said Charles Burnett, Senior VP, Costco.

Wal-Mart's David Badeen commented on the $4 generic discount program. "From the stories I've heard from patients, many had to choose between buying food and paying for their prescriptions. I'd do it over and over every single day because it made health care accessible to those patients. That's the key behind this whole thing. That's what drove it and that's what made it so successful."

Badeen agreed with Lingerfeldt that it is not all about price. "A true competitor is not just meeting someone's price, you actually have to find out what your strengths are, and then go out and compete on your strengths."

Patents and Exclusivity

Long pointed out that for the period from 2000 to 2006, money was generally made through exclusivity periods. Pollock reminded the group that since that time, there have not been many exclusivity periods and the companies that had them often acted irrationally in the market. Some panelists believed that this lack of exclusivity may lead to more at-risk generic launches while others disagreed saying that possible at-risk launches will lead to more settlements.

Pollock said that new generic product introductions fall into three basic buckets. "The first is a natural patent expiration. Everyone knows when that is. The next one is where you know the start date and the end date to the exclusivity. And then there is the at-risk launch."

"The time a brand really loses its exclusivity in terms of how and when generic companies start to produce drugs will vary by product," said Bover. "You may get 24 hours or you could get 24 months advance notice."

"Companies are looking at what's going to happen in 2012 today," said Lingerfeldt. "It may be at a moment's notice; or it may be a few weeks notice."

"There are many companies that are hesitant to talk too much about what's in their pipeline," said Scono. "Then there are other companies that make it public knowledge. But as far as the actual launch dates, that is rare."

The Road Ahead

In their final analysis of the generic industry, the consensus among the panelists was that many of the issues previously facing the generics industry will still continue to be issues going forward. But with a new administration, they are hopeful that many of the problems will finally come to some kind of resolution, either mandated by government or self-regulated by the generic industry itself.

As the future of generic drugs is based on a strong and ongoing flow of innovator products, there was also general agreement that the future of the generic industry depended in large part on the FDA approving new drugs from innovator companies. Pollock agreed with the panelists that the FDA's primary mission should be "guaranteeing that the drug product it approves is safe and effective."

Many of the panelists said that short of universal health care with government oversight, the industry will still have to deal with PBMs and their somewhat restrictive formularies.

The meeting ended on an upbeat note from Pollock who said that while industry consolidation will most likely continue to take place, it is not a bad thing. "In 1984, when there was $10 billion worth of drugs coming off of patent when Hatch-Waxman passed, all of a sudden there were a whole lot of these new generic companies that were coming into the marketplace. There's been a huge amount of consolidation—brand name industry and generic industry." He said he believed the benefits of consolidation will open a floodgate of new generic drug approvals. "This year the Office of Generic Drugs is going to receive a record number of Abbreviated New Drug Applications (ANDAs), many from these new companies. Executives who once fought generics are now starting new generic companies. The FDA approval list has a lot of names never seen before," said Pollock.

The panelists ended the meeting by agreeing that the fundamentals of the generic industry are sound and that there is no doubt that better times are ahead for the industry.

The viewpoints expressed in this document are not those of U.S. Pharmacist, Greenstone LLC, or Pfizer.

Generic Pharmaceuticals 2009:
The Road Ahead

A Roundtable Discussion

Pictured in photo above (l to r): Bill Ladwig, David Badeen, J. Mark Bover, Charles Burnett, Tom Scono, Kristen Reabe, Ted Lingerfeldt, Bob Pollock, Doug Long, Chris Kidd.

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