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Generic Pharmaceuticals 2007:
Critical Crossroads

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Participants in *Critical Crossroads*

Robert W. Pollock, RPh, MS (Moderator)

Bob received his BS degree in pharmacy and his MS degree in pharmacy administration at 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, 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.

Donald J. Dietz, RPh, MS (Presenter)

Don received a Bachelor of Sciences Degree in Pharmacy from Duquesne University and a Masters of Science in Human Resource Management from LaRoche College. He is the Vice President of PHSI (Pharmacy Healthcare Solutions, Inc.). His emphasis is in marketing program development, implementation, and measurement, delivering clients' desired results. His focus is on solutions that enable clients to effectively manage the appropriate use of both prescription and OTC products.

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.

David Vucurevich, RPh

David did his undergraduate work at the University of Arizona and is a graduate of the University of New Mexico, College of Pharmacy. David is Group Vice President Pharmaceutical Purchasing & Clinical Services for Rite Aid Corporation. David's responsibilities include overseeing pharmaceutical purchasing, regulatory compliance, formulary management, compliance and persistence programs, medication therapy management, acute care clinics, and retail pricing.

Thomas E. Scono, RPh

Tom received his BS in Pharmacy from The Ohio State University. He is Vice President of Contracts for EPIC Pharmacies, Inc., a group purchasing organization of over 700 members. He is responsible for contracting and performance evaluation.

Sandy Greco

Sandy is currently President & CEO of Altro Pharmaceuticals, a privately held company that specializes in manufacturing products for both the human and veterinary markets. Prior to starting Altro Pharmaceuticals, Sandy was Vice President of Purchasing and Marketing for wholesaler Kinray.

Paul Hines

Paul received a BS in Pharmacy from the University of Florida College of Pharmacy and an MS in Health Sciences from the University of Central Florida. He has been with Publix Super Markets for 21 years and has held several positions including responsibilities for managed care, technology, and pharmacy supervision. Paul currently is the Manager of Procurement for the pharmacy department.

Brian Jones

Brian is a 30-year veteran of the wholesale pharmaceutical distribution industry. In his current position as Vice President Program Operations at AmerisourceBergen Drug Company, Brian manages the company's generics commercialization engine, PRxO Generics. PRxO Generics is a comprehensive product and service bringing value to all pharmacy provider channels.

Steve Grossman

Steve is a registered pharmacist and owner of JE Pierce Apothecary in Brookline, MA.

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While August 10, 2007 might have been a sunny and calm late summer day outside the Boston Westin Copley Place hotel, inside a panel of 10 distinguished pharmacy executives gathered around a conference table to discuss the changing climate of the nation's generic industry at the second annual U.S. Pharmacist Dialogs in Generics meeting. Supported by Greenstone Limited, this year's theme, Generic Pharmaceuticals 2007: Critical Crossroads speaks volumes about the challenges and opportunities facing the generic pharmaceuticals marketplace. Participating in this year's discussion were executives representing every facet of pharmacy. They included: moderator Bob Pollock, RPh, MS, Senior Vice President of Lachman Consultant Services, Inc; presenters and panel participants Doug Long, Vice President of Industry Relations, IMS Health and Don Dietz, RPh, Vice President of Pharmacy Healthcare Solutions, Inc.; Panel members Kristen Reabe, PharmD, Vice President of Contracts for Pharmacy Select; Brian Jones, Vice President of Generic Rx Product Development, AmerisourceBergen; Tom Scono, RPh, Vice President of Contracts for EPIC Pharmacies, Inc.; David Vucurevich, RPh, Group Vice President of Pharmaceutical Purchasing & Clinical Services, Rite Aid; Paul Hines, Manager of Pharmacy Procurement, Publix; Steve Grossman, President of J.E. Pierce Apothecary; and Sandy Greco, President & CEO, Altro Pharmaceuticals.

The generic drug industry is facing some of its most significant challenges and opportunities in the more than two decades since the passage of The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Waxman-Hatch Act. This single piece of legislation changed the complexion of the generic and branded drug industries by essentially restoring eroding patent expiration dates on innovator products while allowing generic pharmaceutical companies to submit new drug applications without duplicating the clinical trials of innovator companies. Under this Abbreviated New Drug Application (ANDA) scheme established by the Act, a generic manufacturer must demonstrate that its drug is the same as that of the brand name drug, including a showing of bioequivalence. As a result, this act, which has thus far stood the test of time, was largely credited for a rebirth in the generic drug industry and gave innovator companies the ability to better invest in new chemical entities providing new structure to patent expirations. This has culminated into what has become today's generic industry which has reached a critical crossroad in what many industry experts are referring to as the most competitive and challenging generic marketplace in history.

" It's a very dynamic time. We always thought that when Waxman-Hatch passed in 1984, by now everything would be resolved. But clearly it has not."

Robert Pollock

The path the industry takes today could determine its overall success or failure for years to come.

While sales of generic drugs have increased exponentially since Waxman-Hatch, so have the competition and other external marketplace forces. Over the years generic companies have fought valiantly to increase market share and sales of their products despite the innovative techniques used by branded competitors to protect their intellectual properties. Moderator Bob Pollock of Lachman Consulting Services and Past Acting Deputy Director of the Office of Generic Drugs set the tone of the meeting during his opening comments when he told the panelists "It's a very dynamic time. We always thought that when Waxman-Hatch passed in 1984, by now everything would be resolved. But clearly, it has not."

It is those market forces that were responsible for the lively discussion at this year's *Dialogs in Generics.*

An Ambitious Agenda

This year's meeting agenda was an aggressive one covering timely and important topics. Any one of them could alter the course of the generic drug industry. Topping the list was the imminent implementation of the final Medicaid drug-pricing regulations that arose out of the Deficit Reduction Act of 2005 (DRA). If not amended, these new regulations will exert key changes in the way prices are calculated for Medicaid prescriptions, which will have far-reaching consequences for generic manufacturers and retailers alike. Pharmacy could be facing major pressures on the pricing of Medicaid prescriptions as the Centers for Medicare and Medicaid Services (CMS) promotes three major initiatives: a new pricing calculation based on using the Average Manufacturer Price (AMP); a new definition for the Federal Upper Limit (FUL) on multiple source drugs; and the publication of Average Manufacturers' Prices gathered from a monthly CMS survey.

Other topics covered during the full-day meeting included in-depth discussions on authorized generics, biological equivalents, at-risk generic launches, and a close evaluation of today's generic industry and where it could be heading in the future.

The "Golden Age of Generics"

Doug Long of IMS Health kicked off the meeting with a comprehensive presentation titled *U.S. Pharmaceutical Market: Trends, Issues, Forecast*. While Long set an optimistic tone at the start of his presentation by saying "it is the Golden Age of the generic business," he quickly tempered his comments of "record performance" by adding that the overall prescription market got off to a "very fast start in 2007 – due to Medicare Part D" but it could be a "very slow finish." But Long delivered good news to the group by saying that "if you're in the generic business, [generic] prescriptions are very solid." Long said he expects the U.S. prescription market to end up approximately 5% with much of that growth already taking place in the first half of 2007. He attributed a large part of that increase to the escalation of prescription utilization resulting from Medicare Part D, "the availability of high quality, low cost generics," a decrease in brand name drugs as a result of increasing co-pays, and a late flu season (**TABLE 1**).

Table 1. Factors Affecting Growth in Generic Sales

- Medicare Part D
- Availability of high-quality, low-cost generics
- Increases in insurance co-pays
- A weak flu season in 2006; stronger in first quarter of 2007

Long's forecast for generics was also bullish. He said one big reason for the upward sales trend is the lack of innovation on the part of brand manufacturers. "They're not … able to replace what they are losing," he said.

Long cautioned that while he forecasts solid generic growth potential overall, he said the competition within the generic industry is also expected to remain strong. "Hypothetically, you have an industry that has very low barriers of entry. Virtually anybody can get into it." He cited examples of generic companies from India and China starting businesses in the U.S. "Eastern European players are thinking about coming." As an example, Long said, that as of the 2nd quarter of 2007, it was the first time that the Indian company, Dr. Reddy's Laboratories, made the list of top ten generic corporations by dollar volume. He pointed out that it was significant to note that in the 12 months ending with the 2nd quarter of 2007, the top 10 generic companies did 70% of the total generic volume, $30 Billion, in the U.S., while the number one generic company, TEVA Pharmaceuticals USA, had nearly a 20% share on its own. However it should be kept in mind, due to the significant price differential between generics and brands, the total generic dollar market represents only 10.6% of the total pharmaceutical market (**SEE TABLE 2**).

"It is the Golden Age of the generic business. If you're in the generic business, prescriptions are very solid."
Doug Long

Medicare Part D

According to Long, as of August 2007, prescriptions filled under the Medicare Part D program already accounted for 18% of all prescriptions dispensed. Much of that came from what were once Medicaid prescriptions, which was cut in half as a result of Medicaid patients switching to the Medicare Part D program ("dual eligibles"). This is expected to affect some 270 million prescriptions. However, this transition from Medicaid to Medicare Part D has softened the blow to retail pharmacy. The move of dual eligibles from Medicaid to Medicare Part D will reduce the impact of DRA as Medicare Part D claims are paid at a rate in the pharmacy contract between the Medicare Part D provider and the pharmacy.

More fallout from Medicare Part D revolves around the fact that commercial third-party prescriptions will shrink as a result of some people abandoning their retiree programs in favor of one of the many Medicare Part D prescription drug programs being offered.

Table 2. **Generic Sales by Leading Corporations (12 months ending June 2007)**

Company Name	US $ bil	% Share
Total U.S.	30,141	100%
1. TEVA Pharm USA	5,866	19.5
2. Sandoz (Novartis)	2,910	9.7
3. Mylan Labs, Inc.	2,578	8.6
4. Watson Pharma	1,911	6.3
5. Greenstone (Pfizer)	1,884	6.3
6. Apotex Corp	1,871	6.2
7. Par Pharm	1,272	4.2
8. Barr Labs (incl. Pliva)	1,039	3.4
9. Roxane (BI)	968	3.2
10 Dr. Reddy's Lab	882	2.9
Top 10	**21,180**	**70.3%**

Source: IMS Health, National Sales Perspective, June 2007

"Allowing the AMP to be published is going to have a widespread effect on transparency and eliminate the confidentiality of generic acquistion cost data."

Don Dietz

Looking to the Future

On the issue of generic biologicals (Long prefers to use the name "Biosimilars"), "the question that comes up at the end of the day, is: are [generic biologics] going to be similar or are they going to be equivalent? Equivalent means interchangeable (ie. generic biologic); similar means not necessarily so (ie. biosimilar). It's just one little word, but its impact is big depending on which way it goes," said Long. "My guess is they're more likely to be similar than they are interchangeable."

It was Long's estimates that generic biologicals, whether they are similar or interchangeable with the innovator product, would not be on the market for another three years. "I've always said it's going to take five years, but I've been saying that for more than five years now. The clock is going to start running on this."

According to Long, the pharmacy marketplace will experience some gains and disappointments over the next five years. On the positive side, many pharmaceutical companies have robust pipelines that include new chemical entities, specialty products, biologics, and vaccines. The Medicare D drug benefit will continue to have a positive effect on the marketplace, and the aging population will keep prescription medications in demand. Some of the challenges the brand/innovator industry will be facing are future patent expirations which will cause a further proliferation of generics; a risk averse FDA will continue raising safety concerns for many NDAs and existing medications; smaller pharmaceutical company detailing forces; and a continuation of therapeutic substitution.

One of the biggest challenges for new generic companies will be to overcome the trend of consolidation that has been occurring over the past several years. Smaller companies are being consolidated in to larger companies meaning the big get bigger, and for others it is more difficult to compete against. Sandy Greco, who has formed Altro Pharmaceuticals, a fairly new entry into the generic manufacturing field, said the key to success is to get a little bit of an edge over competitors. "You've got to get a product that doesn't already have multiple players in the market," said Greco. "Then you have a chance."

The Deficit Reduction Act of 2005

During discussions among the panelists, there was a clear consensus among the group that topping their list of worrisome issues facing the industry was passage and the implementation of the Deficit Reduction Act (DRA) in 2007. The genesis of this law was a realization by the federal government that it was paying too much for prescription drugs to Medicaid recipients. So legislators set out to pass a law that is expected to save the federal government nearly five billion dollars in prescription drug payouts over the next five years. That resulted in the passage of the DRA on February 8, 2006.

Since Medicaid is basically a state

"It is easier to substitute an authorized generic for a brand name drug for certain classes of drugs. A good example would be those drugs that have a narrow therapeutic index."

Kristen Reabe

David Vucurevich

"We provide pharmacy services to some 32 million people…this new reimbursement formula makes it financially difficult to operate a publicly held company in locations with a high Medicaid population. Unfortunately, at the end of the day on the 6 o'clock news, it's the company that's going to look like the bad guy leaving those neighborhoods."

run program subsidized by the federal government, pharmacists throughout the U.S. have become used to changes in Medicaid reimbursement throughout the years. But arguably, those changes were not enough to financially effect most retail businesses since the way reimbursements were calculated had not changed dramatically since Medicaid surfaced in 1965. Another reason for the somewhat cavalier attitude among pharmacists was that a majority of drug store customers at that time still paid cash thus the risk to profitability was not as big an issue. Over time prescription employer drug programs that were offered to employees increased dramatically, thus reducing cash-paying customers to all-time lows. But at least the formula for reimbursement hadn't changed and pharmacists were still able to eke out a fair living. But all of that is about to change.

For the past 40 plus years, Medicaid prescription reimbursements have been calculated on a formula that uses the Average Wholesale Price (AWP) of the drug being dispensed. Originally the AWP was thought to be a fair and equitable way of calculating reimbursements for Medicaid prescriptions. But AWP did not take into consideration many factors that reduced the actual acquisition cost to retailers. So while the calculations were based on full AWP pricing, due to quantity discounts, rebates, prompt payments, and a host of other built-in cost savings, most retailers were able to purchase and make a profit on prescription products since in actuality they were generally purchasing at a percentage below the published AWP (especially generics). Retailers felt this was fair since the higher profit from cash-paying customers was drying up. However, it didn't take third-party payors long to figure this out and start discounting the AWP to seriously low levels in calculating their reimbursement formulas, creating hardship for thousands of retail stores. As bad as that may seem, according to industry experts, it is about to get worse.

Because the federal government felt that the AWP is a poor metric to use in estimating drug costs, it has incorporated a new benchmark for calculating drug cost into the DRA, the Average Manufacturer Price (AMP). While it should be noted that individual states are not required to use the AMP in its calculations, like the AWP, the AMP is slated to be a published number. But unlike AWP, the DRA requires manufactures to report their AMP monthly, inclusive of rebates including prompt pay discounts. "Allowing the AMP to be published is going to have widespread effect on transparency and eliminate the confidentiality of generic acquistion cost data," said panelist and presenter Don Dietz of Pharmacy Healthcare Solutions. Dietz believes that using AMP in pricing calculations will create "continual downward pressure" on margins, including those of generic drugs. Dietz, a registered pharmacist, believes that the entire industry needs to come together and be equitably paid for their respective services. "Whether it occurs in the dispensing fee or whether it incurs off the ingredient cost, it needs to happen in some way, shape, or form." Dietz said that there are some states that are looking at passing laws to increase the dispensing fees to help offset the AMP calculations. And while it may help, he said that it is really just a "goodwill gesture" and "certainly does not address the root of the problem."

Dietz noted that the issue of AMP and all the negative connotations connected to it has not been well received in the industry. As a result, some government officials are looking for another, more equitable methodology in calculating

"I don't perceive [at-risk] generics as a major issue. I think the customers have learned over the years to trust their pharmacist for drug information."

Tom Scono

Medicaid pricing. "There ought to be a more appropriate metric for calculating what pharmacies should be paid," commented Dietz.

The Fallout from AMP Will Be Widespread

So who ultimately will feel the effects of the new Medicaid pricing structure? According to Dietz, retail pharmacy will probably feel it the most. "Retail pharmacy is going to be more visible in this because that is where the public has a face. If phpharmacies leave the market, stop filling Medicaid prescriptions, it will create service issues."

But Dietz warned that the drug wholesaler is not immune from the new pricing pressures. "I think they've got a lot to lose because it's behind the scenes," said Dietz. "Under the new law a manufacturer has to post publicly what they sold their product for," he explained. "If that is not what the pharmacy paid for it, they are going to go back to the wholesaler looking for a lower price." He said this will ultimately put greater pressure on wholesalers' already reduced margins on generic products — and potentially generic manufacturers.

Brian Jones of Amerisource Bergen concurred. "Unquestionably our livelihood depends on pharmacies surviving. [AMP pricing] is going to change the profitability landscape [at the retail level]. Obviously, that's going to translate back up the distribution channel." To the extent it will change the profitability on generics, Jones believes the new pricing structure will "change the whole dynamic of the marketplace."

One fear is that the pressure on profits at the wholesale level will have an effect on their service levels, specifically the number of deliveries that are made to retailers from wholesalers. The domino effect of less deliveries means that retailers will either have to carry more inventory or partial fill more prescriptions.

The topic drew similar reactions from the retailer panelists. Paul Hines of Publix Super Markets said he was trying to equate this situation with the "old days" when he practiced on a regular basis. "I got paid AWP plus a professional fee for Medicaid. That formula remained stable for the longest time. Now the AMP formula can change every quarter. So you can conceivably buy a product in one quarter and get paid less for it in the following quarter."

David Vucurevich of Rite Aid was concerned about the effect the AMP calculations would have on those stores that serve a primarily Medicaid population. "We provide pharmacy services to some 32 million people, 10% of which are Medicaid recipients. This new reimbursement formula makes it financially difficult to operate a publicly held company in those locations. Unfortunately, at the end of the day on the 6 o'clock news, it's the company that's going to look like the bad guy if it must leave those neighborhoods. So until access becomes an issue, we're going to have a hard time changing [the AMP pricing formula]."

Some of the panelists' worst fears were that the new pricing formula

Impact of AMP on Generic Manufacturers

- Posted AMPs on CMS Web site may create significant price pressure
- Structure of AMP reimbursement metric drives pharmacies/wholesalers to seek lowest cost
- Continued consolidation of generic manufacturers expected
- Niche generic manufacturers may expand scope of manufacturing capabilities to seek profitable therapeutic areas.

Source: Pharmacy Healthcare Solutions, Inc.

You've got to get a product that doesn't already have multiple players in the market. Then you have a chance."

Sandy Greco

will eventually extend beyond Medicaid and be applied to the third-party private sector which could spell the ruin of retail pharmacy as we know it today.

Doug Long agreed that the new pricing schedule would have a negative effect on the profitability of generics. He pretty much summed up the panel's feelings when he said "I think it's the wrong place to cut spending. The government is trying to take the savings out of generics, the best value proposition there is."

At-Risk Generics

Another topic of interest to the panelists was what is commonly referred to as "at-risk generic launches." This is the term given to generics that are launched before a patent case against the innovator product is finally decided. Should the generic company lose its patent challenge against the branded version of the drug, the generic drug could potentially be withdrawn from the market and the generic company would most likely be held responsible to pay damages for patent infringement. With those possibilities in mind, panel members pondered the question of whether at-risk launches are a problem for their business.

"I don't perceive it as a major issue," said Tom Scono of EPIC Pharmacies. "I think the customers have learned over the years to trust their pharmacist for drug information. And there are some times where there is a reversal of the court cases, and the product is no longer available." He said in those cases he believes that pharmacists can handle those kinds of questions adequately. But until and if that happens, it is a big cost savings to the consumer. "That's the bottom line," said Scono. "I've got it and I'll get it to the customer. I can make a profit and the customer saves money."

"I think pharmacists are relying on their wholesaler and buying groups to make sure that they get proper information about [at-risk] products," said Kristen Reabe of Pharmacy Select. Regardless of the fact that it is an at-risk product, third parties are dictating that you dispense a generic. In the end, it is likely you're going to do what you're going to get paid for."

The only independent pharmacist on the panel had a somewhat different take on the issue of at-risk generics. Steve Grossman, owner and operator of J.E. Pierce Apothecary thinks that trying to explain to a customer why an at-risk generic was pulled from the market "ties up your bench. The pharmacist is no longer talking about the clinical aspects of the prescription being dispensed." He said it becomes an issue of economics trying to explain to a patient why one month they paid nearly half the price for a generic then had to pay a higher price for the brand product when the generic gets withdrawn from the market. Grossman said in the end "it all takes away time that you spend with the patient doing positive things trying to explain the absurd."

While pharmacists continue to debate the value of at-risk generics, authorized generics continue to make their way to pharmacists' shelves creating what our panelists see as an opportunity

"You can conceivably buy a product in one quarter and get paid less for it in the following quarter."

Paul Hines

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Unquestionably our livelihood depends on pharmacies surviving. AMP is going to change the profitability landscape at the retail level. That is going to translate back up the distribution channel."

The Impact of Authorized Generics

An authorized generic is described as a generic distributed under an approved new drug application (NDA). Authorized generics are generally distributed by the innovator company itself through a generic subsidiary or an independent generic supplier. According to some of the industry participants, there are several positive reasons why authorized generics should be embraced in today's marketplace. These include a better availability of the product, increased generic competition that leads to lower generic prices overall, the ability to dispense a generic product that is the same color, shape, and/or size as the referenced brand product and an overall savings for the consumer.

Other industry participants aren't so positive about authorized generics. They say one major drawback of authorized generics is the perceived impact they have on the 180-day exclusivity. 180-day exclusivity is granted to the first generic company filing an ANDA that contains a challenge to the drug patent (the so-called Paragraph IV certification). There is fear that should branded companies launch authorized generics, it may discourage other generic companies from challenging patents. This is due to the fact that an authorized generic for the product being challenged might already be on the market, thus diluting any financial benefits derived from the 180-day exclusivity period should the patent challenge be successful.

Independent storeowner Steve Grossman thinks authorized generics are good for his business. "It's a great time saver," said Grossman. "There is no question that the authorized generic is exactly the same as the branded product and it only costs customers who are on prescription benefit programs a generic co-pay instead of that of a branded product. Everyone is happy and it avoids a lot of questions and problems."

Kristen Reabe also sees an advantage in using an authorized generic for certain classes of drugs. "It is easier to substitute an authorized generic for a brand name drug for certain classes of drugs. A good example would be those drugs that have a narrow therapeutic index."

From a legal perspective Bob Pollock explained to the panel that "there is nothing in the statutes or the regulations that precludes an NDA holder from distributing its drug product the way it sees fit." Pollock said that while petitions have been submitted to the FDA to ban authorized generics, "FDA's position is that it doesn't get involved with the business of dealing with competition. The courts have supported FDA's position."

Kristin Reabe speculated that authorized generics may not necessarily deter the larger generic companies from filing Paragraph IV certification, but they could have an impact on the smaller companies who are not financially able to challenge a patent.

Given the fact that Medicaid calculations will in all likelihood be based on AMP, Pollock asked the group what they thought the impact of authorized generics

Key Issues Driving Future of Generics

- Continued consolidation and expansion among U.S. generic manufacturers
- DRA and its AMP calculations likely to have a negative impact
- An increase in the proliferation of foreign markets
- The development of a User Fee Act

Steve Grossman

"When pharmacists have to explain why an at-risk generic was pulled from the market, it ties up your bench. The pharmacist is no longer talking about the clinical aspects of the prescription being dispensed."

would be on AMP.

"That's a tough one," said Don Dietz. "The ability to garner lower costs is better with an authorized generic during the 180-day exclusivity period, but the real impact on AMP will be seen following the exclusivity period with the entry of additional competitors."

The Debate over Generic Biologics

The main issue surrounding generic biologics is that there is more variability in developing a biotech drug than there is in developing oral solid products. Doug Long alluded to the issue early on during his presentation. As you remember, he said in the end, the question remains, it is either similar or it is identical? The consensus among the panelists was there might be a liability issue in dispensing a product that is *similar* to the brand name biologic instead of an AB-rated equivalent.

"If we look at how the debate has been handled in Europe to date, officials in many European countries said if they are biosimilar we are not calling them interchangeable," said Bob Pollock. "What the biologics industry is saying is that some of these protein products are so large that we're dealing with complex issues like protein folding and other factors that could have an impact on immunogenicity." Pollock said that on one side of the debate is the question of how do you show a side effect profile without doing clinical studies?

He continued the discussion by explaining that although the technology today is more advanced from even a few years ago, it still is how can anyone really be sure that a generic biologic is exactly the same as the innovator product? Pollock said that in government circles the debate is being waged between the FDA and Congress. "FDA is very risk averse. Who is going to make the decision to give a B-rated drug over the innovator drug? "It won't be the pharmacist or the physician.

There may not be a traditional cost savings but Pollock reminded the panel that biologics can sometimes cost hundreds of thousands of dollars a year. "So, if there is even a 10% reduction in their cost that is a lot of money. It's not like saving five bucks a month. It could be a possible savings of ten's of thousands of dollars over the course of a year."

The consensus from the meeting participants was that generic biologicals are still some years away and until the technology reaches a point where it can be used to produce bioequivalent generics of these high tech drugs, the debate will continue.

A Snaphot of the Future

Summing up the day's discussions, the distinguished participants offered their view of the key issues driving the generic industry's future. Several common threads emerged from the discussion. Overall the meeting panelists were in agreement that there would be more consolidation and expansion among generic manufacturers in the U.S.; DRA and its AMP calculations will change the landscape of the pharmaceutical marketplace and are likely to have a negative effect on the profitability of generics in the near term. However, many also believe that this law is likely to be amended in the future to offer relief to retailers, wholesalers and manufacturers who would be most affected by it. There were feelings that foreign companies will continue to proliferate in the U.S., particularly among generic manufacturers; and the development of a User Fee Act for generic companies is inevitable.

There is no question that the generic industry is at a critical crossroads in its development. The viewpoints expressed by this panel of experts will hopefully help to guide generic industry executives down the right path to a successful future.

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

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A Roundtable Discussion

Pictured in photo above (l to r): David Vucurevich, Sandy Greco, Kristen N. Reabe, Paul Hines, Robert W. Pollock, Thomas E. Scono, Donald J. Dietz, Steve Grossman, Brian Jones, Doug Long

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