2nd DRUG STORE NEWS SPECIALTY PHARMACY ROUNDTABLE

In November 2010, The Drug Store News Group/*Specialty Pharmacy* magazine hosted in New York an exclusive executive round-table discussion of leading specialty pharmacy providers. In this installment, the first of a two-part series, guest moderator David Galardi of Apogenics and the panel examine why more therapeutic classes are migrating to a specialty-preferred model, working with Medicaid, genetic testing and REMS.

PANELISTS: Javier Avalos, Endo Pharmaceuticals • Laura Bruce, Teva Pharmaceuticals • Nick Calla, Walgreens Specialty Pharmacy • Anthony Davino, Armada Health Care • Sharon Ferrer, BioPlus • Phil Hagerman, Diplomat Specialty Pharmacy • Tim Kaplan, Amber Specialty Pharmacy • Lee Merritt, MedfusionRx • John Musil, The Apothecary Shops • Bob Roose, BioScrip • Nick Saraniti, Commcare • Jeanne Stasny, Walmart Specialty Pharmacy • Albert Thigpen, CVS Specialty Pharmacy • Burt Zweigenhaft, OncoMed

GUEST MODERATOR DAVID GALARDI, APOGENICS: One thing I always get asked by pharma companies is 'Where do you see my drug fitting in the channel?' In layman's terms that means, 'How much should go through the retail channel versus specialty?' What therapeutic classes are you starting to see move from retail over to specialty?

BURT ZWEIGENHAFT, ONCOMED: I don't remember all the growth hormones, so I'd probably say Xolair as a specialty drug example. ... I think that after watching all these companies emerge, I think what I'm seeing is specialization in a disease — if it's a high-cost disease and there are drugs that treat that disease, pharmaceutical and care management specialization will evolve around that disease. Manufacturers are moving those products into specialty distribution because they get more accountability, better control over data and, ultimately, they could be tied into the global cost of care and have unique contracting capabilities.

GALARDI: Phil [Hagerman], do you generally believe that the manufacturer is having a bigger role in that choice of channel versus, say, the payer?

PHIL HAGERMAN, DIPLOMAT SPECIALTY PHARMACY: Yes, I think we're seeing it all the time. Manufacturers are starting to understand channel management. Early on it seemed to be only the small, niche-y biotech guys that got it. But now the bigger guys are starting to see it, too. And you know, when they do the math and they realize that they're missing one or two turns of their product every 12 months because nobody's managing the patient, it starts adding up. At one of the early pharmacy conferences I went to, an executive from GlaxoSmithKline said, 'If I could get the population to just be 5% more compliant, it would be the equivalent of us launching a billion-dollar blockbuster with no [research and development].'

I once heard a GSK executive say, 'If I could get [patients] to be 5% more compliant, it would be the equivalent of launching a new blockbuster without the R&D.' —Phil Hagerman, Diplomat

GALARDI: Nick, likewise for you, any specific classes that you think are moving more from one side to the other?

NICK CALLA, WALGREENS SPECIALTY PHARMACY: When you start talking the specifics and looking at some of the migration that's occurring right now, the MS class is really kind of migrating more toward a specialty model. Even though it's not being locked out, per se, from the retail channel, it's certainly migrating over into specialty, for a lot of the reasons already mentioned. It's the patient management, the increased compliance and increased diligence over the inventory, [and] the data. All those factors are moving the MS class [more toward specialty] and, to some degree, you're seeing it in rheumatoid arthritis as well.

GALARDI: Laura, from the manufacturers' perspective, are there any particular benefits that you see in some of your products going through one channel versus the other?

LAURA BRUCE, TEVA PHARMACEUTICALS: Specific to MS, one of the things that we recognize is that MS [patients are] much better educated about their disease state and about the therapies available to them. They also embrace a lot of different avenues to receive their product. Our preference, though, is to still have that patient being managed within the specialty pharmacy arena. The primary reason for that is that monthly touch, that monthly outreach.

Our preference is to have that patient managed in specialty pharmacy. The reason is that monthly touch. —Laura Bruce, Teva

We've got a patient call center. We can reach out to these patients, but they're more receptive to calls from the provider that actually is holding their medication. And so that, in addition to looking at improved compliance and adherence — it's more that patient care and that patient management aspect that we believe you see more so in the specialty pharmacy environment.

ANTHONY DAVINO, ARMADA HEALTH CARE: One of the things we've been working on pretty closely with a number of manufacturers to date is the mental health category. The patient population, similar to HIV and [hepatitis] C patients, requires a little more management and control, and I think that'll be an area where we'll see a shift into more specialty-type services.

I think a lot of the shift also is driven by changes in drug regimen. So if you're originally taking a weekly drug and then you're taking a monthly therapy, that then goes to a six-month therapy, all those changes require a little extra hand-holding just because of the differences in treatment regimens.

A lot of the shifts we see are driven by changes in drug regimen. ... All those changes require a little extra hand-holding. —Anthony Davino, Armada

GALARDI: Any other products or therapeutic areas that get you excited?

JEANNE STASNY, WALMART SPECIALTY PHARMACY: Diabetes. I think that diabetes is exciting because it's a step into a mainstream area. I think the earlier comment about better control of the patient

Diabetes is exciting because it's a step into a mainstream area. In the past, we tended in specialty to focus on disease states that are little microcosms. —Jeanne Stasny, Walmart

interface, better control of the data also applies [to diabetes]. ...

Obviously, diabetes is a tremendous cost to our country and is growing faster than just about any other disease due to obesity and other underlying lifestyle issues. But I think it's an exciting move away from the more rare types of disease states that specialty traditionally has been focused on. In the past, we tended in specialty to focus on disease states that are very much their own little microcosms versus the mainstream. It will be exciting to extrapolate our value to a larger population.

ZWEIGENHAFT: I'll give you another one — personalized medicine. The genetic targeting, and the predictive tests and the ability to bundle that in the root of services, to be able to rule out the non-responders and better target the absolute responders. ...

GALARDI: Do you see payers paying for that coordination of appropriate use, for lack of a better way to put it? ... Let's use Medicaid as an example. Do you ever see them paying for coordination of care with lab results for, let's say, an HIV patient?

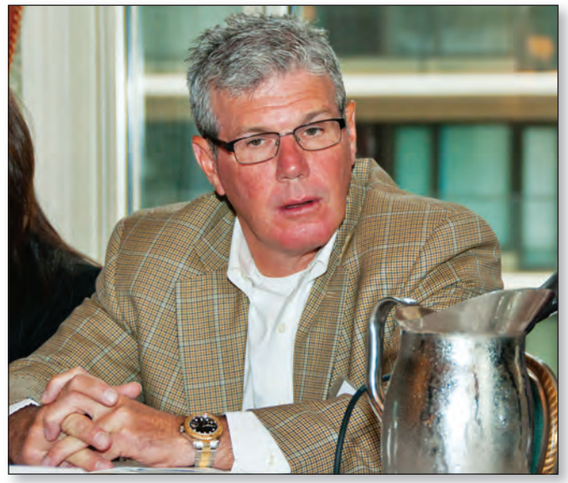
ZWEIGENHAFT: There are a couple of HIV/AIDS studies that are being funded by National Institutes of Health today. I know at the University of Buffalo they're able to show the difference between patients that utilize the coordinated care approach and the ones that don't. And I think those studies will produce compelling comparative economic analyses that will drive the market in that direction.

And there's some experimentation, like UnitedHealthcare has done with genetic testing for the reoccurrence scoring of breast cancer OncoTypeDx, and some other tests where they've allowed for additional payment because they know the advanced economic outcomes from using that technology.

GALARDI: Nick Saraniti, you live in the world of Florida Medicaid, do you see Medicaid paying for that kind of thing?

NICK SARANITI, COMMCARE: I come from probably the worst-paying Medicaid state and ... especially in that HIV space, on drugs like Selzentry or Fuzeon, we've seen the state put prior authorization and other hurdles in place across the Medicaid program mandating that genetic testing be conducted and the requirements of the PI be met.

GALARDI: Do you think the labs are starting to work with you better on this?



To me, the word 'standardization' sounds like 'commoditization,' ... and being marginalized by Pharma equals fair-market value. —Bob Roose, BioScrip

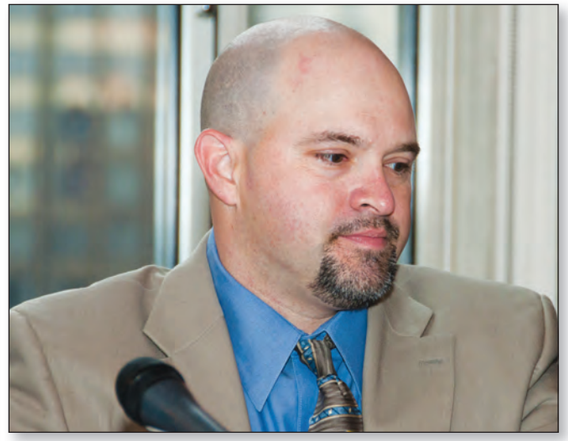
BOB ROOSE, BIOSCRIP: Absolutely. Take a look at the specialty pharmacy mission. Generally speaking, we do prior authorizations; we look at clinical outcomes; we assist with financing for the patient ... I do think the labs are going to come on board with us.

GALARDI: Is that starting, Lee?

LEE MERRITT, MEDFUSIONRX: It is a little bit for us — I can't say it's a big part of our business yet at this time.

GALARDI: How's it starting? You work in a state primarily where you've got a single-payer model, for lack of a better way to put it, right? You've got the state and then you have Alabama Blue Cross Blue Shield ...

MERRITT: Yes, that's very true — it's a ridiculous number. And with our recent change in Medicaid reimbursement in Alabama, its really been ... an eye opener.



We're trying to educate Alabama Medicaid more on what specialty pharmacy can do for them. It's a work in progress. —Lee Merritt, MedfusionRx

GALARDI: Right, and they're not necessarily paying more for the services — it's more of an issue of drug acquisition costs.

MERRITT: That's exactly right. So we're trying to work with them. We're being proactive with Alabama Medicaid, actually trying to educate them more on specialty pharmacy and the benefits of what we can do for them. So it's a work in progress, but across the retail side of things, they've kind of made their mind up. And even the antipsychotics ... have taken a huge hit because it's such a large amount of that budget.

GALARDI: One of the questions I have about Medicaid is, are we seeing plan designs out of Medicaid that are affecting specialty pharmacy, and how?

JOHN MUSIL, THE APOTHECARY SHOPS: What we've seen in Arizona — Arizona last year released an RFP for Medicaid specialty drugs under the 340B component. ... A 340B is a special section within HHS that allows for systems that are federally qualified healthcare systems to participate in the lowest-cost drug purchasing and passing those savings back on to the insured. So it allows for people to buy at VA-like-level pricing.

They wanted us to try to wrangle up every single provider within Arizona to say, 'we're going to make you part of the federally qualified healthcare program; you're going to be a physician with one of the clinics, oh and by the way, the state Medicaid program is going to keep all the money that's saved.' We're not going to share it with any of the FQHCs, which irritated the FQHCs, primarily Children's Hospital and University Medical Center down in Tucson.

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Arizona released an RFP for Medicaid specialty pharmacy drugs under 340B. ... They wanted us to wrangle up every provider in the state, ... and the state is going to keep all the money they save. —John Musil, The Apothecary Shops

So we were seeing this trend — I know it started in Oregon; Arizona was second. And who knows where it's going to go from here? But it's a scary proposition because it completely removes the incentive for specialty pharmacy to manage their patients well because there's just nothing there for us to [pay for it].

GALARDI: Javier [Avalos], as a manufacturer, when you hear that states are moving into specialty and basically encouraging collaborative purchasing under 340B, what are some of the things you consider?

JAVIER AVALOS, ENDO PHARMACEUTICALS: I consider the possibility of having patients who may already be difficult to manage, given their status. As for having some possible compliance benefits from going into specialty pharmacy, I have to come back to the panel and ask, who's going to pay for all that? As manufacturers, we can step up for certain patients, but across the board, I don't know that our small piece of the pie covers everyone's costs.

GALARDI: That pricing that's available under those 340B programs is meant for a specific type of patient population — the disproportionately disadvantaged — but when you expand into greater populations that becomes a concern, right?

DAVINO: From a manufacturer's standpoint, since I was on that side, ... it's a prudent pricing strategy to always maintain a portion of your business at WAC. In most cases that ends up being the retail sector, but that's where the manufacturers actually can make money on price increases. Because price increases, as much as people think that makes money for a manufacturer across the board, actually only relates to a portion of the total book of business. If there are discounts in place, a price increase actually causes bigger discounts to be paid back. So I think, in the same vein, there's always a patient population that will always be untouched, to Javier's point.

GALARDI: Biosimilars — it's a big topic. What do you all see in biosimilars?

ALBERT THIGPEN, CVS SPECIALTY PHARMACY: Biosimilars probably is in our top three [in terms of the] specialty [pharmacy-related] topics [we're considering at CVS Caremark] at this time — not only with respect to specialty, but [also] the retail segment and the entire payer segment in general. And you have to break it down into a couple of different segments: what we think may happen from an industry perspective versus what the expectations are of the payer community today.

And they are two radically different [perspectives]. The vast majority of payers have this unrealistic expectation that biosimilars are going to bring a huge windfall of cost savings similar to what generic drugs have achieved in the past, and that is not the case. ... So they hear the term 'biogeneric,' and they think 'I'm going to save 40% or 50% off the innovator brand.' We have to work to educate the payer community that that's not going to happen.

We also have a difference of opinions with respect to substitutability. We anticipate the market will look more like a

The vast majority of payers have this unrealistic expectation that biosimilars are going to bring a huge cost savings similar to what generic drugs have achieved, ... and that is not the case. —Albert Thigpen, CVS Specialty Pharmacy

single-sourced generic — [biosimilars] will be high-priced. I don't get the sense today that there's going to be substitutability in any way in the near future, but we do think there will be competition based on price.

For example, if you think about the generic epoprostenol — A-rated generic availability [and] better priced than the innovator brand Flolan, but [it] has done very, very poorly in the marketplace. And if you think about how cyclical our entire industry is — the specialists in general, particularly in the biotech segment today, [pretty much are] where primary care was in the late '80s, early '90s. There is this very, very slow adoption of bioequivalents or other therapeutic alternatives that may be less expensive than the innovator.

So we have payer education that goes through resetting and re-gauging expectations; we have the physician/specialists segment that we need to re-educate and say these are at least therapeutically equivalent. And whether or not we do that with or without the assistance of the Food and Drug Administration has yet to be seen. We do need to have some federal authority weigh in, whether it's through comparative effectiveness or substitutability — whether it's an A-rating or some new Orange Book equivalent that evolves from it. But our single biggest challenge will be educating the provider community to adopt these other molecules as being safe and cost effective.

GALARDI: So it's going to require marketing?

THIGPEN: I don't really know if it's marketing so much as it is having the data to prove equivalency. So the manufacturers have an incredible onus on them to prove the value of these biosimilars that are coming out.

Take the FDA out of the equation for a minute. If the FDA doesn't come up with a bioequivalent coding or ranking system at all, the onus will be on the manufacturer to say these are at least equivalent or at least better for you to use it. Whether you call it a biosimilar, a biogeneric or another brand that acts in that category, it's going to compete like a brand in the biotech space; it's going to be priced a little bit differently.

So the manufacturer has this incredible task of marketing, if you will, or proving the difference, proving the value compared [with] the innovator to show the worth. And I think that's where, not to pick on epoprostenol, but that's where that did not occur; and the equivalence studies didn't happen until after the launch of the product. And by that time the train has left the station. It's hard to rebound after that. ...

And I don't want to jumble the issues together, but one of the differences we'll see from the specialist communities is how ASP and physician reimbursement is managed with those products as well. Its common knowledge, high-ASP equates to high prescribing. That's probably one of the biggest concerns that will impact the pricing in the biosimilar landscape.

GALARDI: Right, and that's a fabulous point. The takeaway there is that it's possible you can have two competing products in a generic equivalency type of a setting, but one becomes the WAC reimbursement product and the other becomes the ASP reimbursement product. We see this all the time in oncology — Burt [do] you want to comment?

If it's a high-cost disease, ... manufacturers are moving those patients into the specialty channel because they get more accountability, better control of the data. —Burt Zweigenhaft, OncoMed

ZWEIGENHAFT: What I'm facing all the time now is managed care asking about disease pathways in cancer care. This translates into therapeutic equivalency. We see it in cancer, and payers are really kind of driving that mentality — they're not looking at a particular product, they're looking at therapeutic alternatives using cost-comparativeness as drivers. Some are suggesting they should be paying doctors more to use almost the cheapest therapy [available], which is not what pathways are about.

So is there a play we can take out of the old playbook that we can apply to specialty pharmacies in the future. For example take MS — you now have orals coming into the market and you have the MS injectables of today — so are there going to be pathways that determine which therapeutic selection we treat with or are we just going to let the prescribers select without cost-comparative analysis?

CALLA: If you think about it conceptually, it would kind of make sense that maybe you go down that road at some point. I don't think we're there yet in MS or RA the way we are in oncology because in oncology, there's still that whole dynamic of a lot of off-label type usage — compendia listing for usages. So I think there's another level of complexity to the oncology space that's led more toward pathway development at this point in time.

Whereas in MS or RA, the indication and what you're going to be using it for is a little bit more established. I could see some-

where down the road even in MS — could there be a step therapy-type approach? I could see something like that happening at some point. We're not quite there yet, but I could see that happening.

GALARDI: How about growth hormone?

CALLA: I could see something like that happening in growth hormone as well, especially now [that] you have a bunch of them on the market. A lot of them are therapeutically equivalent, so I could see that sort of strategy happening there, absolutely.

GALARDI: I think growth hormone is a good example of an area where I think it is generally accepted that biosimilars work similarly, right? So in those cases, has anybody seen any payers step up to the plate and prefer one over the other as first line versus second line?

THIGPEN: From my perspective, growth hormone has probably been the stepchild of therapeutic substitution and maybe preferred formulary management in that category in general. Payers have opted to go down that road — it seems the most aggressive ones always have been the managed Medicaids, for obvious reasons. Growth hormone formularies ... started [more than] eight years ago, and it's taken some time to get there. But I agree that it's generally accepted medical practice that they're substitutable in most cases. I think there's very unique differences in some of the technology and the pen devices that's more preferentially chosen by the caregiver in most cases, but I think it's pretty well accepted that you can substitute them out.

GALARDI: So, if we use [growth hormone] as a proxy, maybe it's five-plus years for some of these products to gain enough traction in their specific specialties?

SHARON FERRER, BIOPLUS: I think so. I think it's just going to take a while, as they mentioned earlier, to educate the prescribers on getting accustomed to biosimilars and putting their patients on those types of treatments versus the brands they currently are familiar with, and also wondering if the biosimilars are going to function effectively, like the brand products.

So it will take some time for the market to adjust, but I think we're getting close as we're already seeing some traction with certain disease states. But for the smaller disease states, where you may see generics coming to the market soon, it will take some time for the education to take place within the prescriber base in general.

I think it's going to take a while to educate prescribers on biosimilars and putting their patients on them versus the brands they are familiar with. —Sharon Ferrer, BioPlus

GALARDI: So, let's switch topics and talk a little bit about market access. Tim [Kaplan], REMS ... how is it affecting the pharmacy business that you're running?

TIM KAPLAN, AMBER SPECIALTY PHARMACY: Speaking as a smaller, independent pharmacy, our biggest challenge with REMS is proving our salt back to the manufacturers — that we are capable of handling REMS programs. We've all been doing REMS sort of stuff over the past several years, but now that they've actually given it a name, I think a lot of the manufacturers automatically think that only the big boys can handle REMS programs. So my challenge as a smaller company is to prove to them that we can handle it, too.

GALARDI: When you say 'handle it,' what do you mean by that? Is it data related, patient management related, interaction with the practitioner?

KAPLAN: Patient [management] and data-related.

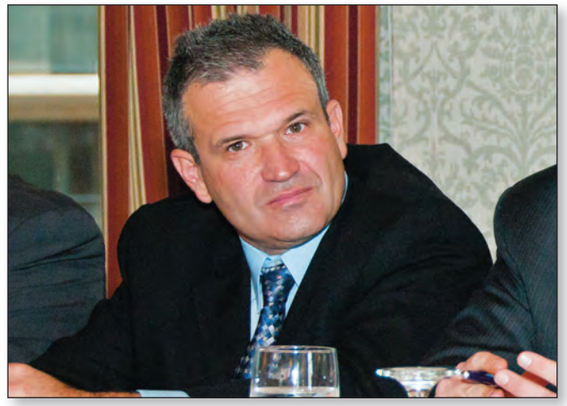
GALARDI: What are some of the more common elements that folks are seeing in a REMS program?

HAGERMAN: Well, one of the things that we see is side effect management. Does the drug have a specific catch in it that can cause a problem with pregnancy? Or does it have anything that could be a health issue? So the REMS program allows them to quantify the patients, to require testing if it's necessary. And so we see the first part of it is that kind of area, and then they can take that side effect profile information and use that to reshape their sales.

GALARDI: Nick Calla, when you look at a REMS product coming down the pipe, take us through the first level, the medication guide level. Is there anything that specialty pharmacy can be doing that maybe is different than what other parties in the channel are doing?

CALLA: In my mind, that's one of the big values of specialty pharmacies in being the facilitator of that process. You know, whether it be as simple as a med guide being put into a box and insuring that it is going out each time that medication is dispensed, up to and including some of the more difficult REMS processes that we deal with, where you're looking at mandatory monthly counseling, mandatory pregnancy testing, mandatory liver functioning testing. ...

[Just like] we were [mentioning] before about personalized medicine ... in the REMS process, the specialty pharmacy's role is [to be] that gatekeeper. [It is to ensure that the] product does not get dispensed unless X test is done and Y test is done. ... In the specialty channel, we dedicate a lot of resources within our operations to doing nothing but managing those processes and making sure that they're done every time.



The MS class [of drugs] is migrating more toward a specialty model. ... It's the patient management; it's the increased compliance. —Nick Calla, Walgreens

GALARDI: So, Jeanne, on the med guide issue ... is there any role that specialty pharmacy can play in helping assemble that data that comes back, the effectiveness of those tools that are being used?

STASNY: Absolutely. There isn't a standard yet. We've done a lot recently in trying to re-engage in the specialty space. ... We've been talking with a lot of folks, and most programs are very individualized, depending on the specific REMS program and what the pharma company personally is concerned about — liability is a priority, they are definitely focused on collecting data that would demonstrate responsible provision of their medication, and show that they are trying to manage that. They're also very interested in making sure delivery is consistent.

I think the difference between specialty models and the other channels is the reliance on our specialty pharmacies to be thorough and very consistent in our standards of practice. Whereas you go to a retail venue and you see a lot of variety, you might get an excellent experience for one patient — excellent documentation and excellent data — then you might shift over and see almost the polar opposite with another patient, even within a particular pharmacy practice itself, depending on the staffing and other factors.

I believe the more structured patient interface infrastructure is what they appreciate about specialty. This needs to be standardized, at some level for all providers, then more advanced value propositions can be established beyond that for competitive needs. That being said, at this point, it's still very individualized between each pharma company, drug and specialty pharmacy provider.

GALARDI: The next question has to do with this whole issue of standardization.

SARANITI: It is important that the patient touches in the specialty channel are documented and auditable. So, for a manufacturer, it's a big plus if you have a REMS program and approval of your drug is dependent upon the success of that REMS program. Once you throw it out into the retail channel, you lose that ability to document and audit those patient touches — it just doesn't exist in that channel.

And I'm not going to say I don't want to see standards exist, because that would make all of our lives much, much easier, because on a daily basis we're having to change and adapt our technology to meet the demands of the FDA or even the manufacturers themselves. [For instance], a manufacturer may have three drugs and REMS programs that are very similar, but the REMS programs themselves or the way it's reported back to the manufacturer is very, very different.

GALARDI: Javier, you've had a lot of experience with these types of programs — is that more of a function of the team that works in the channel, trying to convince the brand teams to do things a certain way?

AVALOS: It certainly goes both ways, and I think that pulling [the] FDA into it as well is going to add a lot. As you guys were talking, one of the things that kept coming up in my mind is exclusive of the payer and the benefit that is set up for a given drug — if a drug is a self-administered, injectable product that has, for example, some type of anaphylactic reaction that requires REMS elements to have the product injected in the presence of a healthcare pro-

I consider the possibility of having patients that might already be difficult to manage, … and I have to ask, who's going to pay for that? —Javier Avalos, Endo

vider. I think specialty pharmacy plays a huge role in that specialty pharmacy would not be dispensing the product directly to the patient. They would have the ability to dispense the product directly to the healthcare provider, be it a nurse, be it whomever. You avoid brown bagging, you avoid a patient taking the product and saying, 'You know what? I didn't have a reaction last time, I'm going to go ahead and take it this time.' And liability exists in that regard.

So I think specialty pharmacy has a lot of control around it and the ability to exercise that control. So whenever we do talk to our brand teams, it's putting these options before them, having them really consider those things and making it part of their entire thinking process, rather than them driving down to us what they think should be done. Because, quite often, what they think should be done may not be operational.

HAGERMAN: I think as an industry, it's a little concerning for me if we try and just create a single-model REMS or a few specific buckets of REMS. I think that one of the biggest advantages of our industry is when complex challenges get thrown at us on drugs that need special care, and we want to ... try to fit it in a 'box.' The easier it is to meet REMS requirements, the broader the market will be.

And there will be, and there have been, products out there that have been on the retail side that have some basic REMS elements. I don't want to make it more complex just so that we can get the channel [exclusivity], but it gives pharma significantly more control also in that area. If they've got a complex therapy and they want to create a REMS that they think is best-in-class for that therapy and for that patient population, then selectively those people that want to be aggressive get to go after it. So, I really see REMS being a chance for pharma and specialty pharmacies to try and create best-in-class models that don't exist today.

DAVINO: Now I would say that standardization sounds like a really good idea, but without provider input, standardization typically leads to set costs — it potentially can trap you in a commoditized scenario.

ROOSE: The word standardization to me equals being marginalized by pharma. And being marginalized by pharma equals fair-market value.

GALARDI: Is there anything that pharma is doing that's helping you improve market access for these patients? How do we make this out-of-pocket burden to the patient palatable? They passed all the REMS gates — what are some of the trends that you're seeing in the market that are helping patients get coverage or at least reduce their out-of-pocket burden?

SARANITI: Specialty pharmacy was sort of born out of removing barriers to care and making sure that patients get the medication they're prescribed, and removing those REMS programs barriers, or making it easier for the prescriber to prescribe the drug and get the product to the patient. So, the natural offshoot of that is removing the financial burden to the patient as well. And depending upon the specialty pharmacy channel — maybe not in some of the large PBM-specialty pharmacies, but outside of that — finding and assisting the patient in completing the paperwork to get financial assistance from different agencies so [that he or she] can meet [his or her] co-payment requirement is a big deal. You may have a patient not receiving a $10,000 drug because [he or she] can't afford the $40 co-pay.

I come from probably the worst Medicaid state ever (Florida), and ... we've seen the state put prior authorizations in place ... that mandate genetic testing. —Nick Saraniti, Commcare

So, [it is] identifying that and working with the manufacturers to ensure that there's a program in place for the commercial patients, but [also one] for those Medicare Part D or those other government-payer patients, having a network of community-based organizations that are willing to fund that drug and the co-payments for those patients.

THIGPEN: I think it is such a tough spot for pharma to be in with respect to REMS. On one hand, less-onerous REMS would be very beneficial to pharma, particularly in crowded therapeutic classes. ... One example that I think we can use as a benchmark here is the oral MS agents. So let's talk about Novartis and Gilenya coming out, and potentially Serono with Cladribine and Teva's Laquinimod later down the road. So there's a huge race in that marketplace to cannibalize the interferons and be the first oral in MS, and the less onerous the REMS is, [the easier it] could make it [for] the prescriber and the specialty pharmacy to manage.

A less onerous REMS could create market access more easily; could get physician adoption quicker; could get patients on product quicker. But lets not do that at the expense of patient safety.

For example, if we look at the ESAs, those products came out, widespread acceptance and then boom — safety issue hits and then safety concerns crater the entire market in general. And we don't want necessarily to see that happen with some of the newer biologics coming out. We have got to put ourselves in a position with pharma to show them how the product is performing and guide them accordingly.

The REMS clearly are designed for safety in mind, that's it. That's what the FDA wants to do is make sure that the drug being used is safe and efficacious. And I think the clinical trials are very easy to show in a vacuum where you're clearly giving [the drug] to the patient every day on a regular schedule; that's not indicative of what's going to happen in the commercial population [and with] all the other co-morbidities that exist.

HAGERMAN: I think the one thing Albert said that really hits me is that outcomes data. I think all of us recognize the biggest shortage we still have as an industry is outcomes data, both on the value of our services and on the improvements that we can make by adding compliance and persistency. But I haven't seen pharma yet use their REMS as a tool to create outcomes models. When you look at their ability to grab data points that they can't get in a broad distribution, this is where I would challenge pharma a little bit to use that information.

Historically, pharma hasn't been great at creating any economic outcome information, but they're going to have to, because they're getting challenged more and more to prove the economic viability of their products. And so, a REMS gives them the ability to do that in a much more controlled area.

The one other thing I wanted to circle back to, just really quick was [Nick Saraniti's] comment about patient access and co-pay support. We've seen a nice movement by pharma to create models around channel management, where they're adding co-pay assistance programs to an specialty pharmacy distribution that's a product that's still available at retail. It's a huge chance for them to move market share, but to me, it's a win-win for everybody because you get a lower cost of therapy to people and you open therapy access up. Pharma [also] gets reimbursed for it because they're going to get those additional turns of product from a well-managed patient. And patient outcomes should be better too because of the management.

THIGPEN: I don't necessarily agree that [the co-pay assistance programs are] a win-win for everybody. I can tell you that there are several very sophisticated payers that are completely against co-pay assistance programs in general. I support the need for co-pay assistance on a needs basis. If a patient has legitimate need, we need to get product and coverage for the patient, no questions asked. But some of these programs have evolved into a concept where it actually is funding and subsidizing any co-pays at all, regardless of whatever the impact or the cost burden is to the consumer. More sophisticated payers realize that, and if they figure out — most of them have — that pharma will subsidize the co-pay, they will reduce their coverage of that particular product over time.

So, for example, let's start with a 10% co-insurance out of pocket for specialty drugs, and come to find out that trend continues to grow because they are seeking coverage anywhere else. The payer could say, 'Let me take it up to 40%; let me take it up to 50% co-insurance.' There's this really fine balance that we need to be cognizant of because the payers are very focused on those types of programs today.

SARANITI: But the economics vary among payers, because some payers will have that patient for a lifetime, so the economics is very important to them over the lifetime of a patient. But then you have a lot of the other plans, where they know they're only going to have that life for only another 12 months. The employer's going to change insurance again, and they're going to dump them off on someone else. In these plans it's a short-term strategy, and they really don't care about the outcome.

GALARDI: Bob Roose brought up this issue of fair market value. And my question drives at the issue of services versus cost-of-goods discounts ... are you finding that type of drug, meaning is it IV versus PO — where it's administered primarily — affects whether there's a service component in the marketplace, or if

there's an acquisition component in the marketplace that these folks are looking at? What is causing fair market value to come to the table in these discussions?

ROOSE: Just stepping back a little bit, five or six years ago, the big wholesalers — McKesson, Cardinal [and] AmerisourceBergen — basically changed their procurement and their supply chain efforts by looking at more of a fee-for-service arrangement. Instead of doing speculative buys, forward buys, to beat price increases and develop a profit margin that way, they essentially went to big pharma, as well as the biotechs, and said, 'We perform a number of services for you: we warehouse product, we do charge backs, we can give you traces on your product. What we want to do is charge you a fair market value for those services.' Thus they came up with inventory management agreements.

I think that scenario is impacting our market right now. [For instance], recently, I looked at a contract where basically the discounts were taken away on all the brand drugs in exchange for services defined and priced out at fair market value. And I guess fair market value is somewhat defined as: it's a quantified service, it has a true value, it can be tested and it's something that they could have done in-house or contracted out for.

What we're looking at with these fair market values, and I used the term prior, is marginalization of what specialty pharmacy brings to big pharma. My experience so far is that it's a way, essentially, to enhance the margin of a pharmaceutical company. One of the largest contracts that are on the table right now, that I think most of my colleagues are looking at, ... will cost Bioscrip millions to lose discounts and to go to a fair market value concept.

FERRER: It is definitely a trend that we're seeing on our end. I speak directly with the manufacturers, selling our services and discussing the value of our services. What I think pharma needs to do is clearly identify or become familiar with what are considered basic services and what are the additional or enhanced services that specialty pharmacies can deliver for their product.

[From] my perspective, pharma is having a hard time understanding the true value of these services after the specialty pharmacies have identified and explained their cost or expenses incurred by providing any specific type of service. The trend has steered more toward an undervalued pharmacy fee versus a product-purchase discount. I'm not saying that purchase discounts are a better reimbursement strategy than a set pharmacy fee; however, [you have to] compensate or reimburse the pharmacies appropriately for the services pharma is requesting to further support their product in the market.

Pharma also should keep in mind how their competitors are partnering with the pharmacies in the market for the same disease state where they may be ahead of the game by partnering in more robust ways with the specialty pharmacies than what they currently are doing with their own products.

So, I think they should evaluate in great detail what the fair market value is for the specific types of services — such as data collecting, literature fulfillment, compliance programs, etc. — within a broader scope of pharmacies rather than only a handful. Pharmacies are taking the burden of that cost most of the time, so pharma needs to really analyze that process, that concept and how they want to enhance that partnership with specialty pharmacies.

GALARDI: Nick Calla, do you think any of the services that folks expect you to do, that they may be paying for them elsewhere?

CALLA: Well, that's the big debate right now. There's a lot of what you could term 'duplicative services' going on between what's happening within, for example, a hub for a manufacturer and what we do from a specialty pharmacy perspective. So, to drive into this whole idea of fair market value, it really comes down to each organization's definition of what that really is. The term that people are throwing around is that it's services over and above what would be considered your 'normal services' or your 'standard services.' And how you define that, how you negotiate that in, to me, at this point, it's been a company-by-company, contract-by-contract type of discussion. So there's no real, overall answer to that at this point in time.

GALARDI: Laura, are you seeing the same sort of perspective as a manufacturer?

BRUCE: For Teva, frankly, we struggle with fair market value. And all of these guys have touched on it. When you think about when specialty pharmacy first evolved, all the services [were] what specialty pharmacy did. And now, in distinguishing the specialties and the different services that they can bring to the payer, our legal department still, in [its] mindset, well that's still what specialty does, so why am I paying for it? And to Nick's point ... it is very much determined on a case-by-case basis. We do look at other things that, frankly, bring additional value, additional opportunity back to Teva and back to our patients outside of what you think of as traditional specialty pharmacy services.

GALARDI: I'm going to ask one question about one of my favorite topics that I never discuss with my family, that's healthcare reform. Healthcare reform, relative to pharmacy — are you seeing anything that you think is going to impact the business? And let's just put this in a very short time frame; say the next two years.

MUSIL: If it all goes like it's supposed to starting in 2014, in the next two years what we're going to see is the Fed decreasing the amount of funds that [it offers] to Medicaid programs within each state. In Arizona alone, [they are expecting] a billion-dollar shortfall per year — and that's just Arizona. So, in the long and short of it, yes we are going to be impacted. So anywhere from 24 million to 50 million new lives will enter into the marketplace; the problem is there's not enough physicians to take over that care.

GALARDI: So I heard three issues. First, Medicaid programs are going to be underfunded, which eventually means that there's going to be tighter controls on Medicaid drug spend. Second was this issue of the lack of prescribers for that Medicaid population, meaning more and more physicians are opting out of treating federally sponsored patients. And the third piece was related to states pushing back on your reimbursement levels in addition to the amount of coverage they provide to the patients. Are these the three big issues in the near-term for healthcare reform and its impact on specialty pharmacy?

SARANITI: I think there's a fourth one in that most of the Medicaid states know they are underfunded, and there will be more patients pushed into those programs as a result of healthcare reform changes to the federal poverty level guidelines for eligibility into those programs.

GALARDI: So you have a ballooning population in an underfunded program, which will require less coverage and eventually lower reimbursement. That just sounds like a mess.

ZWEIGENHAFT: It's the adoption of ASP in some states — ASP doesn't work. In cancer, you've got 8% rebate by brands and 3% on generics. So, you think about cancer. You know Genentech's portfolio, 45% of Herceptin, you have to give 80% back to the government, so we're going to tax everybody else. And it's just a shift in driving cost ... I mean 40% of cancer patients today get patient assistance. That's a pretty high number.

And now [with] Medicare, [it's cheaper to go under Part D than Part B]. ... There were six protected classes under Part D, so cancer drugs are covered under D, but at 25% or 30% tiering. So if you just look at [a drug] like Avastin at $5,000 over eight cycles, as a Medicare B patient, it's going to cost you $8,000 out of pocket at the 20%; if you go through Medicare D, it'll cost you $4,000 because you're going to go through the TROOP, the manufacturer's going to fund the TROOP for 50%, then you're going to blow through catastrophic at 5% and then it's going to cost you $4,000 out of pocket.

It's such chaos that's going to happen, and who even knows who's going to run Washington in two years? Like you said, 2014 — will it actually ever get implemented?

GALARDI: Tim, question on health records in your community; are you starting to see dovetailing into federal programs, all the efficiencies around healthcare records, etc.? Is there any critical mass coming? Are docs prescribing with e-records in specialty?

KAPLAN: We see it building. We don't see critical mass yet. We still need some infrastructure on the pharmacy side to be able to handle the electronic records.

Our biggest challenge is proving our salt back to the manufacturers — that we are capable of handling the big REMS programs.
—Tim Kaplan, Amber

GALARDI: And yet physicians have incentives to do this, right? But in the case that was just discussed, they're not doing it. Jeanne, are you seeing any use of e-prescribing in specialty?

STASNY: You know, we've tried several different strategies to make sure that we stay in the game ... I think it is external to pharmacy — there's a lot of momentum from the government-funding perspective. There are incentives to get organized and more data-driven on the provider side, with the push back from the providers for professional reasons. And there's a lot of hot debate, and the emotions are, I think, what's keeping the critical mass from building. I don't think it's possible to predict exactly how it will play out. I don't see pharmacy as the sole driver in that; I think it's going to be heavily influenced by providers and other healthcare stakeholders.

GALARDI: So it's still nascent, for the most part. So anybody that really tries to come through and do an e-prescribing program in specialty is going to be way out in front of the curve at this point.