

Interview Transcription:

Todd: Alright Todd and Todd live in Chicago kicking off our day 2 coverage from this grand event. Todd I'm looking forward to it, yesterday was a stellar day, talked to some amazing people doing some amazing things, I expect day 2 to be just as grand.

Todd: And we're going to start just as grand right out of the shoot I can tell from our pre-show conversation here this is going to be interesting, this should be a really enlightening conversation, let's say hello to our guest his name is Walter Berghgham, he's an executive director of the healthcare compliance at the Gene Council. Walter welcome to the show.

Walter: Good morning Todd.

Todd: Good to have you, thanks for stopping by and joining us. Walter, before we get into our conversation, do take a few quick seconds and inform the audience about you and your background.

Walter: I've been involved in packaging for just about 30 years now, the last 20 years focused in pharmaceuticals and spent a good part of that time working for a lot of the large distributors in the US which gave me a broad view from not only the manufacturing perspective but what happens in distribution of pharmaceuticals and right on through to pharmacy and that perspective has really helped me in this conversation.

Todd: Alright, well walk us through the ACPC healthcare compliance packaging council, what do you do, how do you serve your membership?

Walter: Well we're a trade association, we're made up of packaging component suppliers, packaging machining suppliers and contract packagers and each of those companies has an interest in promoting compliance promoting packaging and that is packaging which helps patients understand how to take their medication and to know whether or not they've taken them properly.

So each of the members has a driving force in that so what we do as an association is to try to bring that message to a broader audience, not only the pharma manufacturers but also the healthcare community.

Todd: Walter, you're not exactly always complimentary about the efficiency of the pharmaceutical market, tell us a little bit about why?

Walter: Well, we've got a number of problems, we have an antiquated system, especially in pharmacy, we're dealing with a distribution method which really hasn't changed much in the last 60 years while the rest of the world has changed pretty significantly.

We're the only major country in the world that's still doing bulk distribution in pharmacy and repackaging drugs at the counter, which is kind of amazing when you consider that we're the largest market in the world and yet we're the most antiquated in how we deliver drugs to the patient.

Todd: Talk a little bit about why, what's underneath all that?

Walter: Well there's a big disconnect in the US because we've got FDA and then we've got 50 individual state boards of pharmacy, and so FDA cannot control what happens in pharmacy and we've got a real disconnect there. They're protecting turf which is very sad.

Todd: I'm trying to get my head around the fact that how have we let this happen? We can put men on the moon, we can put probes on Mars, but we can't seem to regulate. What needs to happen, why isn't it happening, are there forces fighting against that?

Walter: There are. You know every segment of the market has their own trade associations and people who protect the turf, and it's very political. Watching how the recent DQSA or drug quality legislation developed over the last 2 years you saw that, you saw these groups protecting the interests of pharmacy, protecting the interests of the manufacturer and every segment of the supply chain, everybody had a voice and everybody was pulling the chains the best they could.

Todd: So do we keep trying to rewrite that act or scrap it, start all over, or what's the best way to approach it?

Water: No I think from the standpoint of the supply chain itself and when I say that I'm going to stop at the back door of the pharmacy I think the act is good, and I think the act can do a lot of good, but where it fails is to drive the safety through to the patient and that failure is because we lose control in the pharmacy.

I'm not suggesting that DQSA needs to be completely rewritten because it would be a nightmare to try to drive anything through 50 individual boards of pharmacy, but the group that really has the power and the muscle to affect change here is the healthcare community.

The healthcare community could, and I'm talking about insurance providers like Blue Cross or even Medicare, which ensures 100 million Americans has the muscle to say to the industry, 'we want to change how you deliver drugs to patients, we want the patient to have the original manufacturer's package, in their hands'.

So that would be one way to do it without rewriting the legislation is to get those insurance providers, those healthcare providers to raise their voice and I think they haven't done it until now because they just don't know that they could do it. They don't know that they could affect change.

Todd: You testified before congress when this legislation was being considered and drafted and put together. What were your comments on that whole process, was congress asking any questions, were there organizations such as yours advocating for the right path, walk us through that whole experience, I'm sure it was quite enlightening.

Walter: It was very interesting, so there were 7 people brought to the panel as it was a democratically controlled congress, 4 were invited by democrats, 3 were invited by the republican side and they asked a lot of great questions and I came away from that session thinking, wow, maybe they get it, and then the law came out and I thought no, I guess not. They were just playing politics with us as normal.

Todd: I'm putting myself in a position of the manufacturer, and if I was running a pharmaceutical plant, the notion of packaging up a set of medication that's going to go to a specific patient, I mean that's something that as a manufacturing guy, I know how to do that, it's not that hard, I can, but why, I don't want to say it's easy, but there's all kinds of other products delivered in that extremely customized fashion, why aren't the manufacturers all over this?

Walter: Well it's kind of sad because if you were to go to any other market in the world, they are doing it. So, and I don't want to bring up specific names of pharma manufacturers, but you know, the big 3, big 5, if you go look up their drugs in any other country in the world you're going to find it in the blister, and in the United States they're delivering it to the pharmacy in a bottle, 500 count, 1000 count bottle.

Now by all means it's cheaper for them to deliver it that way and it is the market norm, but it's not the world norm and they could have increased the safety by changing it, and it's not an easy change, it takes a while.

Todd: I'm still processing in my mind the comment you made where you said the healthcare community itself has the power to really affect this change? Why aren't they doing it and what has to happen? Is there some, I don't want to say cataclysmic, but some major issue that has to happen for them to snap into it and take the initiative on this?

Walter: Some of it's starting to happen. So in the various rewrites of Medicare, a few years ago there was a section written called Medicare 5 star, I don't know if you're familiar with it or not, so 5 star is about reimbursing healthcare providers based upon performance.

Part of the Medicare 5 star actually deals with pharmaceuticals specifically and it talks about reimbursing healthcare providers based on whether or not their patients are compliant with oral diabetics, oral hypertensive, oral drugs for diabetes, and so now if I'm a healthcare providers and it might specifically affect my wallet and income by improving adherence and compliance, I'm going to start looking for solutions, and it is starting to happen.

But in the past I think it just hasn't happened because they didn't know they could affect change and that's one of the challenges for our association is to make sure that they understand that they have the power to change it.

Strangely enough, one of the big gorillas, growing gorillas in healthcare is Walmart. Walmart is fast becoming one of the largest pharmaceuticals in the United States and Walmart distributes more client prompting format packaging than any other group in the United States.

Now they're doing it for a slightly different reason because you can't say that it's entirely altruistic that they're doing this just for the benefit of the patient, they're doing it, they're bringing product down these 30 count blisters, it's a little injection moulded base with a slide up blister so it still has a child resistant safety feature which it needs to have.

But they're reducing risk in pharmacy because every time a pharmacist cracks open a bottle and repacks it you have risk. You have a risk of making an error, you have a risk of introduction of a counterfeit drug, you have, you know, make a list, there's a long list of things.

So by bringing pre-packaged drugs into the pharmacy, they're reducing risk, and they proved to themselves over many years, and there's published study on this, that the patients using these compliance packs were coming back to their pharmacy 3 to 5 days more accurately.

Now if you're Walmart, that's one more visit to your store per year, and you know every time they walk in your store they'll spend 20 to 35 dollars, so there was an economic driver behind it.

There was a safety driver for themselves in reducing risk and reducing liability for the pharmacy, but at the end of the day the patient is benefitting because the patients are taking the drug more accurately and they've already tracked it.

Todd: Now are others noticing that model?

Walter: They are, and there are some other chains, and it's kind of funny because the 2 other chains I can think of are actually supermarket pharmacy chains that are picking it up and running with it, and the same thing, they're driving traffic, see the problem I think with the major retail pharmacy chains is that they're not seeing the same economic lift that Walmart sees every time someone walks in the store.

Todd: Is that where the change is going to come from? Is it going to be more from the regulatory side, is it going to be from manufacturers or is it a distributor like Walmart?

Walter: I think it's going to come from downstream. I really think that either the Walmarts of the world who are already changing it will continue to do so and I think that as healthcare providers see more pressure to improve the performance of their patients, they'll drive the change.

Todd: Why not the insurance companies? I mean if I think of someone who has a direct economic interest in improving efficacy and adherence, you'd go on and on with all the pieces of the economic incentive for payers it seems to me is obviously there.

Walter: And it's starting. So I was at a conference about a month ago in Washington and there was a gentleman there from Blue Cross Blue Shield speaking about it and he said absolutely compliance prompting packaging is part of their formula now and they're beginning to build on it and they understand it. So that's an important piece of it.

Todd: So walk us through what Walter and ACPC are doing here at pack expo and pharm expo to help tell the story.

Walter: Well it's not just here but it's contributing to what life science is doing here, a lot of our member companies are here, we speak and attend conferences all year long to try to drive the message in different venues so it's not just about speaking to pharma manufacturers but we also try to speak to other groups and audiences.

We publish constantly and we just completed a study which is interesting, it's kind of a parallel to this space, but it was very much a target so we did a study looking at product stability and how safe products are in the current distribution method.

So if you're a drug manufacturer, you put product upon stability to see how long it's going to last in this particular container, and that's all done with an un-open container.

Now we did a study that said well let's look at the real use, let's look at what happens when it's in a pharmacy vial for 30, 60 or 90 days, or a white propylene bottle you might get through the mail order versus blister versus barrier blister, so a high barrier blister.

What we showed in the study was that within 30 days, you're seeing significant changes in hardness and disintegration time of these products, as much as 50% or more changes, changes in the hardness of the product and changes in the disintegration time.

Now the disintegration time of these products directly affects how it's going to get into your body. It doesn't mean that the active ingredients have been damaged, because we didn't try to measure that in this particular study, but it does mean that the way it behaves in your body, how quickly it can get to you, or how slowly it gets to you is changed dramatically.

Todd: You're talking about the pharmacy, take it one step further, in the consumer's home environment, what happens there?

Walter: Yes that's the real problem, so if you get a vial from the pharmacy, the first thing that happens with most seniors is they never put the cap back on tight because they hate the CR, the child resistant closure is a pain so they don't put it on, so it's even worse.

Our study was really on pristine condition because we made sure the containers were closed every time and we studied 3 different conditions, so we did nominal, room temperature, average humidity condition, we did a high humidity condition because we know that people leave things in the bathroom, something that we should never do, and then we did a high temperature condition which somewhat simulates what happens in mail order.

Insurance companies are driving more and more mail order because they think it's reducing cost but it's already been proven time and time again that when you cook these drugs, you're killing them, you're killing the efficacy of these drugs.

There are some drugs actually says on the container, if this drug experiences a temperature of above 86 degrees, bring it back to the pharmacy. 86 degrees, that happens in your car, you know, so people are just assuming the safety of the drug, they're not thinking about it the way they think of bread or their cheeses which turns green and shows them something's wrong. You're drugs don't do that.

Todd: 86 degrees is pretty much what my parents keep their thermostat at these days so, goodness. Walter I'm interested in the prevailing attitude across the industry, I mean this is a huge problem, lots and lots of moving parts, lots and lots of different people and organizations involved, I could look at it on the one hand and say wow, what an exciting challenge and I know we can do this and be really excited about it.

Or I could jump to the other end of the spectrum and say, good god, there's just so much to do here, I'm going to hunker down, I'm going to do my piece of this industry really, really well, make money and cross my fingers and hope it all works out someday. Where are folks? The whole spectrum I assume?

Walter: I mean there's certainly a lot of interest in trying to drive change and like anything the best way to do it is to take it one step at a time. So what we always look at is that in the United States, the top 5 health conditions which include diabetes and hypertension, high cholesterol and asthma, those 5 conditions represent 75% of our healthcare spend.

So if you just attack the drugs in that space and say we're going to change this, we're going to change how these are distributed, change how they're packaged, try to help patients take them better, you'd make a huge, huge difference to the market because you don't have to address the 16,000 drugs that are distributed in the United States, you just attack those conditions and already impact the overall cost situation dramatically.

Todd: Clearly you're on the, we can do it, end.

Walter: Absolutely.

Todd: Alright, so you said one step at a time, is focusing on the higher utilised medicines, is that the first step?

Walter: I think so yes, I think that would be the best plan.

Todd: And then?

Walter: Well you know the biggest, and then, is to get the industry, and now I am looking back at the manufacturers to recognise what they do in the rest of the world and to admit what they do in the rest of the world and say there's no reason that they US market is getting different treatment.

The US market should be getting the same level and quality of packaging that the rest of the world's getting regardless of the fact that we have this antiquated system.

You know this antiquated system it's survived for a number of reasons, I mean, you know, in the 50s, the pharmaceutical industry was much in its infancy and we weren't rebuilding and a lot of the rest of the world was rebuilding, and they started over.

Todd: I never really thought of it in that context.

Walter: And so we were left with these 100 year old pharmacies, in the 50s I think almost 40% of the drugs were still compounded in pharmacy, which means that the best place to package it was in the pharmacy, because you were compounding it. Not too many compounding pharmacies anymore, why are we packaging in pharmacies, it doesn't make any sense, it made sense 50 years ago.

Todd: Is the local pharmacy a barrier in this? Is there a group that's saying, hey I'm doing extra work, there's more value added right in the pharmacy so there must be a group that says I want to preserve that chunk of it?

Walter: The pharmacists are absolutely afraid that their reimbursement rates will change if the products come in pre-packaged. They're absolutely afraid of that, yes, it's a good point. It follows the money, it never changes.

Todd: Well Walter we're about out of time, before we let you go, how can people get in touch with you to learn more about the healthcare compliance packaging council?

Walter: Well they certainly can visit our website which is www.acpconline.org. If they go there they'll be able to download a white paper which looks at 20 years of compliance prompting packaging and how that has been demonstrated to help patients and within 2 weeks we'll have a paper published on the stability study which shows how products behave in normal pharmacy containers in the home.

Todd: Alright, Walter Berghgham, the executive director of the healthcare compliance packaging council. Walter it was great to have you on the show, thank you.

Walter: Thank you, appreciate your insight.

Todd: Alright, day 2 off and running, this wraps this segment. This has been Life Science Connect Radio with Todd and Todd signing off from Chicago, our live coverage will be right back.