# SPEAKER FEATURE

## Commercial Patient Access Programs

With Dane Hartung, Director Marketing and Access,
Fougera Pharmaceuticals, Inc

**How are PAPs different from clinical trials and open-label trials? In what circumstances should you be considering PAP vs. the other 2?**

**Dane Hartung, Director Marketing and Access, Fougera Pharmaceuticals, Inc:** Clinical trials are used to produce the label that you're going to promote from while open label trials would usually be a phase 4 trial and not traditionally used in the product insert. Both are completely different from a PAP which is utilized post approval for supporting the patients who will be receiving the drug to provide and drive patient access and not intended to support your label.

They're really 2 different areas of responsibility – one is more on the clinical area of providing a label and one is more of a marketing/access role.

**What are the different types of patient access programs (PAPs)? How do they differ when it comes to access and compliance repercussions?**

**DH:** At the outset, I want to make clear we are talking about commercial patient access programs and not the patient assistance programs that typically are used in charitable cases. We will use the term "PAP" here to refer to commercial access programs. So, there are a couple of different PAPs that traditional brands may employ. First, you have co-pay programs, which usually utilizes a co-pay card that is handed out by the clinicians and/or a website where patients can check their eligibility and enroll in the program These co-pay programs require an active role on the behalf of the patient &/or clinicians. To ensure compliance with regulations, copay cards are limited to commercially insured patients. Some companies may opt to use these to help buy down the patients OOP (out of pocket) reducing and in some cases eliminating out of pocket costs for patients so that they can obtain the drug. The great thing about co-pay cards, especially early on, are that they may help lower out of pocket costs for the patient., This may help reduce attrition (patient walking away not getting product) if they would normally would have a high out-of-pocket costs associated to their insurance coverage.

Another type of copay program is the e-voucher system. With e-vouchers, there is an electronic "card" that is applied at the point of purchase (usually the pharmacy), if the pharmacy determines the patient is eligible under the terms of the program. In this instance, there are defining business rules that will reduce (buy-down) the patients OOP which also has the impact or reducing attrition. In both instances, patients obtain the medication prescribed by their healthcare providers with a potentially lower co-paymentand for the manufacturer, they gain utilization. The advantage of the "active" co-pay program is that it provide the opportunity for manufacture to physician and physician to patient interaction.

Other PAPs are considered "patient services approach" and these usually associated with a hub and/or patient services model. These services include things like a buy down similar to a co-pay card, cash options that provide product for a specified dollar amount, refill programs, home delivery, educational services, and sometimes, these services work with the office and patient with prior authorizations that may be associated with the plans benefits structure. In the continually increasing restrictive managed care environment, there are a lot of plans that require preauthorization or steps edits according to the benefit structure. The prior authorization services don't fill out anything for the physician, however, some of them can provide either information about the product or the proper insurance form for that patient and/or the requirements of the payer. Thus, is if there is a prior authorization required by the insurer, the PAP hub may help getthe right information to the office, thereby increasing the chances that the patient will get the medication prescribed by the patient's HCP .

Lastly, the charitable patient assistance programs. These programs are aimed at assisting indigents and are based on strict financial need, typically in the range anywhere form 2x to 3x the poverty level for qualifying patients. These programs are created for those who can't afford the medication and would qualify under the services of that program. Depending upon the population you're looking to serve with your product, indigent programs can offer another great way for patients to access product as well.

Finally, a word about regulatory compliance. In order to run a sustainable program, you need to be aware of the compliance rules around these programs. Work closely with your legal and compliance departments and partner with them to ensure continued compliance.

**When it comes to determining whether or not to create a new commercial patient access program, what is the first step? Is there any specific data or information you should collect first to help ensure you make the right decision?**

**DH:** One of the critical understandings before creating an commercial access program is understanding the competitive landscape. Identify if there are other companies within your class of product that have programs, and if so, you want to find out what they're offering and to whom. Especially in this tight environment, physicians are taxed with time and extra effort for submitting the information required in prior authorizations. The managed care landscape for certain products may impact their clinical decisions. The clinicians may make a clinical decision for one product but, if there is another one out there that is similar in the mind of the clinician but the product has a better access program that takes up less time or resources for the office, the physician could potentially decide to switch or utilize the product with easier patient access. So again, having a commercial PAP is very valuable but you need to find out what your competition is doing first so you can at least match if not supersede what they have. Ultimately, determine how will an access program help differentiate your company and it's products.

**What are the top 3 key considerations or questions you should be asking yourself when determining whether or not to create a new commercial access program?**

**DH:** First of all, you need to understand your positioning in the market and what it's going to do to drive utilization or access. Many products, when they first come onto the market, need utilization to even get considered for formulary access for different tiers. So understanding how commercial PAP programs will drive access and utilization is probably one of the first considerations.

A second consideration is how the commercial PAP is going to impact your ROI. Obviously all of these services cost money and effort whether its being done internally or with a 3rd party, and you need to understand how that positive impact of increased access and to your product and the related revenue is going to be offset by the cost of the buy down services and related patient assistance programs you're providing to the patient.

And the third, is most important in determining how the PAP is going to differentiate your product. With many of the products out there, access is one of the key considerations for physicians as they consider therapy for patients. According to an article in Medical Economics, approximately 20 hours per week per physician are spent dealing with prior authorization and as much as $83,000 is spent per year per physician interacting with insurance plans. Due to the varying differences in payer requirements for completing things like prior authorizations, clinicians are faced with a time-consuming process that is subject to error. In fact, the majority of prior authorizations are rejected due to missing data or clerical mistakes. These rejections mean more time and effort. There will be a need for resubmission, which ultimately causes a delay or abandonment for the therapy that clinicians prescribe. Therefore, it's important to identify how the access program is going to help your product and services stand out against the competition in the eyes of patients as well as physicians.

**What are some best practices when it comes to conducting risk/benefit analysis? Furthermore, what are some of the top risks (ethical, clinical, financial or regulatory) and top benefits of PAPs decision makers should be taking into consideration?**

**DH:** the short answer, first you need to stablish a sustainable and ethical program that establishes consistency in the offerings – changes confuse the HCP and patients. Ask yourself, do you need to gain patient consent and how are you going to do so? This will allow you to provide promotional services and could increase adherence.

The long answer is, number one, you need to have an ethical and compliant program in place. As I mentioned before, consult with your legal and compliance/data privacy departments when designing your program. That will help you build a sound, sustainable and compliant list of offerings. Also, understand how your program is going to impact your gross –to-net. It all comes down to the access and the revenue that you're generating so you need to look at what sort of an access program is going to help drive that as well as the cost. Gross-to-net is a key indicator of all of this.

Secondly, you want to make sure the PAP meets the needs of its key stakeholders: the payer, patient and physician. Now more than ever, there is a heightened awareness amongst the payers (insurers) to look at what is consistent, ethical and in alignment with their needs and wants. You need to determine how your PAP is going to affect the patient and how to provide them access to your product. When, it comes to the healthcare practitioner, again, differentiating your product while providing access is key. Find ways to simplify the requirements of your program (to the extent you can) and communicate the enrollment process to practitioners in a clear manner. Then, if you're aligned to all 3 key stakeholders, you'll have an ethical and compliant program.

Thirdly, once you have a solid program that fits your key stakeholder's needs, make sure you are aligned to fulfillment in a manner that will not create ongoing disruptive change. If you make too many changes where to fulfill product, not only do the patients get frustrated, but so will the physicians. In a worst case scenario, beyond the constant change, if your fulfillment channel is out of contract for the payers, your patient may not be able to get product. Meaning that when it comes to specialty Pharmacies or mail order programs, insurance companies usually have anywhere from 2 to 3 preferred and/or contracted mail order and/or specialty pharmacies depending on the therapeutic area you're looking into. If you're product fulfillment is outside of that, in many cases, the insurance companies will block the distribution out of those channels so the patient will either have to go somewhere else that's in their contract or have to go out of pocket which most patients won't do and you will end up with an increased attrition.

Though the market does change and some adjustments may be unavoidable, avoid the potential fatigue of changing fulfillment channels, therefore it's critically important to consider your distribution model and figure out how you're going to get your product out to the patient ahead of time.

*Disclaimer: This content in this interview was provided by Mr. Hartung in his personal capacity. The opinions expressed are Mr. Hartung's own and may not necessarily reflect the view of his employers.*

# ABOUT Dane Hartung

SPEAKER BIO

As Director Marketing and Access, Fougera Pharmaceuticals, Inc, Dane is responsible for Product Branding and Access. In the past, he's successfully led, developed and executed market plans for access and brand commercialization in support of franchise products, including setting strategic direction supporting corporate payer and reimbursement objectives. He also developed a first-in-kind HUB/patient service, aligning payer/patient preference to ensure fulfillment resulting in NRx growth, reduction of operating costs and increased Prior Authorization approvals.

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