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Consulting Firm, VOZ Advisors is enabling Pharmaceuticals and Biotechs build Productive Relationships with Patients, Patient Organizations, Caregivers, Professional Societies and Consumer Groups

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CEOCFO: ***Ms. Coleman, what is the concept and approach behind VOZ Advisors today?***
Ms. Coleman: As a niche consulting firm, VOZ exists for one reason: We help pharmaceuticals and biotechs build strong, strategic, and productive relationships with key external stakeholders who can offer input across the drug development continuum. Those key stakeholders are patient organizations, patients and caregivers, professional societies, and consumer groups. We help bring the patient's voice to the drug development process.

CEOCFO: ***What do drug development companies want to know from their patients that they do not intuitively recognize?***
Ms. Coleman: There is a long history of patients being involved in drug development; it began years ago with the AIDS crisis when people with AIDS demanded a seat at the table as companies were developing drugs. They wanted pharmaceutical companies to know what was happening to them and act quickly. Lessons learned from the experience of people with AIDS over time morphed into other disease groups, particularly women with breast cancer asking for greater involvement in the development of treatments.

Over the last five to eight years, the interest from pharmaceutical and biotech companies in understanding the patient experience has exploded, ranging from whether they are asking the right research questions to address unmet medical needs, to understanding whether a trial protocol is patient-friendly so people will be willing to participate in it, to understanding more about how people get information about diseases and innovations once a drug comes to market. Gathering patient input is now happening across the whole of the drug development continuum.

This has also been encouraged more recently by the regulators, the FDA and the EMA (European Medicines Agency), as well as by health technology assessments, particularly in Europe. More and more, these entities want to know what companies have done to understand the patient's perspective on a particular submission. They want to approve and pay for innovations that patients feel are going to be of use to them, which patients have been involved in giving input. There is a push all over the place, not just in drug development from a company perspective, but also from the payor and the regulator perspective, to understand if this innovation is meaningful to patients.

CEOCFO: ***Would you walk us through a typical engagement?***
Ms. Coleman: A very typical engagement for us is when a company is going into a new therapeutic area--lung cancer, for example. They are looking to develop treatments in lung cancer, but they do not know the community of lung cancer patients and key organizations. We recommended what we call an environmental assessment. First, we will listen to what

their business objectives are. For example, are they interested in clinical trial recruitment and early engagement of the patient voice in the research process, or are they interested in creating disease awareness about innovations once the drug is approved? Whatever their business objective is, we will development an environmental assessment helping them understand all of the key patient organizations and professional groups in that space in the geographic areas of interest. We are a global company; we can provide global assessments, or they can give us a more narrow scope of Europe or the USA. Whatever their geographic and therapeutic areas are, we will provide an environmental assessment that does a number of things. It tells them first who the groups are and what they do.

The second thing it tells them is what each group's key areas of focus are so we can suggest priority groups based on what the groups can do and how they can align with the company's mission and business objective. An additional part of the assessment is our key insights into the community. We have long and deep histories in these communities; many of us have worked in the non-profit space or advocacy relations within pharma. We don't only know the landscape from doing secondary research, but we have also worked and been involved in a lot of these communities ourselves. Our key insights help a company understand areas that may be important overall to the community. Lastly, we offer an engagement plan, which is devised to help them maximize their connections and partnerships with these organizations.

"When you ask patients about their experience, you will always learn what is important to them, which translates into better research and treatments."- Ellen Coleman, MSSA, MPH

Most importantly, we are looking to encourage relationships that are mutually beneficial. Patients and organizations are never going to promote a particular drug, but they are interested in new innovations for their constituents. They are attentive to making sure that patients get what they need and have access to--and are aware of--medications. Keeping with our example of lung cancer, while organizations will (rightly) never promote a particular drug, they can offer educational information about innovations all across the lung cancer space and the company's drug may be one of them. We think of it as "the rising tide floats all boats," meaning the more educated patients are about their disease, the more likely they will go to the doctor and ask questions which may result in them getting better treatment and care. The more drug developers know what the patient experience is, the more likely they are to have a better understanding of how to craft a patient-friendly clinical trial and how to make sure they are developing an innovation that is necessary and important from the patient perspective--that it will be something that patients want and thus contribute additional information to the decisions on approval and payment.

CEOCFO: ***Are you primarily working with larger pharma companies?***
Ms. Coleman: No, we actually work across the whole spectrum. We help small companies, for example, that may not yet have what is called an internal patient advocacy relations function. We may work with that company to not only help them understand the disease area environment but also help put into place some of the critical structures needed to appropriately engage external stakeholders. Do they have a person who will be in charge of working with patients and patient organizations? Do they have compliance in place to understand what compliant relationships look like?

An extraordinarily important aspect is making sure that companies do not do things that are, or appear to be, influential and that groups remain independent in their decision making. This requires compliance and legal structures along with standard operating procedures that they can follow to engage appropriately. We also help set up these kinds of internal structures to ensure relationships occur according to the set guidelines and regulations.

We do work with larger pharmaceutical companies that may have very sophisticated efforts. We offer strategies meant to enhance what they are doing, or support work when they may not have the staff to run the projects that they want to execute. For example, if they want to do an advisory board, they may need support, so we put all it all together and facilitate the meeting for them.

CEOCFO: ***How does a company decide to pursue a drug or drug development before they have some of this information? Do people usually come to you early enough?***
Ms.Coleman: One strategy a company may use is a Target Product Profile, which is a valuable tool to address issues early in development by working backwards, describing the desired final label for a product before it enters into trials. They may understand what the need is and what the market is going to look like. Traditionally, they might include the physician perspective, survey data, and health outcomes research. What is happening more recently is the addition of the patient experience to all the things they normally would examine at this stage. We are finding this addition is really critical, as they are learning things from patients that are different from the information physicians have provided. I have been in a

room where you have doctors describing what they have seen and then you have patients saying, yes, that might be true for some of the people that the doctors have treated, but the patients present often describe something very different. If you get viewpoints from patients and caregivers, physicians, and patient organizations, they all have a place; each can provide excellent input and they are often times very different.

CEOCFO: ***What is an example of what you might learn that would make a difference for a drug company?***
Ms. Coleman: A couple of years ago, I was at a meeting with patients who had a very rare disease called Pachyonychia congenita. The patients were talking about how calluses build up on their feet and hands that are very painful. They told us that doctors thought shaving the calluses down would help, but the patients were saying "absolutely not", that their pain increased when the calluses were decreased--that is an example of how different the patient's view might be from a health care provider or researcher--the patients said, "Are you kidding me? My pain is five times as bad if you do this." You will hear differences like this.

Another example is a company who invited researchers about to start a clinical trial for Friedreich's Ataxia, and one of the tests that they were putting in the trial was a peg board test. The patients gave the doctors oven mitts to wear to try to do this exercise to show them what it was like for a patient to put pegs in the holes in the board. The researchers came away with a greater understanding of the patient experience. In research for Duchenne Muscular Dystrophy, a six-minute walk test is often used as a measure of improvement; however, if you talk with boys who have Duchenne, you hear other endpoints that may be important as well. For instance, quality of life may mean the ability to use their arms and hands to brush their teeth or to be able to work on a computer. When you ask patients about their experience, you will always learn what is important to them, which translates into better research and treatments.

CEOCFO: ***Would you tell us about your global reach?***
Ms. Coleman: Our main office is located in Manhattan. We have people in Cambridge Massachusetts, Washington D.C., Paris, and London. We have made a conscious decision not to open offices globally because we are a small, boutique firm. What we have developed over the years is what we call "on the ground" networks. If we are working in Latin America, where we are just starting a project, I have another consulting group that does a lot of work there that I brought into the project. In this age of virtual meetings, however, it is not unusual for our US staff to work on projects all over the world while sitting in New York City; but we use our on the ground networks to extend our global reach when we need to.

CEOCFO: ***You are a niche company. What is the industry like? Are there many other companies that do some of these functions?***
Ms. Coleman: We are probably the largest niche in this function. Our competition tends to be smaller groups and often times one or two consultants that have gone out on their own in the advocacy space. They are smart and do good work and we know a lot of them, but they are much smaller firms. We are at 25 people right now, heading towards 30. We have a leg up just from the fact that we have a lot more people and 23 years of experience; some of these other smaller groups that work in the same niche just do not have the bandwidth that we do. We also have competition from larger public relations or communications firms where they will often say they do patient advocacy and can make connections with groups, but what I think is often missing is the depth of knowledge that we have.

My background is a good example: I worked in the hospital with people who had AIDS in my early career, and I had a stint with Johnson & Johnson where I learned about drug development. I spent 13 years in the cancer community, most of that time as an executive at a cancer patient organization. My job, at the time, was to help develop relationships between the organization and pharmaceutical companies, so I sat on the other side. Many of the people we hire have very similar backgrounds; they were in patient organizations, developing company relationships on that side, or they were in industry in an advocacy relations position. We like to hire people who have deep connections in communities we work in and considerable experience with nonprofits. That is not always what we see in businesses that may be doing communications, public relations, or advocacy.

CEOCFO: ***Finally, what is next for VOZ?***
Ms. Coleman: We are excited because we just rebranded as VOZ Advisors in October. The firm was sold, and we rebranded from our previous name of MK&A. We are really excited about the opportunity that we have to move forward as VOZ, which means voice in Portuguese. We chose that name for two reasons in particular; our new owner is from Brazil, so VOZ ties to the language she grew up with, and our most important role is to raise the voice of the patient in drug development--so VOZ fits us well.

What we want to do is take the company to the next level by not only continuing to serve our clients, but also by looking at some of the larger, more challenging issues around patient engagement--how we as a company can act as a catalyst for change or help address problems that are on the horizon by bringing pharmaceutical companies, biotechs, and patient organizations together. Cell and gene therapy is a great example; it is a burgeoning field and there are tons of issues around access, pricing, patient education, and ethics. We are looking at how we at VOZ can be leaders to help educate, support, and create new approaches that are helpful to patients and companies in these new spaces. That is where our future direction lies.