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The Most Powerful Name in Corporate News

Automated Genotyping System

Bob Bean
CEO

CEOCFO: ***Mr. Bean, your site indicates that Harmonyx is in harmony with human health. How so?***
Mr. Bean: We believe that medicine in a one-size-fits-all, population-based approach is the way things had to be, and not the way things need to be. Through the sequencing of the human genome and all of the research that has happened in the last 15 years, we now have access to information about genetic pathways and how medications travel through our bodies. We believe people have a right to know in advance whether the medication they have been prescribed by their doctor is actually going to help them, not work at all, or possibly cause them harm. "Harmony in human health," for us, is about giving people access to information about themselves and the medication they are about to ingest, so that they can make sure they end up on a treatment that can actually help them.

CEOCFO: ***How do you do it? What is your plan to show people the right path or to provide the right information so they can decide the right path?***
Mr. Bean: Part of the challenge we have faced in this industry has been breaking through the regulatory hurdles and the infrastructure in order to allow people to even know that these tests exist. Historically, genetic testing companies have relied on physicians to genetically screen patients prior to writing prescriptions. We tried that direction for a couple of years and encountered significant barriers of entry. Our model has evolved over the past two years as we partnered with community pharmacies and retail chains. We feel like the pharmacist is a true patient advocate, and is in a unique position to provide prescription therapy guidance. So, how does it work? Well, the conversation starts as a patient walks in with a prescription for a medication that falls under the Harmonyx test platform. These patients are unique; therefore, their prescription therapy should be, too. Pharmacists educate their patients regarding genetic abnormalities that can cause their medication to be ineffective. They inform them that there are tests available that can provide them insight, based on their genetic makeup, as to whether their medication is right for them. The responsibility given to the pharmacist, who is a highly qualified health care professional in our industry, gives the patient an advocate to tell them about the test and offer them the opportunity to get actionable results. The treating physician makes all the decisions about whether or not to change therapy — neither the patient nor the pharmacists can do that on their own. The pharmacist works in concert with the physician and the patient in the Harmonyx system.

CEOCFO: ***Do many pharmacists still take the time talking to their patient and doing more than a cursory explanation unless they are specifically asked?***
Mr. Bean: The answer is emphatically "yes!" If you have been around pharmacies for the last couple of years, as I have, and listened, watched and seen what is going on inside their industry, you will see a much more assertive approach to direct patient care. The pharmacist's perceived role has evolved from being the person who actually created the medicine to now dispensing the drugs that the pharmaceutical industry produces in mass quantities. The role moved from creator to pill counter. Over the last few years, pharmacists have begun looking to break that perception and are making inroads into counseling, therapy and opportunities where they are dealing with the patient in areas that are new and revolutionary. As you know, many pharmacies now are putting nurse practitioners on-site so that basic health care can be offered in a pharmacy setting. I have seen examples of retail pharmacies that have the pharmacist sitting out in front of the counter acting as a patient counselor and working with patients through their multiple meds and multiple health care concerns.

Many people actually go to the pharmacy for information about things that their doctor did not tell them or that they forgot to ask, and they rely on a pharmacist for this information. The Harmonyx test program is really an expansion of that role. Pharmacists feel the pressure of filling prescriptions and moving people through in a fast and efficient way, however, nothing is more important to a pharmacist than ensuring their patients are taking medications that will be effective and safe. In the same way a pharmacist consults with a patient on how and when to take a medication, pharmacogenetic testing is becoming a natural part of the conversation. Pharmacogenetic testing empowers pharmacists to make sure that they are dispensing a medication that actually has the ability to function properly for their patients.

CEOCFO: ***You have a new model and a new website. How is it working today, and how will it work a year from now?***

Mr. Bean: Operationally, it works this way. We currently offer three tests: Antiplatelets, Statins, and ADHD. Pharmacists have conversations with patients, who decide whether they would like to take a Harmonyx test. The patient provides a sample through a swab of their mouth and the pharmacist submits the patient information online to a state licensed physician. The pharmacist mails the swab and the patient consent form to Harmonyx. Once we have received the pharmacist order, indicating medical necessity, and the documentation of patient request for testing has been verified, the state licensed physician may choose to place the order on behalf of the patient. The results are sent to the patient's treating physician and to the pharmacist, so that an appropriate consult can proceed, if necessary. Starting in 2015, we moved away from the insurance reimbursement game and toward a progressive patient payment model. This testing is useless if patients cannot afford it. Other companies may charge thousands of dollars, but with our approach, we bring down the cost to affordable levels that work for the patient. The patient pays for the test at the pharmacy. Over the next year, our vision is that this testing program will expand as we launch additional tests and more pharmacies get involved.

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CEOCFO: ***Why the decision to go in this direction?***

Mr. Bean: The reason we have moved toward this uncharted territory is simple. Pharmacogenetic testing should not be viewed as a luxury, but rather, an integral part of a patient's health care. We arrived at pharmacogenetic testing through a bit of an odyssey. We were introduced to it by a large PBM a few years ago, and we learned the business by doing some development with them in their early days. We never participated in their program commercially, as it never really got off the ground. We went to the market with a pharmacogenetic test because we believed that the technology our company offered was extremely fast, targeted and inexpensive. We knew that there were many companies out there that were testing hundreds, thousands or even tens of thousands of genetic markers and trying to build an encyclopedia of a patient's genetic information. That was not practical given the economic pressure to lower the cost of healthcare in the short term, even if it made sense for the long term. We took a different approach. We thought you should start by asking what a person really needs to know: if the drug they are about to take is going to work or not work. They do not need to know the efficacy of 15 or 20 other drugs. They just need to know *today* if the drugs they are going to take today are going to work effectively in their bodies, or could cause them harm by not working properly. When we took that approach, we looked at the drug Plavix, and we decided the Plavix test was where we would start. This is a great drug; people die when it is not metabolized properly. They are taking this drug to prevent strokes and heart attacks; however, three out 10 people taking Plavix do not metabolize it properly, which puts them at serious risk. Thirty percent of the people in America taking this drug are at risk, which equals approximately six million people in America today. That seemed like a logical place to start. We looked at it as a mission to help healthcare professionals save lives. We marched into the community trying to get cardiologists to use the test, but there was no reception for it. There just seemed to be no audience, and we are talking about hundreds after hundreds of cardiologists that we worked with, and we just did not see them changing their behavior. They continued to write prescriptions for a drug that they knew was not going to work. Along the way, out of true frustration, our light bulb moment moved us to the pharmacy. Although the pharmacy was very receptive to help patients in this way, unfortunately we found that the complex systems were the same. You bill insurance, and insurance pays for it. Last fall, most of the Medicare administrative corporations in America (the MACS) made a policy change to stop paying for Plavix testing for all but about eight percent of the people taking Plavix. Those people had been diagnosed with ACS and PCI. If you do not carry one of those diagnoses, Medicare states it is not willing to pay for your test. Since 75 percent of the people taking Plavix were on Medicare, it made no sense to continue to bill insurance when they were not going to pay for it. The worst part of billing insurance is that you cannot make a patient pay anything less than what Medicare reimburses because that violates federal law. If Medicare reimburses $300 for a Plavix test, you have to charge a patient $300, whether they have Medicare or not. If they cannot afford it, then you have to go through all kinds of gymnastics to

do some sort of discounted rate adjustment based on their income, and the whole system is just fraught with time consuming clutter and chaos — it is just a mess. We looked at our business and asked what we did well. We provide fast, accurate and very inexpensive testing. We decided it was time for a patient-centered revolution of sorts. We decided to change this game and change the model. Instead of charging $300 for a Plavix test, how about we just charge $59? Let's make it affordable for everybody. We are uniquely able to do that because we process hundreds of thousands of samples per month through our automated genetic testing system. We already have the power of scale, and we have the power of full automation of testing. We are able to produce these tests and provide this information inexpensively — very different from most labs in the world. We think it is time to make pharmacogenomics available to everybody.

CEOCFO: ***Where are you in getting pharmacies onboard with the concept?***
Mr. Bean: We are currently in over 1,000 independent pharmacies, and we are in the process of rolling out this testing with a national pharmacy chain over the next several months. For patients who want access to these tests, we will help them find a Harmonyx pharmacy in their area that will administer the tests and place the order for them.

CEOCFO: ***What is the reaction when you approach a pharmacy?***
Mr. Bean: We are finding that the pharmacists have been extremely excited about an opportunity to do something like pharmacogenetic testing right there in their store. It is quite uplifting to walk into a rural pharmacy in a small town in Alabama and realize that you can provide world-class genetic testing through that pharmacy today, and return the results within a few days. For an independent pharmacist in a town of 8,000 people, to be able to provide genetic testing for their patients is quite exciting to them.

CEOCFO: ***What is the patient response?***
Mr. Bean: With our previous model where we were billing insurance, the patient response was extremely positive for people who were on Medicare. For people who had private pay insurance, there was a great deal of concern as to whether or not their insurance company was going to pay. The model we have today takes all of that mystery away. Here is the price. It is a fair price, it is a low price, you have access today and you can swipe your card or use FSA or HSA. In independent pharmacies, they even have a payment plan, so if a patient cannot afford an ADHD test, we will allow them to pay over two months so that they can find out this information for their child before they take the medicine. Patients can submit to their insurance company if they so choose, but with prices as low as we are charging, many people don't see the need.

CEOCFO: ***What is your plan? How are you going to reach more pharmacies and become a standard?***
Mr. Bean: As you know, you have to be able to crawl first, then you walk and then you run. We are in that mode right now. We are in about 18 states, and we are moving as quickly as we can to enlarge our reach around the country. Our target is to try to be in every state by the end of the year, or at least 49 of them. Part of that happens from hiring sales reps to be able to go out and meet with each pharmacy, talk with local physicians and make sure they are aware that these tests are available. The other part is working with pharmacy directors and clinical directors at these local small chains and grocery store chains to expand our reach.

CEOCFO: ***Put it all together. Why pay attention to Harmonyx today?***
Mr. Bean: You want to pay attention to Harmonyx because this model is completely different than anything else in the pharmacogenomics world. It is very disheartening to see what has passed for genetic testing in the market. First of all, U.S. citizens paid for roughly 95 percent of the genetic information that is available today. Many of these companies act as if they have some proprietary right to this information or that they have some secret data. They are really misleading people. Most of this research and discovery came through NIH-funded laboratories and research projects. Millions of dollars were invested in charities and research foundations around the world to fund the discovery of which drugs go through which pathways and the genetic markers that are involved. As taxpayers, these patients should have this information. They paid for it — they have a right to it. Harmonyx is not interested in trying to find a way to bill as much as we can on a patient event. We are trying to find a way to bill as little as possible to make patient information available. That makes us very different than every other genetic testing company in America. There is a dirty little secret about all these companies. They are charging $3,000, $4,000 or $5,000 per test, and they are going to provide a book of information. The issue with that is that does not cost them anywhere near that much money to perform these tests. You will find that out if you ever fill out one of their financial assistance request forms. They will settle a $3,500 bill with you for $150, but you have to know how to do that. You have to understand the game — they are going to soak every insurance company they can for as much as they can, because they know they are going to have to give some of these away at $150. Their costs are well below $150, and that is why they picked that number. That is the only time that patient will ever get that gene paid for. If your internist tests a few dozen genes and the lab bills your insurance company, five years from

now when you are at your urologist's office and he or she prescribes a drug that goes through one of those pathways, you might never know. If the urologist tries to order that test for you again, your insurance company is not likely to pay for it, since you are the one who really needed that test one time. Laboratories are taking giant pictures of people's genomes because they can stack up codes and try and get paid more by insurance companies, whether the patient is taking all those drugs or not. We just think that is wrong. Patients should have information that is guided by the latest clinical research and published evidence, and delivered to their pharmacists and treating physician in actionable and simple ways. In addition, the patient should not have to pay hundreds or thousands of dollars for that information. It should be inexpensive so every American can afford this information if they want to know. Americans have already paid to discover this information; the broken healthcare system and companies trying to exploit its weakness should not force them to go broke trying to pay for it all over again.

Interview conducted by: Lynn Fosse, Senior Editor, CEOCFO Magazine

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