BIGFOOT BIOMEDICAL:

Solving the Puzzle of Diabetes Device Interoperability and Payor Value

>>Tracy Schaaf

Bigfoot Biomedical is breaking new ground in reducing the pain points in diabetes management with a simplified monthly subscription, one prescription, and one copay service model for its integrated insulin delivery platforms, to treat insulin-dependent type 1 or 2 diabetes.

More than 9% of the US population, or about 30.3 million people, has diabetes. Of those, current insulin users total roughly six million, while another nearly six million with type 2 diabetes could benefit from insulin therapy. And, according to the Centers for Disease Control and Prevention (CDC), diabetes is one of the eight most costly chronic diseases in the US, and its incidence around the world is increasing.

To add to this growing burden, insulin therapy is challenging, requiring people with diabetes to constantly measure, calculate, and plan ahead in order to metabolize carbohydrates and essentially stay alive. It's not unusual for patients to be managing several devices including insulin pumps or pens and supplies, a blood glucose monitor, and a continuous glucose monitor (CGM), all sold by different companies, along with software apps, and to be juggling 10 or more different prescriptions—all reimbursed separately with different copays—to cover all of the products and supplies that they need. This cumbersome and inefficient disease management model is ripe for an innovative approach.

One company looking to completely rethink how insulin-dependent diabetes is managed by patients, caretakers and providers—and reimbursed by payors—is five-year-old **Bigfoot Biomedical Inc.**, headquartered in the Silicon Valley, in Milpitas, CA. A pre-commercial company, Bigfoot is developing a digital drug delivery platform intended to support and simplify insulin delivery across all populations with insulin-requiring diabetes—from those just starting on injections to the most intensive infusion pump users. The company plans to commercialize its systems not as individual components, but rather as a first-of-its-kind, one-stop-shop, bundled subscription model—providing customers all the necessary supplies with a single prescription/insurance claim and order. This pioneering, integrated device model represents a significant shift from the historical diabetes durable medical equipment (DME) landscape, and it is also breaking new ground with FDA and payors.

"Today, fragmentation is a big barrier to people being able to use [diabetes] therapy effectively. What Bigfoot is doing is essentially taking all these pieces and making them a whole," says the company's co-founder and CEO Jeffrey Brewer, in a recent interview with *Market Pathways*. "We're creating a system of licensed components and components that we own ... we're integrating them, packaging them together, and pricing them as a service for a subscription fee, on a monthly basis per member per month, that dramatically simplifies getting all the components that patients need in order to take insulin on a daily basis."

JEFFREY BREWER

According to a June 24th research note from Canaccord Genuity, "Thoughts on Diabetes Post-ADA: Technology on the Cusp of Catching Up to Patient Preferences," Bigfoot's first-of-its-kind model potentially reduces the barriers to entry for new patients, given they no longer need to manage insurance claims for multiple items. More importantly, it positions the company to offer payors risk-based pricing models across the continuum of care.

Bigfoot anticipates FDA regulatory clearance and a commercial launch of its first system, the Class II *Bigfoot Unity* system for individuals on multiple daily injections, in 2020 (see *Figures*). The device is currently in development and Bigfoot is in active discussions with FDA. This is to be followed by its closed-loop *Bigfoot Autonomy* automated insulin pump system, which received the FDA Breakthrough Device designation. This will likely be a Class III PMA device and require a pivotal clinical trial (details to be determined) and subsequent regulatory approvals. The company anticipates launching *Autonomy* in the 2021-2022 timeframe.

BIGFOOT AUTONOMY

BIGFOOT UNITY

A Pathway Forged by JDRF and the FDA

Bigfoot's bundled device approach is providing some challenges as well as opportunities for its pathway through the FDA. "We're very happy that there's been substantial regulatory innovation in the FDA divisions with whom we work ... there's now a pretty robust pathway through the regulatory process for both our *Bigfoot Unity* and *Bigfoot Autonomy* systems. That's been a great journey for us," says Brewer.

"FDA, the Diabetes Branch within the Division of Chemistry and Toxicology Devices in particular, is really open to thinking about the best way to get technology to the market and is thinking about interoperability," adds Kate Lee, Bigfoot's VP of Regulatory and Quality, in a recent interview with *Market Pathways*. "We will continue to leverage that openness and find the least burdensome path forward for us to get these products out quickly, and to be able to iterate on them quickly, as well." Lee's longtime experience in device R&D engineering, and later, regulatory affairs includes working for the pioneering minimally invasive cardiac surgery company, Heartport Inc., as well as medical robotics maker Hansen Medical Inc., founded by Fred Moll, MD.

Bigfoot's journey through the FDA is closely tied with the nonprofit JDRF (formerly called the Juvenile Diabetes Research Foundation), along with supportive key officials at FDA. Brewer, prior to co-founding Bigfoot in 2014, served as the CEO of JDRF (a Bigfoot investor via its JDRF T1D Fund as of early 2017), where he worked with FDA to help pave the original pathway for closed-loop diabetes management technology. (*See "JDRF's T1D Fund: Can Venture Philanthropy Spur Diabetes Device Innovation?"* MedTech Strategist, *August 22, 2019.*)

Brewer has long been involved in the diabetes advocacy and research community, based on his touch point with the disease; in 2002, his son Sean was diagnosed with type 1 diabetes. In 2010, Brewer collaborated with the FDA's then-Commissioner

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>
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Margaret Hamburg and Center for Devices and Radiological Health (CDRH) Director Jeffrey Shuren, MD, along with JDRF's Chief Mission Strategy Officer, Cynthia Rice, and the current President and CEO of JDRF, Aaron Kowalski, PhD, to drive regulatory innovation and define that pathway—from a patient's perspective. Brewer says that Shuren was the one who suggested to JDRF to propose regulatory guidance to FDA.

"We were trying to put in place some basic infrastructure that all the different companies could be able to leverage in getting innovation to patients sooner," he tells *Market Pathways*. "It's really exciting to be able to, as a company, take advantage of that now and to work with some of the same people that helped to set it up. It is only possible because of all the work that JDRF and people like Cynthia did, and all the volunteers that support the organization who lobbied to Congress, and then the executive branch, and even the FDA directly."

That's what led to the first publication of guidance for automated insulin delivery systems in 2012. "I was proud to be a part of that, and that is certainly an example of how Jeff [Shuren] has been a key player in getting the ball rolling both in leveraging patient advocacy and the perspective of the patients in terms of the FDA's thinking, and also to actually promote the kind of standardization and regulatory pathway clarity that's necessary to bring these kinds of products to market," says Brewer.

More recently, JDRF has worked with FDA to establish regulatory pathways for interoperable diabetes devices, so a pump or a CGM can be used with different systems rather than FDA having to approve each individual pairing. (*See, "Interoperability and Reimbursement for Diabetes Devices: An Interview with JDRF's Cynthia Rice," this issue.*)

Bigfoot's Integrated, One-Box Solutions

In designing its systems, Bigfoot looked at the broad range of patients impacted by both type 1 and type 2 diabetes: a disease that affects every age, every income level, education level, all different personalities, levels of disease engagement, people seeing primary care providers versus endocrinologists, and those covered by public insurance options versus private insurance. These situations all present very different problems to solve, and so the company's overall system design needed to bridge across all those different constituencies. This took a lot of thought and planning upfront, says Brewer.

Bigfoot's *Unity* system, which will support individuals using multiple daily injections, comes with devices that support the capturing of the dosing information from insulin pens, one for a long-acting insulin, one for a mealtime insulin, and integrates **Abbott Laboratories Inc.**'s *FreeStyle Libre* real-time CGM. Its *Autonomy* system, which is also designed to integrate with Abbott's *FreeStyle Libre*, will incorporate a proprietary automated insulin pump for adolescents and adults (and children, if regulators allow) with type 1 diabetes.

As part of its collaborative agreement with Abbott, announced in July 2017, Bigfoot is able to use Abbott's next-generation glucose sensing technology. (*See "Bigfoot and Abbott: A Match Made in Heaven? An Interview with Bigfoot Biomedical CEO Jeffrey Brewer,"* MedTech Strategist*, July 2017.*)

The *FreeStyle Libre 2*, which includes Bluetooth and blood sugar alarms, was approved in Europe in October 2018, and FDA approval is expected in the coming months. That will be the sensor that Bigfoot will use in the future initial market launch of its *Unity* system (and later, the *Autonomy* system).

Abbott is filing the *FreeStyle Libre 2* as an integrated continuous glucose monitoring (iCGM) system with the FDA. The new iCGM label is given by the FDA for integrated CGMs which are designed to work in an interoperable fashion with insulin pumps and automated insulin dosing systems for closed-loop insulin delivery systems. Currently, the *Dexcom G6* from **Dexcom Inc.** is the only CGM system that has gained iCGM status from the FDA, in March 2018.

A handful of additional business partnerships support compatibility and cover the other system components for which Bigfoot will serve as a vendor. This January, the company entered into a non-exclusive agreement with **Eli Lilly & Co.**, in

which Lilly's insulin products will be compatible with Bigfoot's systems, though Bigfoot's supply service will not include the insulin itself. (*See "How Eli Lilly is Leveraging Digital Diabetes Device Technologies to Help Grow its Future,"* MedTech Strategist, *January 2019*.) Then in February, Bigfoot announced a commercial supply agreement with **Owen Mumford Ltd.** to support inclusion of the latter's family of *Unifine* Pen Needles into Bigfoot's connected injection system subscription supply bundles. In August, Bigfoot announced an agreement with Pittsburgh-based Allegheny Health Network (AHN) to further develop Bigfoot's *Unity* insulin delivery wireless platform. Bigfoot will work alongside AHN endocrinologists and primary care doctors to refine *Unity*'s clinical workflow features. Bigfoot is also open to opportunities to partner with other sensor or component companies as the market advances (including, possibly, implantable sensors).

"We're designing all these pieces to fit together and the software that they work with to be seamlessly tied to the different hardware pieces," says Brewer. "It all comes in one box for a holistic onboarding experience. The training is done through a digital learning app on a smartphone." Software will capture all the patient data and leverage that for patient use, as well as streaming up to the cloud for clinician insights, or payors for use in population health management. "We see ourselves as an integrator of master-breed components that we'll package together and integrate to make them into a useful system," says Brewer.

A Subscription Model Designed to Save Payors Money

In Brewer's view, the next big challenge is moving payors towards a framework where they embrace integrated device solutions that may be composed of products that they currently reimburse individually, to support a total patient solution. And, Bigfoot's reimbursement model seeks to solve problems that payors have struggled with (e.g., the sheer number of prescriptions that diabetes patients currently require for durables and disposables, correlating to multiple contracting relationships that a payor has to maintain), and also address the huge amount of waste in the system, he says.

"A lot of the diabetes supplies have expiration dates, and you end up throwing it away if you don't use it. I know this from personal experience," says Brewer. "Everybody who has a kid with type 1 diabetes, in your kitchen you have a storage closet where you end up doing inventory management for medical device companies. You have all these infusion sets and reservoirs for insulin pumps. Literally, bundles of lancets which come in a box of 100 that people use two or three a year—you're constantly throwing out all this waste. Payors really feel this fragmentation, which is distributing responsibility across all of these parties, which means none of them is responsible for any outcomes, and there is a lot of potential for waste and things that are over-prescribed and not used," he continues.

Another challenge that Bigfoot is addressing is the high cost of going on insulin pump therapy, and the inflexibility of the current reimbursement system. Under traditional models, this cost (up to $9000 for the pump alone, depending on the manufacturer and other factors) is usually amortized by insurers over a number of years, which locks the patient into a technology that "quickly becomes out of date, if it wasn't already out of date," according to Brewer. The pump cost needs to be paid up-front by the payor, along with a 10% or 20% copay by the patient. "Then, that pump could be placed in a drawer the next day and never used, or the patient could switch insurance plans, as they do on average every two years."

Conversely, the month-to-month nature of Bigfoot's subscription model could provide patients with updated technologies more quickly. Also, a selling point that Bigfoot will make to payors is that more accurate insulin delivery via automated insulin pumps could mean fewer expensive emergency room visits caused by dosing error-induced periods of dangerous high or low blood sugar.

"With our model we're saying, 'Okay, we're not going to charge you on a per consumable basis,'" says Brewer. "We're going to give you one fee per person that's going to be fixed on a monthly basis. Some people will use more test strips than others, but we'll deal with that as our problem. We'll do the inventory management, because we have a connected system that knows how much people are using and is it going to dispense it to them, and the amount that's necessary to support their therapy."

Bigfoot's reimbursement model is "No upfront payments, no price variability." "It's only on a monthly basis you have to pay and if you don't see value in it going forward, you can stop using it. So that transfer of risk is really solving a bunch of problems for payors. The folks we've talked to are very excited to be able to take advantage of that efficiency," says Brewer.

Thus far, payor response to Bigfoot's planned offering has been very positive. "We have discussions ongoing with payors, and we're laying as much groundwork as we can for pilots that we're going to do upon clearance of our first generations of *Bigfoot Unity*," says Brewer. "We're discussing pricing and the contracts that will cover reimbursement." The company is finding that the payors who understand and have the greatest demand for this kind of offering are the integrated delivery networks. They're looking for solutions that cover the healthcare economic side, and want to make sure that they have visibility through connected systems to patient adherence and quality of life, he tells *Market Pathways*.

Interoperability, Reimbursement, and Diabetes Devices: An Interview with JDRF's Cynthia Rice


CYNTHIA RICE

Cynthia Rice is chief mission strategy officer for JDRF, which is the leading global advocate for treatments and a cure for type 1 diabetes. She recently spoke to Market Pathways *about important FDA developments in the push toward diabetes devices that can be used together seamlessly no matter the manufacturer, and she spotlighted reimbursement challenges these devices are facing.*

>>David Filmore

Diabetes devices are treading new regulatory ground with recent approvals of interoperable devices—the *Dexcom G6* continuous glucose monitor (**Dexcom Inc.**) and the *t:Slim X2* (**Tandem Diabetes Care**)—and a submission in the works for an interoperable algorithm from health-tech non-profit start-up **Tidepool**. JDRF's Cynthia Rice discusses the interoperability efforts, as well as reimbursement challenges in the space with *MTS Market Pathways*.

>>***Market Pathways: The big trend recently has been toward FDA approval of interoperable diabetes devices, including continuous glucose monitors and insulin pumps, as an alternative to choosing between closed artificial pancreas systems made by an individual manufacturer. How significant is that, and what has been JDRF's role?***

>>**Cynthia Rice:** It is an important area and one that we've been encouraging for some time. JDRF started the artificial pancreas initiative more than a decade ago, back when continuous glucose monitors were first being reviewed by the Food and Drug Administration. Our scientists saw some early CGM data and thought, "Wow, this data could really be used to drive insulin delivery and is anyone making that happen?" JDRF founded the artificial pancreas project in late 2005 to basically fill the scientific and policy gaps, and accelerate the availability of an artificial pancreas system.

And we worked very closely with the Food and Drug Administration on what became their artificial pancreas device system guidance, in 2012. We had funded a whole series of academic centers that had developed algorithms and were testing them in academic settings and those were ready to move out of academic settings, but FDA needed to get comfortable with that, so we worked with them on the pathway for those clinical trials and also the product approval. That's really the pathway that the device companies have been using in developing their automated insulin delivery systems.

Then more recently, we've been working closely with the FDA on the pathway for interoperable systems. We launched what we called our open protocol initiative in 2017, which is focused on helping people with T1D safely connect their preferred devices—even if made by different manufacturers—to create and customize a diabetes therapy system that best works for them. One of the pieces of that was a meeting we hosted of all the stakeholders that included the FDA, about the pathway for interoperable devices. At that meeting they announced the pathway for the continuous glucose monitor, which was the first device that was approved under an interoperable pathway. They've now since approved an insulin pump.

And currently, **Tidepool** is preparing to submit to FDA an algorithm for an interoperable system.

>>***So what Tidepool is working on is the third part. We have the two pathways established for the insulin pump and the CGM***

and now, the third part that needs to have a pathway for it to be interoperable is the algorithm that connects those two elements, right?

Correct, and more than one brand can become approved. At the moment, we have one CGM and one pump.

>>Right, and now new interoperable CGM and pump devices could use 510(k)s to reach the market.

Yes. Tidepool, which JDRF is funding, is basically taking the *Loop* algorithm and doing the work to submit it to FDA for review. And one of the exciting pieces of news that came out at the ADA's 79th Scientific Sessions [in June] was Tidepool announcing that in addition to Dexcom being part of their new *Loop* platform – which people expected based on what Dexcom had done before – now Medtronic is joined into the interoperable world and is going to connect with a future version of their pump, to make it available to be used with the Tidepool *Loop*.

>>What are the key benefits of FDA-approved interoperable systems and what were the main regulatory challenges to overcome to reach the point we have?

The thing to keep in mind is, from the perspective of the type 1 diabetes community, what interoperability brings is the ability to innovate more quickly. The first premise is that good algorithms and automated insulin delivery, these diabetes devices, these artificial pancreas devices, can achieve better glucose control, then people can by manually calculating.

Automation that is obviously tested and secured, is good for glucose control. But the reason interoperability matters, is that you can, first of all, choose the versions of a pump and sensor that work best for you, and these are devices that people live with 24 hours a day, seven days a week. Different people have different needs... and different challenges.

So, it might matter to them what kind of pump they're using, what kind of sensor they're using. If you have an interoperable system, if a new sensor becomes approved, you can keep the pump you have, keep the algorithm you have, and add in the latest sensor.

It speeds up the availability of innovation, because people don't have to wait until the entire system, with all of its parts, is approved as one system. That's the real advantage to it.

In the big picture, I think, FDA, and JDRF, want to make sure software is in place that enables a secure communication between devices. I think the other issue is the relationship, if there's an adverse event, in how the reporting is done and that's something that needs to get considered and reviewed and planned out in advance.

>>What are the next steps, priorities for supporting diabetes device development?

There's great innovation going on in terms of the diabetes devices and the regulatory pathway that's enabling interoperable devices and we expect there to continue to be more innovation in the devices themselves.

But we're focusing a lot of attention on the reimbursement landscape, because there are still challenges that make it difficult for people to access some of these technologies. One example of this is that currently both Medtronic and Tandem have automated insulin delivery systems on the market that contains glucose monitors to adjust insulin dosing. They are covered by private insurance plans, but Medicare is not yet, so we've been working closely with them to try to get those systems covered by Medicare.

At the same time, there's a challenge in the private marketplace, where nearly all the major private health plans are covering all FDA-approved insulin pumps. But UnitedHealthcare, which is the largest plan in the country, has limited the choice of insulin pumps. Instead of covering whichever pump the physician and the person with diabetes decide is the best to meet their priority clinical needs, they've limited choice by no longer covering all brands of pumps.

JDRF and the entire type 1 diabetes community has been advocating to UnitedHealthcare to change this policy. Over 140,000 emails have been sent to UnitedHealthcare and there's a very active set of clinical organizations, like the American Association of Diabetes Educators and the American Association of Clinical Endocrinologists that are also weighing in with the fundamental message that the choice of diabetes device, which is so important to people being able to maintain good control and have good health, should be made not by the insurance company but by the person with diabetes and their doctor.

>>Is that linked to Medtronic and the agreement between Medtronic and UnitedHealthcare? Is that the issue you are referring to?

Yes.

>>I believe it is tied with a risk-sharing agreement that Medtronic has with UnitedHealthcare, correct? I'm curious as to the impact of that sort of arrangement, where they're collecting data and offering rebates based on outcome.

"WE'RE NOT AGAINST OUTCOME-BASED PAYMENTS. OUR CONCERN IS REALLY AGREEMENTS THAT LIMIT CHOICE, SUCH AS IN THIS CASE WITH UNITEDHEALTHCARE."

—Cynthia Rice

Medtronic has inked risk-sharing arrangements with UHC and other payors. (See "Medtronic and Blue Cross and Blue Shield of Minnesota Partnering to Impact Diabetes Outcomes," Market Pathways, June 2019.) Are those things distinct issues – the risk-sharing agreements with payors versus having the preference item that JDRF is advocating against?

In this case it is tied together, but it doesn't necessarily have to be. We're not opposed at all to insurance companies and device manufacturers developing payments that are tied to outcomes. If a given person does better on a certain device, the manufacturer would get paid more money by the health plan. There's nothing wrong with that. We're not against outcome-based payments. Our concern is really agreements that limit choice, such as in this case with UnitedHealthcare.

Consider a person with diabetes, that is a 50-year-old with type 1 diabetes who has had type 1 diabetes for 40 years. Their number one clinical issue may be that they need to get more exercise, because people with type 1 diabetes have an increased risk of cardiovascular disease. It may be that they need an insulin pump that works for their current exercise regimen. They may want a pump that's waterproof or a pump that enables them to do the kind of exercise they want to, and different pumps have different form factors and they're not all interchangeable.

Different people have different challenges that they're trying to address in their clinical care around type 1 diabetes, and that's why having options really matters. It's also why the interoperable pathway is so important, because that enables people to put together a system that best meets their needs.

>>You mention emails and letters to UnitedHealthcare. Is there any use also engaging with Medtronic on the matter?

Of course we want UnitedHealthcare to cover Medtronic's system, we just want them to cover all of the systems. It's not that we oppose them covering Medtronic's system. In general, we expect, whether it's a device company or a pharma company, for them to try to become the preferred provider. That's in their own economic interests, but, fundamentally, it's the health plan's decision about whether they entertain such ideas. UnitedHealthcare is the real decision-maker here.

>>On the Medicare side, I would say CMS recently has been signaling and forging policies that seem more specifically focused on access to medical innovation and medtech innovation, in particular. Is that something you're finding in practice when dealing with the agency?

We were really pleased last year when CMS reconsidered an earlier decision and provided more access for continuous glucose monitors. As you may know, some continuous glucose monitors can display data on people's cell phones. And the reason why this is significant, in particular, is that it's not just for the person themselves to be able to use their phone (which is helpful), it's also that the data can be shared with family members or other loved ones in order to respond in an emergency situation.

They can see if someone has a severe low blood sugar that would make them unable to help themselves. Many family members of people with type 1 diabetes have called 911 to send someone to their college student's dorm room to revive them when they've had a severe low blood sugar. These sorts of features that share data are an extremely important safety component.

The initial CMS decision had been that, well, if it's something that can be used with a cell phone it's not durable medical equipment, because if you can use it with a cell phone, you don't need the transmitter. JDRF was really pleased that CMS reconsidered this decision, looked at it more holistically and decided that the additional use of a cell phone in a situation like that shouldn't bar CMS coverage, which in this case is relevant for older people with type 1 diabetes who may have family members that they don't live with, but who are helping monitor their safety with this disease.

CMS took a big step forward for innovation in that decision and that's why we're hopeful in working with them on the remaining issues to advance access.