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VIRTUAL REALITY: The New Game In Mental Health Care To Improve Outcomes

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A growing number of researchers and companies worldwide are exploring the power of virtual reality (VR) and gaming technologies for developing innovative solutions to help clinicians diagnose, treat and manage some of the most challenging behavioral conditions. Researchers believe that the use of VR technologies is rising for health care applications, fueled largely by technological innovations, such as the **Oculus** *Rift* headset, which are making VR therapies more affordable. This article takes a closer look at how VR is being used for exposure therapy at the U.S. Department of Veterans Affairs to help soldiers recover from post-traumatic stress disorder (PTSD), for cognitive behavioral therapy at **Akili Interactive Labs Inc.**, which plans to file for US FDA approval for its *Project: Echo* to treat pediatric attention-deficit hyperactivity disorder (ADHD) and by researchers in the Netherlands to prevent relapse in patients recovering from mental illness. We'll also address limiters and growth opportunities and other projects in the works in this trending space.

BRAVEMIND

One of the most promising and widely used VR technologies today is an interactive VR-based exposure therapy tool to assess and address PTSD in soldiers, which was developed at the University of Southern California Institute for Creative Technologies.

Bravemind is designed to recreate the most traumatic experiences that patients encountered during combat situations in the virtual world. It uses a VR head-mounted display, directional 3-D audio vibrations and even smells and exposure therapy, where patients, guided by a therapist, are taken back to the memory of their trauma over and over until their triggers no longer produce anxiety.

Peter Tuerk, associate professor of Psychiatry and Behavioral Sciences, Medical University of South Carolina, and director of the PTSD Clinical Telehealth Team Charleston, VAMC, told *Medtech Insight* psychiatrists call this process habituation, where through repetition, the bad memory is slowly robbed of its power.

"We need to process emotional information and the ability to create file folders to organize new information," Tuerk explained. "It's not necessarily that the event was so stressful, it's that the event is so emotionally different from anything we've experienced that we

WATCH

Click here or visit MedtechInsight.com to check out videos of the Bravemind VR technology and a TEDxASB talk on VR. http://bit.ly/2rKMuCV

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FROM THE EDITORS OF: **THE GRAY SHEET, CLINICA, START-UP** AND **MEDTECH INSIGHT NEWSLETTER**

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A stronger supply chain
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Vendors of eight critical manufacturing processes will have to be accredited to new industry-managed supply-chain oversight program MedAccred if they want to do future business with Stryker Corp. – and other big medical device firms will likely follow suit. And now US FDA has taken notice.

Device Debuts
http://bit.ly/2tT08Zy

This edition of *Medtech Insight*'s Device Debuts covers the innovative devices introduced into commercial markets since mid-May, including Medtronic's long-awaited launch of the *MiniMed 670G Hybrid Closed Loop* insulin pump system, OrbusNeich's entry into the US coronary dilation catheter market, and Shockwave's *Lithoplasty* system for treating calcified peripheral arteries.

Invacare closes Chinese plant
http://bit.ly/2tO4wrU

US home medical device giant Invacare shut down its factory in Suzhou, China – once considered to be one of its most important markets – underscoring increasing challenges facing multinational device firms in the country.

"Smart" ICU tubes
http://bit.ly/2uM7WZz

Israeli start-up ART Medical has raised $20m to commercialize its *smARTrack* "smart" feeding tube and monitoring platform that detects and prevents medical complications in intubated patients.

Device Week
http://bit.ly/2tK8C4A

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COMPANIES

POLICY & REGULATION

Security Firm Confirms 'Petya' Has Affected Medical Devices

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Over the past week security experts around the world have scrambled to contain the so-called "Petya" worm that has severely crippled corporations and at least one reported health-care system in Pennsylvania. Now the security company TrapX confirms to *Medtech Insight* that at least one other hospital in the US has been affected by the malware, which has affected legacy medical devices at the facility.

Ori Bach, TrapX's VP for products and marketing, says they have a hospital client in the US that has been infected by the Petya worm, which has prevented medical devices in that facility from functioning properly. He declined to be more specific about the attack, but says the problem isn't really about those specific medical devices; rather, it's an industry problem.

"The hospital is an enterprise; you've got workstations, servers and electronic medical records systems that are using both up-to-date operating systems, and by this point [after the recent "WannaCry" ransomware attack] they're patched," he said. "The medical devices that sit on medical networks, your MRIs, your CTs, your blood-gas analyzers – that's where the problem is."

Since the latest version of the Petya malware was unleashed last week, companies around the world, including Heritage Valley Health System in Pennsylvania, have reported being severely crippled by the attack. This is the first confirmation that medical devices are being adversely affected by the worm that originated in the Ukraine. *(Also see "Expert: New Ransomware Has Potential To Shut Down Medical Devices" - Medtech Insight, 28 Jun, 2017.)*

The Petya malware is an updated version of the Petya worm unleashed last year, but this time malicious hackers have incorporated elements of the recent WannaCry ransomware using the Eternal Blue exploit and an open-sourced Windows credential scrapping tool called *MimiKatz*. According to Bach, it's the use of the latter which is the biggest sign of escalation in the recent attacks because MimiKatz allows the malware to extract plaintext passwords, hashes, PIN codes and kerberos tickets from memory to automate the process.

For now, it seems the current variant of Petya has been contained and is on the decline, but based on the way WannaCry was released and how Petya spread, Bach worries that the worst is yet to come.

"Petya – unlike WannaCry – has some additional features built into it that actually make it more dangerous and self-spreading, which is the ability to scrap credentials," he said. "If it has already penetrated in one place using Eternal Blue, at that point that device is now an entry gate to the network; it's scrapping the credentials of the device and using it to connect to other devices. So, once it has breached it can spread to devices that are already patched."

TrapX has recorded seeing the latest Petya variant at certain hospitals and manufacturing facilities that are running older versions of Windows operating systems, including Windows 2000 and Windows XP.

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While device companies have long-advised hospitals to buy newer versions of products that don't rely on legacy Windows operating systems and are patched, many hospitals have refrained from doing that because they can't afford the updated devices.

After WannaCry, hospitals realized that the worm had the potential to shut down their floors if their systems were not patched – and according to TrapX, all of the hospitals they've talked to did exactly that. But then along came Petya and changed the equation. The worm hit medical devices that were unpatchable and allowed it to spread to even patched devices and scrapped computers for credentials to access other computers.

While device companies have long-advised hospitals to buy newer versions of products that don't rely on legacy Windows operating systems and are patched, many hospitals have refrained from doing that because they can't afford the updated devices. It's this problem with unpatched devices that is causing the biggest headache, according to Bach.

"It's not just about the medical devices being compromised, but medical devices being breached, and that they can be used to jump to other areas in the network," he added.

So far TrapX has seen the worm hit hospitals and mostly smaller health-care clinics that have smaller IT staff to handle such attacks. But on the positive side, they have not seen the worm attack patients at home.

"People who use [medical devices] at home are less likely to be connected to a larger network, so maybe they were safer because they were small and not significant enough," said Bach. He also

says devices that connect to private computers at home have a lower threat level because those computers tend to have self-updating antivirus programs.

While governments were already on heightened alert after WannaCry, Bach says they are even more serious about what chaos such malware can cause with Petya. But, he added, the big problem is with manufacturers and hospitals that need to step up and make major investments to prevent such attacks from severely hurting their businesses and patients.

"They are currently the slowest ones in the pack," said Bach. "You don't need to be the fastest one in the pack, but you can't be the slowest one."

So far Bach confirmed what other experts have found, which is the latest Petya attack seems to have originated with an accounting software in the Ukraine called *MEDoc*, and the way the attack was conducted suggests it is part of the ongoing war between the Ukraine and Russian separatists supported by the government of Vladimir Putin.

"Obviously, whoever decided that was the original attack vector was focused on the Ukraine," said Bach. "Also, our analysis of the malware code found out that one of the variants – one, not all – has a condition in it not to work on computers that use the US English keyboard."

Based on that information, Bach and his associates theorize the attack was not just primarily aimed at Eastern Europe with the intent of extracting money, but was also aimed at creating mayhem and exerting political pressure.

"Think about this as biological warfare," said Bach. "You develop a certain agent – that's easy – but how to control that is less easy."

Bach said with Petya the intention seems to be to have a longer-lasting effect than WannaCry, but in a localized area in the hopes of not eliciting a response from Western countries such as the US. He says Western countries have the resources to not just come up with defensive solutions faster, but also have the capability to go on a counterstrike against the attackers with their own cybersecurity tools, which may be why the worm seems to try avoiding attacking system in the West.

And, because WannaCry came only weeks before the complex Petya, things are about to get a whole lot worse, he said.

"We believe WannaCry was a test-run for Petya," said Bach. "There were elements of WannaCry that were puzzling at the time it came out, such as having a kill switch, which isn't typical modus operandi for ransomware attackers," Bach said.

Now the use of the kill switch, the low ransomware payment demands and the limited threat area seems to make sense, but shows things will likely escalate.

"You see WannaCry coming out using a certain framework with certain capabilities stolen from the NSA [US National Security Agency], and suddenly you're seeing this new variant with the same base code and concept, but with additional capabilities and much stronger," said Bach. "This is an arms race. And there's definitely going to be more of the same."

So far it seems the people who created WannaCry and Petya are slowly growing their attack vector. While WannaCry only used the Eternal Blue vulnerability, Petya uses that and the MimiKatz tool. Bach also says Petya has moved from simply trying to dupe victims with phising emails to infect their computers to using trusted software updates, such as what happened with MEDoc, to get people to install the malware, which is far more effective.

Maybe the biggest concern Bach has with how things are evolving with these attacks is trying to figure out what is motivating the attackers. Initially it seemed these were nothing more than ransomware attacks, but considering how little money the attackers are making off with, it may be that their ultimate goal is to simply create mayhem.

"Mayhem is more problematic than money because that means ... if [the hackers] don't want you back in operation, that could mean a much longer recovery process and potentially critical medical processes are being disrupted," said Bach. "That's a bigger problem and much bigger threat."

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START UP SPOTLIGHT: Hemonitor, Continuous Bloodflow Monitoring With Ultrasound

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The crucial need for a less-invasive method of measuring cardiac output has long been the focus of development for medical device companies. The current gold standard, thermodilution, involves inserting a thermistor-tipped catheter into the pulmonary artery via a peripheral vein. While effective, this technique of measuring cardiac output is invasive and not without risks. The high cost associated with the procedure also restricts healthcare professionals from measuring the output of every patient entering ICU or sedated in surgery.

One Israeli start-up, **Hemonitor**, is developing a new non-invasive solution - a hemodynamic monitor that uses a wearable ultrasound patch technology for continuous monitoring of blood flow. "There have been several attempts to solve the need in clinical practice by doing indirect non-invasive measurements of other parameters to assume what the cardiac output is but there is still no direct solution which is non-invasive or continuous," Hemonitor CEO and co-founder Tom Mayblum told *Medtech Insight*.

The concept for the technology evolved from research projects led by Mayblum and his co-founder Samer Toume. Both were biomedical engineering graduates of the prestigious Technion Israel

Institute of Technology in Israel. Hemonitor initially envisioned using ultrasound technology for monitoring internal bleeding and began to meet with physicians and directors of ICU trauma. "It was clear that our technology would not solve this but we did discover a different need which was hemodynamic monitoring for ICU patients or patients under surgery where there is a need to continuously monitor the blood flow or the actual volume of blood which flows by the beat or by minutes," said Mayblum.

After validating a clinical need for the solution, the pair solidified their business plans through the Technion's Accelerator entrepreneurship program for pre-seed and seed companies. In March 2016, the start-up was the first company to be accepted by **MindUP**, Israel's first digital health incubator and joint partnership between Medtronic, IBM, Pitango Venture Capital, Rambam Hospital and the Impact First investment fund. As part of the two-year program, the company is supported through the stages of development, clinical studies and regulation.

By the end of 2017, Hemonitor aims to have completed testing and development of a fully functional autonomous, continuous and non-invasive ultrasound-based system for patient monitoring. "We call it autonomous because – in contrast to standard ultrasound devices which are manually held with a probe that is manually held and requires a trained physician to find the correct orientation with the probe and find the blood vessel and image etc. – with this device, it has the ability to search for the vessel and track the movement of the vessel, so it keeps the vessel in focus the whole time. Then once its focused on the vessel, it can track the movement of the vessel and get the blood flow measurement and the velocity of the blood flow."

The device includes several components including the hardware itself – a patch attached to the patient and connected to a smart processing system with artificial intelligence and machine learning features. The algorithms automatically detect and measure blood-flow parameters, with the ability to apply ultrasound imaging continuously for accurate measurement.

"Continuous measurement is a crucial need because nowadays if you go to ICU you see patients monitored for vital signs such as blood pressure, oxygen saturation and so on but it doesn't tell the whole story and their not monitored for cardiac output or stroke volume," Mayblum said. "The same patients that will present with normal parameters in blood pressure can develop shock because their cardiac output is extremely low or extremely high. They could be septic, have internal bleeding, dehydrated or get heart failure. All these cases you'll have abnormal cardiac output but may have normal blood pressure."

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Contact: Tom Mayblum

Industry Segment: Continuous patient monitoring

Business: Autonomous ultrasound patch for non-invasive and continuous hemodynamic monitoring

Founded: 2016

Founders: Tom Mayblum, Samer Toume, Avinoam Bar-Zion

Employees: 2

Financing to Date: $700,000

Funding: MindUP Incubator (a joint venture of Medtronic, IBM, Pitango VC & Rambam Healthcare Center)

Board of Directors: Dan Shwarzman, Dan Rapaport, Alex Silberklang, Samer Toume, Tom Mayblum

Advisory Board: Avinoam Bar-Zion, Lior Teitelbaum

Hemodynamic monitoring for ICU patients is Hemonitor's initial focus but the company is recognizing the potential to adapt the device for other applications in future. "With the type of technology we are developing, there are many other clinical applications which we think will be relevant using an autonomous ultrasound patch that can detect an object or an organ and continuously monitor it," Mayblum said. "We've heard and met with other potential partners that MindUP introduced us to and who are interested in other clinical applications such monitoring organ, kidney, liver function or monitoring tumours."

As engineers turned entrepreneurs, Hemonitor is finding the MindUP incubator a nurturing environment to face the many challenges of getting a start-up off the ground. "Being part of the MindUP incubator is such a great opportunity for us as from each of the partners, we get extreme added value," Mayblum said. "Whether it's engineering and business in selling/distributing medical device from Medtronic or help with the software and algorithms that we can get from IBM or with Rambam we are lucky enough to be able to clinically collaborate."

The company will begin a pilot study at the beginning of 2018 after completing functional prototype testing, safety testing and other required tests by the end of this year. "The challenge is doing everything and combining everything," said Mayblum. "I'm managing the company and learning new things every day about financing, HR related issues, safety, regulatory processes and of course the technology. As well as the expertise from the companies, MindUP is able to help us with practical day to day support like administrative and financial services. We also get advice and guidance on business, strategy and regulatory affairs all the time."

MindUP CEO Dan Shwarzman said "This is the rationale of the incubation program. As a start-up there are so many things that need to be dealt with and there are so many things we can help with so that entrepreneurs avoid making unnecessary mistakes. Every company will make mistakes but the fact that we can assist so that Tom and his team can manage this small venture and really focus is our goal. We aim to free up as much time as possible so that they can deal with developing the device and the technology which should be the main focus."

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START UP SPOTLIGHT: 4C Addresses Mitral Regurgitation With Unique 'Dome' Device

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Start-up **4C Medical Technologies** is addressing the unique problems of dysfunctional mitral valves with a device that sits in the atrium rather than within the valve annulus itself, which will hopefully allow it to last longer and avoid many of the complications faced by other minimally invasive mitral valve replacement technologies.

The mitral valve is more challenging to address than the aortic valve currently addressed by a variety of transcatheter devices because the mitral valve has an asymmetric shaped, 4C CEO Robert Thatcher explained to *Medtech Insight*. "It's not a cylinder so it doesn't fit nicely and the ventricle is generating huge forces, so having it stay in place when the ventricle contracts and pushes blood into the aorta is a big deal because it wants to just pop the valve out place."

4C's yet-unnamed device is a flexible self-expanding, laser-cut metal stent "ball" frame around a bovine pericardial tissue valve, and a fabric-sealing skirt. It can be delivered through either a trans-apical or trans-septal catheter intervention and sits entirely in the heart's left atrium, outside the annulus of the valve with only "atraumatic fixation." The ball's dimensions maximize atrial apposition while minimizing the disruption of blood flow and epithelial tissue injury. The geometry mains the systolic "flush" cycle and minimizes the risk of stasis, while the radial force of the implant keeps it in place while preserving atrial compliance.

"Those are the [solutions to] technical hurdles that we're working to demonstrate," Thatcher said. The company has already had informal meetings with US FDA to plan the first-in-human feasibility trial and will soon enter formal talks with the agency. It plans to start clinical trials in the US by the end of 2018.

Philippe Généreux, of Columbia University in New York, presented a summary of 4C's pre-clinical development at the Transcatheter Valve Therapies conference in Chicago on June 14. He said that, so far, 10 of the 4C devices have been successfully implanted in animals with no paravalvular leak or embolization. The device has proven feasible in two 30-day chronic animal tests, demonstrating good hemodynamic function with no paravalvular leakage, device migration, embolization or thrombus. Also, the animal tests have shown that the device's stent-frame endothelializes within the atrium with no occlusion of the pulmonary veins.

> "What makes us different and highly disruptive is that our device is 100% in the left atrium so it resides above the native annulus and because it's above the native annulus we don't need to be concerned about that unique shape of the mitral valve," 4C CEO Robert Thatcher says.

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Phone: 612-599-0650
Contact: Robert Thatcher, CEO
Industry Segment: Structural cardiology
Business: Minimally invasive mitral valve repair
Founded: 2015
Founder: Jeff Chambers, MD
Employees: <20
Financing to Date: About $3m
Investors: "Angels," family, friends
Board of Directors: Robert Thatcher, 4C Medical Technologies; Jeff Chambers, MD, Metro Cardiology LLC

Thatcher said that, as with the early development of transcatheter aortic valves, the first subjects enrolled in trials of this mitral technology will be people with severe mitral regurgitation who aren't candidates for surgery. They are "the sickest of the sick, who don't have an option, so this is literally life-saving technology for them," he said. Future trials will expand into patients with moderate mitral regurgitation who are not surgical candidates and then, perhaps, into patients who are surgical candidates, but who are expected to have better results with a less-invasive approach.

The Twin Cities-area, Minnesota company is has almost closed its series A round of $8m, which it raised from "family and friends" and angel investors. The B round of financing, which will be include venture capital investments along with strategic investments from other device companies will total about $15m and hopefully be closed in early 2018, Thatcher said. The company will need at least some of the round B money to support clinical trials, he said.

COMPLEMENTS, NOT REPLACES MITRAL VALVE

So far, many of the technologies developed for minimally invasive treatment of mitral regurgitation in heart failure patients rely on "really draconian fixation methods - hooks barbs and tethers to hold the valve in place," Thatcher explained. "And because of the unique shape and size of the valve, they are limited on how many patients they can treat right now

in their feasibility studies because one valve doesn't fit all and because they have these fixation technologies that go down into the ventricle, and once you start going into the ventricle, you start to create other problems."

For example, the cusps of the mitral valve are tethered to the papillary muscles by inelastic chordae tendineae, which can easily be damaged, and the scientific literature on mitral surgery shows that damage to the chordae tendineae frequently leads to negative remodeling of the ventricle, which can be catastrophic for patients already in heart failure. Mitral valve replacements that sit in the mitral annulus can also cause left-ventricular outflow tract obstructions, which constricts the blood flow into the aorta.

"What makes us different and highly disruptive is that our device is 100% in the left atrium so it resides above the native annulus and because it's above the native annulus we don't need to be concerned about that unique shape of the mitral valve," Thatcher explained. "We don't have to worry about fixation in the ventricle or chordae tendinae damage or LVOT obstruction, so it is truly new and novel and it eliminates all of the other clinical issues and technical issues that everyone else is facing, by design."

4C's technology leaves the native valve intact to continue taking some of the work-load even though it's not functioning optimally. This reduces the stress on the implant compared to devices that take all of the work-load off the native valve, and therefore should allow the device to be more durable and last longer than most mitral valve implants, Thatcher predicts.

"We're seeing now that aortic valves fail after 'x' number of years because they're taking the full work," he said. "Wouldn't it be great if the native valve, even though it's not fully functional, could extend the life of our device by 'y' number of years over the life of the technology? It's not proven yet, and won't be until we have it in humans, but it's one of the benefits we think we'll have."

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Philips Grows Image-Guided Intervention Focus With Spectranetics Buy

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Royal Philips has signed a $2bn-deal to buy **Spectranetics Corp.**, a US firm that specializes in developing laser atherectomy catheters for both coronary and peripheral indications, accelerating the firm's strategic expansion into image-guided therapy devices

This marks the firm's fourth acquisition so far this year *(Also see "Philips Completes M&A Hat Trick With Neurodiagnostic Buy" - Medtech Insight, 22 Jun, 2017.)*. Just six days ago, the Dutch giant announced the acquisition of neurodiagnostic firm **Electrical Geodesics Inc.** That followed the May acquisition of US airway clearance therapy vests seller **RespirTech** and March buyout of Australia **Pharmacy Sleep Services**, a sleep testing services provider.

In the vascular business, Spectranetics builds on Philips' acquisition of vascular imaging company **Volcano Corp.** in early 2015. *(Also see " Philips splashes $1bn on Volcano" - Medtech Insight, 17 Dec, 2014.)*

Spectranetics' key growth driver in its portfolio is *Stellarex,* a paclitaxel-coated balloon catheter, which is already approved in Europe, and is under FDA review. The company announced final one-year results from 300 patients in the US ILLUMENATE trial last November at the 2016 TCT Conference, and said then that the balloon catheter performed about as well in the study as it had in previous clinical trials, boosting its confidence for FDA approval and launch this year. *(Also see "TCT Round-Up: The Next Generation Of Drug-Eluting Stents, Drug-Coated Balloon Featured At Washington Conference" - Medtech Insight, 8 Nov, 2016.)*

Philips said Spectranetics projects 2017 sales to be in the range of $239m to $306m, and will continue to grow revenues at double-digit rates. The Colorado Springs-based company and its more than 900 employees will become part of Philips' Image-Guided Therapy Business Group.

The combined business, Spectranetics and Philips Image Guided Therapy Devices business (Philips **Volcano Corp.**), is expected to grow to about €1bn by 2020, Philips said *(Also see " Diagnostics A Bright Spot In Lackluster US Interventional Cardiology Market" - Medtech Insight, 27 Jun, 2016.)*.

The company said it targets a high single-digit comparable sales growth and high-teens adjusted EBITA margin for the medium term. In 2016, the business group reported sales of about €1.9bn of which 20% was attributable to device sales. The transaction is expected to be accretive to Philips' revenue growth, margins, and earnings-per-share by 2018.

Under the terms of the acquisition agreement, Philips will offer $38.50 a share in cash for Spectranetics. The price is 27% above Spectranetics' June 27 closing value. Philips reportedly said it will also buy back as much as €1.5bn ($1.7 billion) of its own stock to offset share dilution from an employee incentive program.

"This transaction is expected to be revenue growth and profit accretive by 2018, given the projected revenue and productivity synergies," Philips CEO Frans van Houten said. "Spectranetics' highly competitive product range, integrated with our portfolio of interventional imaging systems, devices, software and services, will enable clinicians to decide, guide, treat and confirm the appropriate cardiac and peripheral vascular treatment to deliver enhanced care for patients with better outcomes, as well as significantly boost recurring revenue streams for Philips."

Published online 06/28/17

Philips Keeps The Pace With More Portfolio Shuffling

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Philips Healthcare is charging ahead on the acquisition trail, announcing it is buying privately-held developer of catheter-based thrombectomy devices for peripheral vascular disease, **CardioProlific Inc.,** just a day after it signed a $2bn agreement to acquire **Spectranetics Corp.** *(Also see "Philips Grows Image-Guided Intervention Focus With Spectranetics Buy" - Medtech Insight, 28 Jun, 2017.)*

CardioProlific's technologies are particularly complementary to the laser atherectomy devices offered by Spectranetics. While there is not much publicly available information on CardioProlific, the company was granted a patent in June last year that covers the methods and devices for treating endovascular disease, where "vibrational energy is delivered to change compliance and increase permeability at the treatment area."

Financial details of the CardioProlific transaction were not disclosed.

While acquiring new technologies, Philips is also trimming parts of its image-guided therapy division with the proposed divestment of its *Sonalleve MR-HIFU* system to **Profound Medical Corp**.

Sonalleve uses real-time MR imaging to guide noninvasive ablation of diseased tissue using high intensity focused ultrasound. Sonalleve MR-HIFU is CE marked and has historically been marketed by Philips primarily for noninvasive ablation of uterine fibroids, although the technology has demonstrated its clinical utility in other applications including noninvasive ablation of abdominal cancers, hyperthermia for cancer therapy and palliative pain treatment of bone metastases.

Profound Medical has its own MR-ultrasound system, the *TULSA-PRO*, which combines MR imaging with transurethral, robotically-driven therapeutic ultrasound and closed-loop thermal feedback control for ablation of the prostate. TULSA-PRO is also CE marked and Profound is currently conducting a commercial launch of the system in key EU markets. It is also sponsoring a multicenter, prospective trial, TACT, for US FDA approval.

The addition of Sonalleve immediately transitions Profound from a development-stage to a growth-stage company.

In exchange for Sonalleve, Philips will gain a 12% stake in Toronto-based Profound. The Dutch multinational will get an upfront payment of 7.4 million shares of Profound stock, at a price of CDN$1.10 per share, representing a 22% premium over Profound's closing share price on June 29, the day before the deal was announced. The agreement also includes earn-out payments, which Profound estimates will result in it Philips getting a 5-7% cut of Sonalleve MR-HIFU's sales, in cash, through to the end of 2020.

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DOCUMENT DELUGE: Just How Many Extra Regulatory Requirements Will EU Introduce?

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The May 5 publication of the Medical Device and IVD Regulation texts was only the start of a substantial amount of additional regulatory documentation that medtech companies should anticipate from the EU as the new requirements are implemented over the next three to five years.

Not only are there delegated and implementing acts, which will provide an additional level of detail for many critical areas of the regulation, but there will also be Common Specifications, device-specific guidance and national documents, too. Together, this adds up to a truly disruptive regulation, Sabina Hoekstra-van den Bosch, of Philips, told attendees of the Knect 365 MedTech Summit in Amsterdam June 19.

In total, for both the MDR and IVDR, there are 83 delegated and implementing acts,

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TABLE 1

Delegated And Implementing Acts

REGULATION	IMPLEMENTING ACTS	DELEGATED ACTS
MDR	32	11
IVDR	32	8

TABLE 2

New Member-State Requirements

REGULATORY AGENCY	MEMBER STATE	DESCRIPTION	TRANSITION DATE
Medicines and Healthcare products Regulatory Agency (MHRA)	UK	Guidance document: Obligations related to "own-brand labeling" (known as "virtual manufacturing")	Sept. 1, 2017
Health Products Regulatory Agency (HPRA)	Ireland	Anticipated guidance: Obligations related to distributors	In consultation
French National Agency for Medicines and Health Products (ANSM)	France	Summary of safety and clinical performance to be notified to ANSM for class III & implantable devices	July 1, 2017

according to Hoekstra-van den Bosch, who is Philips' lead for European regulations, global regulations and standards. (See Table 1, "Delegated And Implementing Acts.")

Delegated acts are powers in predefined areas that have been delegated to the European Commission for drafting, the Philips executive explained. For implementing acts, meanwhile, member states are more in the lead, and may use such acts to amend or complement legislation in predefined areas, she said.

COMMON SPECIFICATIONS

When it comes to Common Specifications (CS), Hoekstra-van den Bosch explained that these are "conceptually like standards."

The intention is to introduce Common Specifications, similar to the Common Technical Specifications (CTS) under the current IVD Directive, to determine technical detail for higher-risk medical devices under the MDR.

Hoekstra-van den Bosch explained that compliance with Common Specifications would be obligatory, where application of harmonized standards is voluntary; and that CS would be drafted by "authorities only," while the standardization process requires the involvement of stakeholders. She also advised those at the MedTech Summit that these specifications may replace harmonized standards.

Common Specifications for Annex XVI (non-medical and generally aesthetic) products, and for device reprocessing feature among the European Commission's MDR implementation priorities.

GUIDANCE

It is also looking like there will be more device-specific guidance under the MDR than currently exists, Hoekstra-van den Bosch said. Under the current directives, the only such guidance that exists is in the post-market area for cardiac devices ("Device Specific Vigilance Guidance on Cardiac Ablation and on Coronary Stents"). In the clinical area, specific guidance for transcatheter aortic valve implantation (TAVI) and drug-eluting stents (DES) is being drafted.

She explained that the legal status of such device-specific guidance under the MDR is unclear, but that it is likely to be a precursor of Common Specifications. She added that there is a drafting procedure under discussion – but formal stakeholder involvement would only be in step seven of an eight-step procedure. That worries some in industry.

Hoekstra-van den Bosch also described the clinical evaluation guidance document, Meddev 2.7/1 rev 4, as a "clinical precursor" of the MDR.

Among the European Commission's guidance priorities is to give a draft mandate to its Scientific Committee on Health and Environmental Risks, SCHER, to produce guidelines on use of phthalates as a material.

MORE EU-LEVEL LEGAL REQUIREMENTS

Hoekstra-van den Bosch also advised delegates that, due to the Common Specifications and specific guidance documents, there could be more legal requirements to come coverings subjects including:

- Classification rules;
- Clinical requirements;
- Non-medical devices;
- Post-market surveillance; and
- Reporting obligations.

WATCH OUT FOR MEMBER-STATE INITIATIVES AHEAD OF IMPLEMENTATION

She also noted that member states may amend or complement legislation in predefined areas ahead of the MDR/IVDR implementation dates of May 26, 2020, and May 26, 2022, respectively, with elements not in conflict with the existing legislative framework.

She cited the three examples of new requirements entering into force ahead of the regulations, known as of June 2017. (See Table 2, "New Member-State Requirements.")

IMPACT BEYOND EUROPE

Just as with assessing the impact of implementing the MDR itself, companies need to look very carefully at the documentation of products sold beyond the EU when making changes to comply with the new EU requirements.

Once these changes are made, there will then be differences between what has been accepted in other countries under the Medical Devices Directive and what will be accepted by other non-European markets. Companies will need to review carefully the content of documents, the continued regulatory compliance and the need to translate any new documents when considering markets beyond Europe.

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UNLOCKING LEGALITIES: To Change How Courts View 510(k) Clearances, Industry Seeks 'Supreme' Support

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US courts have fallen about 30 years behind in their understanding of the 510(k)-clearance process, which, attorneys say, hinders device companies' ability to defend personal injury suits. But industry legal experts are hoping the Supreme Court can right the ship during the court's next term.

Johnson & Johnson/Ethicon is petitioning the high court to hear an appeal of a suit – *Ethicon v. Huskey* – that could provide an opportunity for the justices to redefine how the court system interprets a 510(k) clearance, which is the path most devices take to the US market. And there is even a chance the case could reignite momentum to reconsider the hot-button issue of federal preemption – PMA approval, under federal precedent, preempts patients' ability to sue device firms for injury in most instances, while 510(k) clearance does not.

Currently, according to industry attorneys, courts too often dismiss 510(k) clearance as not having any significance to a company's argument that it reasonably believed a device to be safe when it launched the product. In some suits, including *Ethicon v. Huskey*, the court has barred a firm that is being sued by a patient for injury from bringing up 510(k) clearance as evidence, or even mentioning the 510(k)-review process, to the jury. In others, 510(k) clearance, if mentioned, is given little deference.

"There is a fundamental fairness issue, with a company being accused of putting defective products on the market but not being able to defend itself completely, to demonstrate, 'Actually, we complied with the regulations as FDA has laid them out,'" Matthew Wetzel, assistant general counsel for AdvaMed, said in an interview. AdvaMed submitted an *amicus curiae* brief on June 23 in support of Ethicon's petition to the Supreme Court.

ABSENCE OF 'F-D-A'

The case stems from a suit filed by Jo and Allen Huskey in 2012, following a doctor's decision to insert Ethicon's *TVT-O* mesh-based mid-urethral sling to treat Mrs. Huskey's stress urinary incontinence. As a result of the procedure, she suffered an infection, mesh erosion and long-term symptoms. It is one of tens of thousands of pelvic mesh suits that have been filed in recent years as part of multi-district litigation against Ethicon and several other companies. *(Also see "Court Rules Against Ethicon In Pelvic Mesh Case, But Without Punitive Damages" - Medtech Insight, 2 Jun, 2017.)* The actions accelerated after FDA raised public scrutiny of high adverse event rates for the product class, including a 2011 advisory panel meeting. Ultimately, FDA upclassified mesh for pelvic organ prolapse as PMA class III devices, but retained stress urinary incontinence mesh slings, such as the TVT-O, as 510(k) class II devices, with orders for some additional post-market data. *(Also see "Surgical Mesh And Sling Devices Must Undergo Post-Market Studies" - Medtech Insight, 9 Jan, 2012.)*

The Huskey's won in district court and were awarded about $3.2m. The US Fourth Circuit Court of Appeals ruled in the case in January of this year. Ethicon appealed to that court based on multiple complaints with how the district court handled the suit. But central to Ethicon's concerns were that the district court did not allow the firm's lawyers to mention that the TVT-O device had been reviewed and cleared by FDA as part of its defense to prove that it did not knowingly bring an unsafe product to market.

"The court went so far as to threaten 'very large' sanctions if even a medical article including the letters 'F-D-A' was introduced by accident," Ethicon said in its writ of *certiorari* to the Supreme Court, filed in May. "Thus, in this trial on an FDA-regulated prescription-only medical device, the letters F-D-A were never uttered, not once."

The appeals court, however, did not see this as a problem. "The information Ethicon sought to introduce would, at best, have had 'tangential' relevance to the case," the appeals court's January 2017 ruling states. "This relative lack of probative value, especially given a possible battle of experts over the 510(k) process, underscores the risks of confusion and wasted time that would follow the introduction of this evidence."

In a May 23 petition, Ethicon asked the Supreme Court to take the case, and to move 510(k)s from "tangential" to taking a more central role in product liability suits. Part of industry's argument is around fairness in making a defense and avoiding misinterpretations by the jury. Company attorneys argue that plaintiffs can suggest that at a device was rushed to market or give the impression that a manufacturer *chose* an abbreviated review path. Meanwhile, they point out, defense attorneys are unable to discuss what data was reviewed by FDA and the fact that FDA, rather than the company, dictates whether a PMA, 510(k) or other regulatory route is appropriate.

Industry attorneys also point out that a typical juror is well aware that FDA reviews drugs and devices, so the absence of any discussion about the agency may cause them to assume that the product somehow skipped FDA oversight or make another negative inference, industry groups argue.

"Excluding relevant evidence based on a perception that jurors will not be able to evaluate it properly is increasingly inconsistent with the values of our informed society," AdvaMed noted in its petition.

THE LORE OF LOHR

But the underlying issue, say company attorneys, is that the federal court system, by and large, fundamentally misunderstands the modern 510(k) process. Courts, including the Fourth Circuit, assert that 510(k) clearance is not sufficiently tied up with questions of device safety and effectiveness to help support a company's defense. That conclusion has a very specific source: the Supreme Court's 1996 ruling in the case of *Medtronic v. Lohr*. But attorneys say courts have taken the Lohr ruling way out of its element.

"These courts clearly have an erroneous view of the 510(k) process and its significance," medical device attorney Jeffrey Shapiro, who has written on the evolution of the 510(k) statute, said in an interview. "They clearly do not understand it. They are clearly misapplying the Lohr precedent."

In Lohr, the pacemaker device at issue was 510(k)-cleared in the early 1980s based on a substantial equivalence comparison to a "grandfathered" pre-Medical Device Amendments (1976) predicate device, which FDA never directly reviewed. The high court concluded that 510(k) clearance showed "equivalence," but was not a clear-cut measure of safety, and that achieving such clearance should not preempt patients' ability sue for injury in state court.

Based on the particular device in question, some device attorneys acknowledge that Lohr was decided appropriately for the time. However, they say, lower courts have taken their interpretation of the decision too far. Firstly, attorneys point out, the case was assessing whether 510(k) clearance could appropriately be considered a federal "requirement" that preempts a lawsuit outright, not whether it might be used as supportive evidence by the defense in an ongoing trial. And Ethicon and supporters argue that Lohr was assessing the '80s version of the 510(k) program, which, they say, fundamentally changed with the Safe Medical Devices Act of 1990.

The SMDA added new requirements to the 510(k) process and explicitly defined "substantial equivalence" as whether a device is "as safe and effective as a legally marketed device and … does not raise different questions of safety and effectiveness." The amount of data and time it takes for a 510(k) submission and review substantially ballooned in the wake of that law, and additional legislative and administrative reforms that followed, industry attorneys argue. *(Also see "Q&A: 20-Hour 510(k)? Attorney Calls On Courts To Update Its Figures" - Medtech Insight, 11 Jun, 2015.)*

The fact that case law has not caught up to this paradigm shift in the 510(k) program, but instead is coalescing around the outdated version of the statute should be enough for the justices to agree to hear the case, Ethicon argues.

"Although normally a circuit conflict is what motivates the exercise of *certiorari* jurisdiction, in this case it is the absence of a conflict that warrants *certiorari*: the consensus interpretation of Lohr and 510(k) is unambiguously wrong as to non-grandfathered devices, but at this point will stand uncorrected without the court's intervention," Ethicon states in its petition.

STEPPING STONE TO 510(K) PREEMPTION?

If the case were taken up by the Supreme Court, it would not center around the question of preemption, but it offers a potential first step to reopening the discussion on 510(k) preemption if the Supreme Court were to validate an updated version from Lohr of what a 510(k) clearance entails.

"If the court chooses to take up this case, which we very much hope they do, and the court decides to dig into Lohr a little bit, I think the time might be right to at least to start talking about it," AdvaMed's Wetzel said.

Attorney Shapiro also said the outcome of the case may very well prompt a reconsideration of preemption. But, he said, even if the Supreme Court takes the case and does rule that 510(k) clearances must be allowed as evidence, it does not necessarily mean they will ultimately take the extra step to say 510(k)s actually preempt the suits in the first place.

Including 510(k)s as evidence should be a "low bar," Shapiro said.

James Beck, a prominent defense attorney for device firms in product liability suits who is the counsel of record on AdvaMed's amicus brief, said he "strongly believes that the court should reexamine the scope of Lohr in light of the 1990 enactment of the Safe Medical Devices Act," but, he stressed, the question of evidence is not the same thing as preemption.

"Admissibility of FDA compliance evidence should not be governed by preemption analysis in the first place, since whether such compliance is admissible under the rules of evidence is a far different issue from whether such compliance should be conclusive under the Supremacy Clause," Beck said.

The Supreme Court justices are expected to consider Ethicon's petition during its pre-term conference in late September.

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Draft Drug Executive Order Could Impact Device Regulations

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A draft executive order floated by the White House to reduce drug prices and streamline generic drug approvals also seems to broadly apply to medical products, potentially having some spillover impact for medical devices.

According to the draft order, the executive branch should implement policies that help get medical products to market that are safe and effective more quickly, including novel treatments and technologies and cheaper generic drugs and biosimilars.

The order also states its aim to "reduce burdens caused by regulatory and administrative actions that inflate or distort prices for beneficiaries of Federal health programs or that provide more favorable pricing for intermediate actors in the medical product supply chain than the prices available to beneficiaries."

If signed by President Trump as is, the order would require the federal government to use a value-based approach to reimbursing medical product companies in their health programs instead of a fee-for-service approach, aligning with the direction of the health-care system already. It would also require the government to ensure medical products are not sold cheaper outside with the result of American consumers subsidizing the cost of innovation.

Executive branch health officials such as the secretary of health, FDA commissioner, and administrator of the Centers for Medicare and Medicaid Services are also tasked with specific directives in the order.

"The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall take steps to advance innovation and encourage lower-cost alternatives in order to enhance access to safe and effective medical product options for patients," states the order in regards to FDA's mission. "Such actions shall leverage biomedical discovery, advance the timely development of medical products, increase drug competition, enable generic entry for complex drugs, and address unintended consequences of existing rules that may reduce competition."

At the beginning of the year, President Trump implemented a slew of executive orders including one that required executive branch agencies to withdraw two regulations for each regulation they put in the books. The order has caveats for public health but has still created confusion in industry as to how FDA will proceed with issuing rules and guidance documents.

Since the start of the Trump administration, FDA has only released one draft guidance that affects the device industry and hasn't finalized any. FDA says it is still working with the White House to figure out how to implement the order.

The new draft order again emphasizes reducing regulations but seems to be principally targeting the bio-pharmaceutical sector. The order states the Health Secretary Tom Price, along with various executive branch top officials, will identify regulations that may be outdated, unnecessarily increase cost to the industry and patients, and restrict competition. After identifying such issues, they are also tasked with engaging external stakeholders to figure out how to reduce those barriers to the bio-pharmaceutical industries.

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21st CENTURY CURES IMPLEMENTATION: Device Provision Updates

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The 21st Century Cures Act, signed by President Obama on Dec. 13, 2016, included an array of reforms intended to streamline US FDA processes for medical devices, as well as a few incremental Medicare reforms and increased funding for precision medicine, cancer research and other activities.

It's now up to the Trump administration to implement the package. Here's where things stand as of June 19 on the implementation of key provisions for the device and diagnostics sector, including links to relevant *Medtech Insight* coverage. Look for updates to the table as efforts advance.

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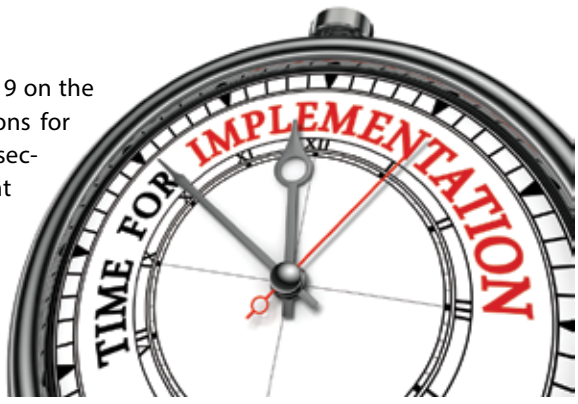

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PROVISION	DESCRIPTION	STATUS	MORE CONTEXT OR COVERAGE
Breakthrough devices (Sec. 3051)	Builds on the FDA device center's Expedited Access Pathway, an accelerated development pathway for devices that address unmet needs for life-threatening or irreversibly debilitating conditions. It extends the program to 510(k)s, in addition to PMAs and *de novo*s, and it removes the requirement for a sponsor to have a data-development plan to be accepted into program.	FDA says it is on track to produce a draft guidance document on the Breakthrough program by December 2017.	The agency is ready to accept breakthrough 510(k)s device applications as of May 2017. *(Also see "US FDA Ready To Accept 510(k) Devices To Expedited Access/ Breakthrough Pathway" - Medtech Insight, 8 May, 2017.)*
Humanitarian device exemptions (Sec. 3052)	A humanitarian device exemption can be granted to product intended to treat a disease that affects no more than 8,000 people annually, up from the previous ceiling of 4,000. By June 2018, FDA must issue a draft guidance defining the HDE "probable benefit" standard.	The 8,000-patient annual cap went into effect with the publication of a June 7 technical amendment. *(Also see "US FDA Moves On HDE, IRB, Reprocessing 'Cures' Provisions" - Medtech Insight, 8 Jun, 2017.)*	One company's plans to apply this reform. (*Also see "Inside The Spinal Cord: InVivo Therapeutics Looks To Reverse Injury, Leverage Regulatory Reforms" - Medtech Insight, 17 Apr, 2017.)*
Recognition of standards (Sec. 3053)	Any person may request that FDA recognize an internationally or domestically developed industry standard on devices. The agency then has 60 days of review to accept all, part or none of the standard, and must train staff in any accepted standard.	No public steps taken.	Aligns with standards-focused provisions in MDUFA IV user-fee agreement. *(Also see "Device Standards Provision In Cures Bill Could Speed Up 510(k) Clearances" - Medtech Insight, 1 Dec, 2016.)*
510(k)-exemption process for class I and II devices (Sec. 3054)	Directs FDA to publish lists of class I and II device types that no longer require 510(k) clearance every five years (beginning three to four months after enactment) and implement the exemptions.	On March 13, FDA proposed a list of class II devices to exempt. It must finalize the list by July 11. *(Also see "US FDA Lists Hundreds Of Devices For 510(k) Exemption" - Medtech Insight, 13 Mar, 2017.)*	On April 13, FDA exempted 72 class I devices from 510(k)s. *(Also see "FDA 510(k)-Exempts 72 Devices, Mostly Diagnostics" - Medtech Insight, 12 Apr, 2017.)*
Classification advisory committee meeting (Sec. 3055)	Adds measures that ensure that several members sitting on an FDA advisory panel that is considering device classifications have relevant expertise, and provide device sponsors the opportunity to present at such panels.	No public steps taken. FDA has not held any device classification panel meetings since Cures was enacted.	
Centralized institutional review boards (Sec. 3056)	Removes the requirement that local IRBs must approve device trials.	This went into effect with the publication of a June 7 technical amendment. *(Also see "US FDA Moves On HDE, IRB, Reprocessing 'Cures' Provisions" - Medtech Insight, 8 Jun, 2017.)*	
CLIA waiver rule/guidance update (Sec. 3057)	Requires FDA to revise its 2008 guidance on CLIA waivers for *in vitro* diagnostics to replace a gold-stand accuracy requirements with an emphasis on comparing test accuracy in waived and moderately complexity labs. *(Also see "Coming Together On CLIA Waivers? Industry Hopes To Recruit Patients, Providers To Push Reform" - Medtech Insight, 6 Jun, 2014.)*	FDA listed revising the guidance document as a 2017 priority. *(Also see "FDA Expects To Draft CLIA Waiver Guidances, Finalize NGS Documents In 2017" - Medtech Insight, 22 Dec, 2016.)*	
Least-burdensome requirements (Sec. 3058)	Requires staff training on least-burdensome methods and auditing of the program (first audit in June 2018); also emphasizes use of least-burdensome approaches in pre-market reviews and in deficiency letters.	Agency staff will begin training on least-burdensome device regulation by late fall or early winter, according to CDRH Director Jeff Shuren. *(Also see "Shuren At FDLI: Least-Burdensome, Real-World Evidence Efforts Picking Up" - Medtech Insight, 10 May, 2017.)*	The agency also plans to release a final guidance on developing and responding to deficiencies in accordance with the least-burdensome provisions this year. *(Also see "FDA Expects To Draft CLIA Waiver Guidances, Finalize NGS Documents In 2017" - Medtech Insight, 22 Dec, 2016.)*

PROVISION	DESCRIPTION	STATUS	MORE CONTEXT OR COVERAGE
Cleaning/ validation for reusable devices (Sec. 3059)	Requires FDA to publish a list of reusable devices that require instructions for use and validation data for cleaning, disinfection and sterilization. Also requires FDA to finalize its 510(k) modifications draft guidance by November 2017.	FDA published the list of devices subject to the provision on June 9. *(Also see "US FDA Moves On HDE, IRB, Reprocessing 'Cures' Provisions" - Medtech Insight, 8 Jun, 2017.)*	Stakeholder comments were submitted on the draft modifications guidance. *(Also see "Industry Urges FDA To Distinguish Between 510(k) Modification Factors" - Medtech Insight, 15 Nov, 2016.)*
Medical software regulation reforms (Sec. 3060)	Identifies five specific categories of medical software that, given certain conditions, will not be regulated by FDA as a device. Requires FDA to risk-classify device accessories separately from parent devices.	On June 15, FDA Commissioner Scott Gottlieb said guidance to further clarify what falls outside the scope of FDA regulation and to explain how the new statutory provisions affect pre-existing FDA policies would be published in the "coming months." *(Also see "US FDA's New Game Plan For Digital Health" - Medtech Insight, 15 Jun, 2017.)*	FDA also included funds to implement surveillance of the excluded software categories in the Cures work plan. *(Also see "FDA 'Cures' Fund Breakdown: Breakthrough Devices, HDEs, IRB Flexibility And More" - Medtech Insight, 9 May, 2017.)*
Combination products innovation (Sec. 3038)	Requires multiple reforms to FDA's combination products processes, including early sponsor interactions, dispute resolutions, provisions to streamline reviews and to allow more variations to complying with current Good Manufacturing Practices. A guidance document describing the process for managing pre-submission interactions, best practices for ensuring that feedback represents FDA's best advice, and information on meetings between the sponsor and FDA is due in December 2020.	No public steps taken.	It is likely implementation will be folded into wide-ranging combo-product reforms already underway. *(Also see "Companies Want New US FDA Council To Help Resolve Inter-Agency Combo Product Disputes" - Medtech Insight, 3 May, 2017.)*
FDA inter-center institutes (Sec. 3073)	Requires FDA to pilot one or more inter-center institutes to coordinate activities in major disease areas between the device, drug and biologics centers.	FDA launched the Oncology Center of Excellence in January. *(Also see "Oncology Center of Excellence Open For Business: Podcast With US FDA's Richard Pazdur" - Medtech Insight, 11 Apr, 2017.)*	FDA Commissioner Gottlieb has alluded to the potential this approach may hold for products targeting pain/opioid abuse. *(Also see "Gottlieb Touts Devices For Pain Control To Help Solve Opioid Crisis" - Medtech Insight, 6 Apr, 2017.)*
FDA workforce (Sec. 3071-2, 4)	Provides FDA with more hiring and salary flexibility to attract experts and allows more access by FDA scientists to attend conferences.		
Devices used with regenerative advanced therapies (Sec. 3034)	Mandates FDA to issue draft guidance by December 2017 clarifying how the agency will evaluate	FDA's biologics center plans to make implementing the regenerative medicines proposals a major focus. *(Also see "Regenerative Medicines Provisions Of Cures Act A Top Priority For CBER" - Medtech Insight, 9 Jun, 2017.)*	
Antimicrobial susceptibility testing devices (Sec. 3044)	Establishes specific standards for clearance or approval of an antimicrobial susceptibility assay as part of a newly established process for publicizing and adopting susceptibility test interpretative criteria. FDA must launch a website that contains a list of appropriate new or updated susceptibility test, interpretive criteria standards and interpretive criteria by December 2018.	No public steps taken.	

PROVISION	DESCRIPTION	STATUS	MORE CONTEXT OR COVERAGE
Precision Medicine Initiative (Secs. 1001 and 2011)	Provides $1.4bn through fiscal year 2026 and establishes the necessary authorities at various agencies to carry out the Precision Medicine Initiative that was launched by the Obama administration. *(Also see "Precision Medicine Plan 'Golden Opportunity' For Device, Diagnostic Firms" - Medtech Insight, 18 Sep, 2015.)*	Funds appropriated for FY 2017 in the omnibus appropriations bill to fund the government through the end of September.	
BRAIN Initiative (Sec. 1001)	Includes about $1.6bn for the Brain Research Through Advancing Neurotechnologies Initiative. *(Also see "Three Next-Gen Prosthetics Projects To Receive BRAIN Funding" - Medtech Insight, 10 Feb, 2015.)*	Funds appropriated for FY 2017 in the omnibus appropriations bill.	
Cancer Moonshot (Sec. 1001)	Provides $1.8bn to fund a coordinated effort to accelerate drug therapy and diagnosis. *(Also see "'Moonshot' Opportunities: Dx Reimbursement, Radiation Therapy Among Medtech Focal Points" - Medtech Insight, 29 Jun, 2016.)*	Funds appropriated for FY 2017 in the omnibus appropriations bill.	
Medicare local coverage determinations (Sec. 4009)	Takes steps to improve transparency for LCDs and to increase accountability for Medicare contractors.	Provisions officially took effect on June 13.	
Telehealth services (Sec. 4012)	Incrementally encourages telehealth by requiring CMS to submit certain information on telehealth to Congress by December 2017, and the Medicare Payment Advisory Commission to submit additional data by March 2018.		Further support for telehealth adoption been offered via proposed legislation. *(Also see "Telehealth Reforms Praised At Senate Hearing" - Medtech Insight, 17 May, 2017.)*
Medicaid DME reimbursement (Sec. 5002)	Part of the pay-for provisions for the bill, this section moves the date of when Medicaid reimbursement for durable medical equipment must be limited to Medicare competitively bid rates from January 2019 to January 2018.		

Acting US FDA Chief Scientist Tapped, As Borio Moves To White House Biodefense Detail

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The chief scientist role at US FDA will remain in acting hands now that the former temporary holder of the position has left for a detail at the White House.

Capt. Denise Hinton, who had been serving as deputy director of the FDA drug center's Office of Medical Policy (OMP), was named acting chief scientist, Commissioner Scott Gottlieb announced in a memo to staff. She replaces former Acting Chief Scientist Luciana Borio, who, on June 26, started a one-year detail to the National Security Council to work on "medical and biodefense preparedness."

Hinton was promoted twice, simultaneously. Gottlieb said in the memo that Hinton has been appointed as FDA's deputy chief scientist and, in parallel, has agreed to become acting chief scientist until FDA fills the position permanently.

As acting chief scientist, Hinton will be responsible for leading FDA's cross-cutting scientific research, as well as its related policies, programs and initiatives. She also will have direct line authority over the National Center for Toxicological Research and the offices of counterterrorism and emerging threats, regulatory science and innovation, scientific integrity, scientific professional development and

health informatics, according to a recent USA Jobs announcement of the vacancy.

Hinton also will be charged with facilitating scientific cooperation between FDA's centers and with outside scientists, and to help develop the FDA Science and Research Plan.

The chief scientist role has proven a tough position for FDA to fill, along with other senior executive positions. There has not been a permanent appointment since 2015, when Stephen Ostroff vacated the position to became acting commissioner. Ostroff now is Deputy Commissioner for Foods and Veterinary Medicine.

The agency formally announced the vacancy in August 2016. For Gottlieb, if a suitable candidate is found, it is an opportunity to make his mark on the senior executive staff at the agency.

HINTON HAS DRUG POLICY BACKGROUND

In addition to receiving Gottlieb's support, Hinton also received praise from former Commissioner Robert Califf, who tweeted that he had the pleasure of working with her and that she is "a solid person who will get the job done."

Hinton, who was an Air Force officer, received a bachelor of science degree in nursing from Florida State University and a master's degree from Boston University, arriving at FDA in 2002. She began in the Center for Drug Evaluation and Research's Division of Cardiovascular and Renal Products.

From 2010 to 2013, she was director of the Office of Medical Policy Initiatives (OMPI). Hinton became director when the office was created as part of a massive reorganization that made OMP a "Super Office" within CDER and renamed the Division of Drug Marketing, Advertising and Communications to the Office of Prescription Drug Promotion.

Hinton was active in efforts to revise patient medication information development and distribution practices during that time. *(Also see "Assurance Vs. Flexibility: Unit-Of-Use Packaging Offers Trade-Offs For Patient Leaflets" - Medtech Insight, 4 Oct, 2010.)*

In 2013, Hinton was named deputy OMP director.

BORIO CONTINUES FOCUS ON BIODEFENSE

Borio, meanwhile, will work on medical and biodefense preparedness while on the National Security Council staff, FDA confirmed, which aligns with one of her primary duties while at FDA.

Before becoming acting chief scientist, Borio was assistant commissioner for counterterrorism policy and director of the Office of Counterterrorism and Emerging Threats within the Office of the Chief Scientist. There she worked on global health security and emerging threats, and led the agency's Medical Countermeasures Initiative.

Borio also was active with FDA efforts to respond to the Zika and Ebola outbreaks. *(Also see "US Officials: Work On Tests To Discern Zika From Dengue Could Slow Without Steady Federal Funding" - Medtech Insight, 31 May, 2017.)*

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don't have a file folder and the associated feelings are so intense that it prevents us from making one … this little bit of unprocessed chaos bouncing around in us destroys or seriously undermines our natural and necessary assumption about how the world works and who we are in it. If avoidance is preventing natural recovery, we need to do prolonged exposure therapy."

Skip Rizzo, research director at USC, noted that researchers aren't erasing memories. He said, people still remember what they've been through, but they don't have the same intense, emotional power that they had before treatment.

Prolonged exposure therapy started in the 1950s. But it wasn't until 1997 that researchers from Georgia Tech linked exposure therapy with emerging VR in a pioneering clinical study dubbed, "Virtual Vietnam". The study enrolled ten veterans who suffered from PTSD and had not responded to multiple treatments and exposed them to two virtual environments, a virtual Huey helicopter flying over a virtual Vietnam and a clearing surrounded by a jungle. After a month's treatment, all ten men showed significant improvement.

> "We need to process emotional information and the ability to create file folders to organize new information," says Peter Tuerk, director of the PTSD Clinical Telehealth Team Charleston, VAMC. "If avoidance is preventing natural recovery, we need to do prolonged exposure therapy."

The lead investigator of the Virtual Vietnam study was Barbara Rothbaum, who in 1996 co-founded Decatur, Georgia-based **Virtually Better, Inc.**, which sells Bravemind, Virtual Iraq and Virtual Afghanistan and produces other VR modalities to treat phobias, addiction, fear of flying, fear of storms, of public speaking, among others.

Dawn McDaniel, executive director of research at Virtually Better Inc., told *Medtech Insight* its clients include more than 50 VA health systems worldwide and military hospitals, as well as hospital systems such as Cedars-Sinai Medical Center and academic institutions such as George Washington University and New York University.

Its top-of-the-line VR exposure system, including Bravemind, encompasses 25 different types of software divided up

into suites such as phobia, relaxation and addiction. It is the only system that comes with a 'scent' machine. The price tag is $10,000-$40,000, depending on the desired features, McDaniel said.

"We developed this integrative platform basically so you can get the most that we can out of Bravemind," McDaniel said. "You're feeling the vibration of the Humvee, you're smelling the market (including body odor, cigarettes, market spices) and you're seeing the scenes, you're hearing what's going on in the environment, and you're carrying (what feels like a real) weapon."

Asked about the fastest growing therapeutic area for the VR product, McDaniel said that the company is seeing an increased demand for PTSD.

"Across the literature there is a discussion about a rise in incidence of PTSD and along with that there's more awareness and because of that awareness, I think there is an increased demand for both evidence-based approaches and solutions for PTSD, but also for innovation around the treatment of PTSD," she said.

Rizzo said in published reports that in 2013, about 69,000 new cases of PTSD were diagnosed in veterans from Afghanistan and Iraq as well as 62,000 newly diagnosed Vietnam veterans, which, according to the researcher, is often due to people getting older and becoming more emotionally vulnerable.

Conventional treatment of PTSD has included medication, psychotherapy and exercise and using graduated exposure therapy, which involves the gradual repeated "reliving" of the traumatic event under a clinician's care. For many patients reliving their traumatic experience was too much of a challenge, which led USC researchers to develop Bravemind.

The potential of VR for treating PTSD is supported by previous reports in which patients with the disorder, who were unresponsive to previous imaginal prolonged exposure therapy treatment, went on to respond successfully to VR exposure therapy.

According to USC, Bravemind is especially appealing to the younger generation, which grew up with digital technology and may actually prefer this type of treatment over traditional "talk therapy."

But McDaniel finds that VR therapy appeals to a wider demographic of people who have played video games all of their lives.

"There is a group of people who are coming to our office who may not otherwise come, because they are curious and they're used to seeing game-controlled and technology displays," she said. "It's more comfortable and acceptable to them than talk therapy with a health provider."

VR is effective, because no matter how abstract the world around one is, the mind is tricked into believing that the patient has entered that world, researchers found. Virtually Better has developed solutions that are more affordable, and thus, can be used in the doctor's office, and is now also working on bringing mobile-based apps directly to consumers.

According to McDaniel, most of the clinical solutions today are used by therapists in anxiety specialty clinics known for work in cognitive behavioral therapy. These systems, which offer a vibrating chair and visual and auditory stimulation, run between $699 and $1,395, she said.

The company's mobile systems, which can be used with an iPhone 5 or laptop, currently come with five programs, McDaniel said, adding but new programs are in the works.

"We're very excited about the ability to take everything that we've learned from the other two systems and making it for a price point that's affordable for the private practitioner," she said.

Asked about the competitive landscape, McDaniel said there are numerous companies that are trying to replicate Virtually Better's solutions, but she feels her company has a competitive advantage.

"We have seen an increase in companies that are trying what we've been doing for a long time, but we have not only been selling and developing these systems, we test them, so we can make sure they maintain their quality," she said.

Among their rivals are two Spanish companies -- **Psious**, which offers solutions for PTSD and phobias, and **VirtualRet**, which also offers tools to therapists for treating phobias.

PROJECT:EVO

Akili Interactive Labs, a subsidiary of UK biopharmaceutical company PureTech Health PLC, is one of the first companies to develop a digital cognitive therapy to pursue for regulatory approval *(Also see "Game On For Akili's Cognitive Control Tech" - Medtech Insight, 13 Apr, 2017.)*.

Akili has shown in a pilot study that playing its video game not only improved cognitive test scores of children with sensory processing dysfunction (SPD), but

Practitioner System

Photo credit: Virtually Better, Inc.

also produced neurological changes in the prefrontal cortex of the brain. Akili is currently evaluating its leading product, *Project: EVO* in a late-stage trial for treating pediatric attention deficit hyperactivity disorder. Results are expected in the first quarter of 2018, upon which Akili plans to file for FDA approval.

Akili licensed the technology from UC San Francisco and developed proprietary adaptive algorithms. In a TED Talk, Adam Gazzaley, founding director of the Neuroscience Imaging Center at UC San Francisco, explained some of the research behind the technology and addressed key aspects of "multi-tasking" and "adaptivity" that have shown to improve cognition in some populations.

Gazzaley said to appeal to children, the game incorporates aspects of music, art and story-telling as well as the key aspect of "adaptivity," meaning as the participant plays the game in real time, the game becomes more difficult as performance improves. This keeps the person engaged where it's not too hard where they get frustrated, but also not so easy, where the person becomes bored, all of which has shown to maximize neuroplasticity in the brain and improves cognition.

He referred to this as "closing the loop," where decisions in the brain guide behaviors, which influences the game; the game reacts adaptively in real time to challenge the player, which changes the environment, and then cycles back to the brain to close the loop and actively changes the brain.

"If the goal is to induce neuroplasticity, we can redefine a whole realm of where you can use all of these different solutions," Edward Kliphuis says.

The idea of using video-gaming technology to activate specific brain regions that underlie cognitive deficiencies in patients sets Akili's technology apart from other video-gaming technologies and made it an attractive investment target, said Edward Kliphuis, investment director in the New Business Fund in digital health and solutions at **Merck Ventures BV**, Amsterdam. Merck Ventures, part of Germany-based **Merck KGAA**, together with **Shire PLC**, **Amgen Ventures**, and other financial investors poured $42.4m in a Series B funding into Akili *(Also see "Akili Has Big Pharma Buy-In For Cognitive Disorder Video Games" - Medtech Insight, 26 Feb, 2016.)*.

"If the goal is to induce neuroplasticity, we can redefine a whole realm of where you can use all of these different solutions," Kliphuis told *Medtech Insight*. Akili is also currently testing its technology platform for depression, Alzheimer's disease,traumatic brain injury and a range of other indications.

Results from a four-week study of 57 children with sensory processing disorder (SPD) – half of which had ADHD symptoms, who received at-home treatment with the gaming technology, then underwent post-treatment cognitive, behavorial and neurological assessments – showed that all children improved. And those with SPD and inattention showed even greater improvement in the Vanderbilt Assessment Scale, considered the gold standard for evaluating ADHD symptoms.

Last December, Akili also announced results of a study with Pfizer using a different screening platform that could detect biomarkers of Alzheimer's disease. The company is also working toward further clinical validation with one potential future path being FDA approval as a non-invasive diagnostic for neurological indications, Kliphuis said.

Other Companies Developing VR Therapies

COMPANY	VR TECHNOLOGY	QUICK FACTS	APPLICATIONS
Ehave Inc.	Ehave Connect	Mental health informatics platform to improve diagnosis and treatment of attention deficit hyperactivity disorder developed in partnership with Multi-Health Systems, a publisher of psychological assessments. Entered a partnership with MedReleaf, Canada's leading medical cannabis licensed producer, to use Ehave Connect to advance the study of cannabis.	ADHD, cannabis
Cogniciti	Brain Health Assessment	Privately held digital health firm formed in 2010. Majority owned by Baycrest, Canada's largest geriatric healthcare institute and minority owner, MaRS, research center. Developed Brain Health Assessment tool for adults to assess memory concerns.	Memory loss
InteraXon Inc.	Muse	Developed wearable device in the form of a headband that senses EEG coupled with smartphone app to monitor users' brain electricity activity. Offers feedback on meditative state and is used to help manage stress and improve mood over time.	Meditation training
Firsthand Technology	SnowWorld, Cool!, Glow!	Develops VR 3D games for therapy, research, education and business. SnowWorld was designed for patients in hospital burn wards to explore a calming winter wonderland to forget about their pain. Now also used for chronic pain patients.	PTSD, pain control, burn patients, training simulator for administering oral injections

In older adults, playing the game has shown improvement in their abiity to multitask and their ability to sustain attention on different tasks, as well as working memory, Dr. Gazzaley explained in the TED Talk.

Kliphuis said a decline in cognitive abilities is a major societal burden.

"We haven't found an agent that works in Alzheimer's," he said. "This is exciting, because it means we can have potentially a non-invasive screening tool to identify if people are prone to Alzheimer's disease or not. The key to the Akili solution is to do initial screening, and thus, reduce the number of PET scans that have to be conducted, which are cumbersome and unpleasant for patients. We hope that doctors will give it to their patients to play the game.

Asked about other investments in health-oriented video-gaming technologies, Kliphuis said, this is the only such investment, saying it hits the "ABCs" of gaming.

"'A'; autonomy gives you control over your own situation; 'B'; belonging connects you with other subjects; and 'C'; competence gives you a sense of autonomy, or a sense of satisfaction to master a task, which is very interesting for us, if people will continue using it," he said.

When asked about the potential market size of Akili's technology, Kliphuis couldn't offer a figure, but said instead that "the sky is the limit."

It is worth noting that drug company, Merck, is also exploring using video-gaming technologies as therapy. In this case, it developed the "MS Dialogue Ecosystem" to watch for the progression of the disease in multiple sclerosis patients.

MOODBOT

Micah Hrehovcsik, lecturer and game designer at the HKU University of the Arts Utrecht, has a long history of working with Dutch companies and therapists and patients at various health systems on developing VR tools for therapeutic use in mental health care settings.

One of his recent projects is the multiplayer game, *Moodbot*, designed to help patients who are recovering from mental illness, such as psychosis, to avoid relapse of violent behavior. He talked about some

Moodbot

of the research that went into creating Moodbot and addressed key challenges in trying to find common ground between all stakeholders involved in creating the game.

Moodbot takes place in a fantasy water world where each player owns a room in a large spaceship. Players work together to make the ship move and collect points by performing actions, such as adjusting their own "moodbot," a robot that depicts mood by facial expression. Each player can also enter another player's room and offer encouragement, if the other player's moodbot shows negative feelings. The ultimate community goal is to move the ship forward, which reaps the players a reward.

"We ask them (players) how they feel in the real world," Hrehovcsik told *Medtech Insight*. The ultimate goal of the game is to allow patients to help each other keep their emotions in check by allowing communication. He said players play daily for five to 10 minutes with health care professionals being able to track and monitor all the action at the backend.

Thus far, Hrehovcsik said to the best of his knowledge there haven't been any validation studies done. But he hopes that as more data becomes available, it will allow researchers and therapists to better evaluate the treatment modality in this patient population.

"By collecting more data from psychiatric patients on a daily basis, the information can be used to understand trends and what causes the violence," he said.

On the upside, he noted that health care workers expressed positive views about the reaction of the patients who remained committed to playing the game and reporting their feelings. He said given that health workers have only limited time to interact with each patient, by being able to monitor patients in this new gaming environment, it helped reduce their workload and increased job satisfaction. Patients expressed that they felt they had more say in their treatment and liked the idea of being able to interact with one another and help each other achieve a more positive state of mind or mood.

Asked about his biggest challenges in creating this game, the researcher said that terminology was one issue. The psychiatrists had their ideas of how they wanted to gather information, while patients and game developers had other ideas. He said in creating a successful VR game takes the buy-in of all entities, constant communication and on-going testing during game development.

"Patients need to be engaged in the game, otherwise they won't provide the information and they know while they are playing the game, the information is also being used by healthcare workers," he said.

Another key issue that came up during the development of Moodbot was that the parties disagreed on "messaging," he said. Hrehovcsik said the psychiatrists encouraged "free-flowing" conversation where patients could leave messages for one another in the different rooms, which he strongly discouraged. He said free-flowing conversations between patients would have required health care workers to constantly monitor what's being said. It also would have left the door wide open for negative talk. Later everyone agreed on using pre-fabricated messages that were all positive and encouraging like "keep it up" for good behavior or "go outside and get some fresh air," if someone expressed sadness.

Jan-Willem Faessen, who did business development for **Red Max**, which marketed the game, told *Medtech Insight* that the company created a simple business case for Moodbot where a user pays €70 to play the game. But he said, thus far, it hasn't been successful in finding investors.

He said most game development companies in Holland are waiting for better times.

"As for the development of the tool and the market, we must conclude there is momentarily very little momentum in investing in the development of games in the Dutch mental health care sector," Faessen said. "The sector and government are very busy sorting out structure, business model, ict architecture, trust data-safety, etc."

MARKET LIMITERS

Market limiters for VR therapy extend far beyond Dutch borders, according to some sources.

According to **Wolters Kluwer Health**, research on health care-related VR applications has significant limitations including small numbers of patients and lack of comparison groups. Also, mental health providers need specific training before integrating VR approaches into the clinical practice.

Another limiter is the problematic connotation of video-gaming. Many people still perceive videog aming as having a 'negative impact on children' and having hidden dangers. Some people even believe that video-gaming induces ADHD.

GROWTH OPPORTUNITIES

Others, see tremendous upside in this space.

Global Industry Analysts, Inc. research projects the global market for VR in health care to reach $3.8bn by 2020, driven by technology advancements in healthcare IT, expanding applications into diverse disciplines, and increasing demand for rehabilitation and simulation training.

McDaniel and Tuerk, who has financial ties to Virtually Better, also believe that VR in health care is on the rise.

"We do see with the second wave of VR [technologies] that the idea of VR is more mainstream," McDaniel said. New hardware technology has made the headsets more comfortable and much more affordable; and with smartphone applications consumers can now stream VR content right at their fingertips.

Tuerk is convinced that VR technology can be an effective part of treatments for phobias, such as PTSD, and allows health care professionals to simulate exposures that otherwise would be too costly or impractical to recreate in real life with a therapist controlling the environment.

And researchers around the globe continue to explore opportunities in this trending field.

At Virtually Better researchers are working on app-based VR tools that can be marketed directly to consumers for self-help and other applications. McDaniel said people hear about it in the news and are curious to see what VR therapy is all about and simply walk into their offices to seek help.

"There are a number of people who might not want to come to a clinical setting, and we would like to get VR into their hands, so they can use some of these tools in the comfort of their own home," she said. One of these areas is likely to be anxieties. "We have a long history of developing tools for the treatment of anxieties, so that makes sense."

In addition, Virtually Better is exploring partnerships with pharmaceutical companies.

"We're really interested in integrating video-gaming technologies with medication management systems, so we hope to develop partnerships with pharmaceutical companies," she said.

As researchers and companies continue to work on web-based approaches, telemedicine and technology-based intervention for disorders as well as smartphone application, the opportunities for VR applications look promising. The key challenge remaining today is a lack of clinical evidence.

Brennan Spiegel, director of Health Services Research at Cedars-Sinai Health System moderated a panel at this week's Digital Health Summit in San Diego with health care partners **Samsung Healthcare** and **appliedVR**, a developer of VR content, outlining the hospital's implementation of VR across multiple areas:

- **Pain Management**
  A study, published by JMIR Mental Health, examined 100 hospitalized patients at Cedars-Sinai with significant chronic pain. Fifty patients who played a 15-minute VR game PainRelieVR reported a 24% drop in pain scores after using VR goggles; the other half, who watched a standard, two-dimensional nature video, saw a 13.2% decrease in pain. Dr. Spiegel said the results indicate VR may be an effective tool along with traditional pain management protocols.

  In Q3, Cedars-Sinai will partner with appliedVR and Samsung Healthcare to launch a pilot study delivering pain management kits to patients at home, Matthew Stoudt, CEO of appliedVR told *Medtech Insight*.
- **Reducing Anxiety**
  VR therapy has shown to be effective in reducing anxiety and stress in children during anxiety-producing procedures such as removing a cast and removing stitches following orthopedic surgery.
- **Reducing Blood Pressure/Manage Stress**
  A project with Holman United Methodist Church in Los Angeles uses a VR smartphone app with Homido VR glasses that can be clipped onto the smartphone, allowing participants to watch an educational video on how foods, in particular, sodium content, affects heart health. The app is designed to help reduce blood pressure and also be used to alleviate stress.

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