CONNECTING PHARMA: INSIGHTS FROM AUTOMOTIVE INDUSTRY EXPERIENCE

– AN INTERVIEW WITH JIM McGOUGH, EDGEONE MEDICAL / EDGEONE VENTURE PARTNERS

In this exclusive interview, Jim McGough talks with ONdrugDelivery's Guy Furness about the current state and future of connectivity in drug delivery and pharma more broadly. In an enlightening discussion, Mr McGough shares insights from his time pioneering connectivity in the automotive industry at Volkswagen Group and how those lessons might apply to the pharmaceutical industry, as well as considering what might be holding pharma back from going full steam ahead on connectivity and how that might change over the next decade.

Jim McGough is a Co-Founder and a Board Member at EdgeOne Medical and a Managing Partner of EdgeOne Venture Partners. He was previously an investor and board member at several Big Data and AI ventures, as well as an impact investor, from 2007 to 2012. Prior to that, he held various executive and intrapreneurial leadership roles in marketing and digital at Motorola (2004–2007) where he was head of Global Digital, Audi of America (1998-2004) and Citigroup (1995–1998).

Mr McGough, as evidenced by his tech-forward corporate employers, likes to be on the bleeding edge of technological innovation – as Head of Marketing & eBusiness at Audi he championed and led the first integration of a smartphone with an automobile, the Palm Treo 650 with the Audi A6, via Bluetooth such that a call could seamlessly transfer from a device to the vehicle. Mr McGough studied International Business at the Thunderbird Global School of Management at Arizona State University (US) where he earned a master's degree in Management of Global Business, and has a bachelor's degree in History from the University of California at Berkeley (US).

Q What do you see as the current status of connectivity in drug delivery systems, and of digitisation in the wider pharma industry?

A When it comes to adopting and leveraging connectivity, pharma is in the second or third inning, to use a baseball analogy. We've moved on from the start, but we've still got a long way to go. For example, some in the industry have really invested in getting into outcomes-based health, most commonly in areas such as diabetes care and some neurodegenerative disorders where connectivity and data can be a critical differentiator in a highly competitive market. On the other hand, some areas are much more sceptical of connectivity, or at least slower on the uptake.

What's clear is that the situation is complex – it's a multifaceted business with a wide variety of stakeholders. A lot of people go into pharma early in their careers and spend upwards of 30 to 40 years here; traditionally, there hasn't been all that much migration between pharma and other industries. This means that, sometimes, there's a lack of an external perspective. On the other hand, those who do transfer in after they become experts in other fields, such as systems engineers from the automotive industry, are often not in a position at that stage in their careers to embrace and understand all the different stakeholders that pharma has to think about when they're developing what I call drug device and data therapy. There isn't really any other industry that faces this particular challenge.

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The other issue that causes complexity for pharma when trying to make progress with connectivity is the heterogeneity of the different therapeutic categories – there are so many different unique categories of therapies, all of which are constantly changing, that it's difficult for any one person to have a strong grasp on what's going on in all of them at any one time. Because of this, it's hard for a big platform to get a foothold and grow to a scale where it can dominate the industry.

Taking these factors into account, it can take two or three times as long for pharma to adopt new technologies, such as connectivity, as it does for other industries. The people pushing for outcomes-based health have so many stakeholders – including pharma's infamously stringent and risk-averse regulatory bodies – and different therapeutic areas needing to be aligned that it's going to take a long time to get where they want to go. Unfortunately, there's not really a way around that; we're not going to see a sudden acceleration, except in specific cases where perhaps an outsider to the industry reaches escape velocity in terms of market cap.

The most recent example of this is Livongo (CA, US), which was an upstart from outside the industry. Their key innovation was in their business model, and in successfully making the case to self-paid insurers in the US that available diabetes management options weren't quite meeting their needs. Livongo really focused

on those companies and, in doing so, they achieved significant traction and growth, which gave them a fairly large market cap. Their connected device for diabetes management wasn't necessarily ten times better than anything else on the market, but it was good enough. Ultimately, they were acquired by Teladoc (NY, US). That's how you attract pharma's attention. There could be a company on the horizon with just the right combination of technology, usability and business model to cause a real stir that leaves pharma alert, so to speak.

That is not to say pharma itself is doing nothing in digital. To the contrary, for a while now, several big pharma companies have been making investments into connectivity for the long term, and we're starting to see some of the fruits of this. Three years ago, it was hard for pharma to acquire the talent, whereas people from the tech industry with the expertise pharma needs are now considering pharma as a serious option. However, as I mentioned before, the issue these folks have is that, while they're world class in what they do, it's going to take them years to figure out the ins and outs of all the stakeholders and sectors that are key to pharma development.

To summarise, it's a long game and most companies are playing it that way. Some companies are really investing in accelerating connectivity and bringing it about now, but they're up against the barrier that, at present, it can't be more than an optional feature. It's seen as too high-risk to commercialise something that's all-in on connectivity, so franchise leaders won't go there. Unsurprisingly, pharma is taking it slow and steady.

Q Although there's not a huge amount of migration into pharma from other industries, you are one of those who came in later in their careers, specifically from the automotive industry. Can you tell us your story in terms of career history, your role at Volkswagen Group and what you achieved there in terms of connectivity in automobiles?

A I had the great privilege of working for Volkswagen Group from 1998 to 2004. With respect to digitalisation, that was the first wave – the dotcom era. At the time, automotive original equipment manufacturers (OEMs) were frightened about being disintermediated by internet-based services, such as Autobytel and CarsDirect.com, which had started to emerge and garner fairly significant valuations. Volkswagen Group, seeing this starting in the US, felt that they needed to keep on top of what was going on there as there was a good chance it would happen in Europe as well.

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As for where I fit in, I was the one of the young Internet kids – I was previously at Citibank – leading their internet banking. Volkswagen Group saw me as somebody from outside of the industry who could help them get set up for the Internet age. That's what you see pharma doing nowadays; they go to industries that are further advanced and look to pull in talent from there. Initially, I was more on the marketing and commercial side, but after a year or so I moved to look at the overall system, seeing where we could create competitive advantage by leveraging data and the Internet.

About five or so years into this, we realised that mobile devices were going to be critical in terms of being the pathway to connecting to other services. At this point, I had the opportunity to evaluate a couple of options. One was the Palm Treo 650, which, back in 2003, was probably the first proto-smartphone that had 'over-the-air' software updates. For context, we're talking about an era when uploads and downloads were only in the kilobytes, but the promise of it was huge and we knew that our users were some of the most Internet-savvy connected people out there. So we made a proactive strategic move to be the first to integrate a mobile phone such that you could seamlessly get into your car, turn it on and your calls would natively come through the car's speakers.

At the same time, Apple was trying to get Audi to integrate the iPod, offering us co-promotion and a strong marketing push if we went with them. However, they had already done a big marketing push with BMW the previous year, who were obviously our main rival. So, we felt that Palm was the better option at the time – they were a publicly traded company and we thought their product would resonate more with our customer base. We initially got some good publicity with the Palm programme but within two or three years they were almost delisted from Nasdaq. They just didn't make the right calls. With hindsight, we should have swallowed our pride a bit and gone with Apple. Looking to the future, there are certainly lessons to be learned from these experiences that can be applied to pharma.

Q There are a range of attitudes towards connectivity in the pharma industry, what's your experience with how different players in the industry are reacting to connectivity?

A There's absolutely a range of opinion. On the one hand, you have folks who are really sold on the potential and are convinced that it's going to be a huge part of the industry, even universal, within years. However, I think that's an overly-optimistic outlook, especially since the people really evangelising for connectivity don't tend to be the ones making the big decisions – the C-level executives. In pharma, at the C-level, there tends to be a lot of traditional 'if it ain't broke don't fix it' thinking, the playbook doesn't change from one generation to the next without serious effort.

One of the big factors fuelling scepticism of connectivity is that there's no real incentive to take risk, and fully embracing connectivity right now would be a big risk. No one wants to be a casualty of moving too fast or making overly bold claims, so they take it slow and steady – pharma very rarely moves faster than you think it will. So, even if some top executives would like to really push connectivity, they often just keep it to themselves and stick to the tried-and-tested playbook instead.

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Personally, I think the right attitude is somewhere between these two extremes. There's benefit in the industry pushing harder than it currently is, but pharma isn't a 'move fast and break things' sort of industry, so rushing headlong into it is asking for trouble. For now, everyone seems to be working on their own connectivity projects internally, with a lot of them choosing to focus on applications in clinical trials for the time being. For example, Roche had a really exciting development when they established a 95th percentile stride velocity with the right authorities in Europe as an alternative endpoint for Duchenne muscular dystrophy. Because of that, they can power their studies with around only a tenth of the number of participants usually required. Those are the kinds of folks who are on the vanguard for connectivity – clinical trials applications are getting a lot of attention internally from the industry, and there is a lot of activity here.

Another group that are resistant to embracing connectivity is hospitals, particularly in the US. I recently attended the JP Morgan Conference and spoke with some friends who are CEOs of hospital systems, and they told me that they've been losing money. In fact, they feel that their whole business model is under attack from the push towards a hospital-at-home model of care, which connectivity is a big part of. Also, hospital systems are struggling with cybersecurity issues, both from the perspective of having to be cybersecure to prevent breaches, such as ransomware attacks, and from the investment that's required to put that security in place. This is a major new expense that's directly related to connectivity.

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In response to this, medtech needs to de-risk their devices and systems so that hospitals feel like they're not going increase their cybersecurity risk. Faced with this cybersecurity concern, a number of big decision-makers in pharma have a reaction of "We don't really understand this all that well, so unless we absolutely need to engage with it, let's just avoid the problem". I think this is actually one of the factors that has really slowed the development and uptake of connected drug delivery – there's a lot of trepidation and concern there.

Yet another factor fuelling scepticism at the upper levels is total cost of ownership of connected devices. Some pharma executives look at connectivity and think that, once they consider lifecycle management, including software upgrades, security patches and so forth, it's adding an unnecessary extra layer of expense. Therefore, many of them would prefer to keep things simple and leave the question of connectivity to someone else.

So, connectivity has its supporters and it is happening, but activity is focused in the digital medicines and clinical trials areas for now. But for commercialised drug delivery products on the market? There are only a few successful examples so far. Diabetes management is one area where connectivity has taken off and there's an expectation for digital features – you need to be taking steps towards connectivity there if you want to remain competitive. As such, diabetes is the most advanced sector of pharma in terms of connected drug delivery.

Q It's often said that, in pharma, everybody wants to be second (and nobody wants to be first). Would you say that the industry is waiting for one big success to open the floodgates or will the progress of connectivity be more incremental?

A What is going to be needed is a combination of both technical innovation and business model innovation. Right now, pharma is paying attention to outsiders looking to break into the sector, wondering if there's a company out there with a revolutionary idea that's going to turn everything on its head. On the other hand, a big push for change might also come from inside the industry if one of the smaller players in a therapeutic category, most likely a mid-size pharma company in combination with a willing group of payers, feels like they've got no other option to improve their market share. However, these players are still pharma industry insiders, so there's a baseline level of risk aversion there. Either way, I don't think that this sort of change is going to come from a number one or number two player.

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Another thing to consider is the slow, almost inevitable, encroachment of Apple into the healthcare sector. They're very much bringing in an outside perspective, but they're not interested in taking big, brazen risks; they know that up to a third, or even half, of their value ten years from now could very well come implicitly or explicitly from products relating to healthcare due to factors such as the ageing population. They don't want to jeopardise their reputation in the sector, so they're not going to move too quickly and take risks that could violate the implicit trust that they've built up from offering a very private closed system. However, once they start getting more data on digital biomarkers and behavioural health in combination with big pharma, then things are probably going to start to move faster on that front.

There might be some reticence from big pharma to work with Apple on this, but I think that could be a mistake. To take an example from the automotive industry, in the early days of satellite navigation one of the big players was Garmin, who decided to develop a closed system – they had their own devices, their own software and no interoperability with other devices from the likes of Apple or Google. They were doing some pretty interesting things, but this lack of interoperability led them to be siloed off in their own niche as far as market share goes. Don't get me wrong, Garmin is still around and is doing reasonably well, but they're not huge like some of the other players. I think there will be companies in pharma that go that way, but the ones that take a more open approach will be the big winners here.

Q To what extent do you think brining in top talent, expertise and lessons learned from other industries is going to be key in pharma and drug delivery's progress towards widespread functional connectivity?

A I've actually done a few talks over the last few years on this topic. A few years ago at PODD (Boston) I essentially said that talent is the real challenge for pharma when it comes to connectivity. In hindsight, I may have been a little harsh, but I said that the stereotype of the talent pharma was pulling in was, rather than true top talent, simply capable people who were seeking a safe role – pharma wasn't about to suddenly go out of business in a year or two, whereas that's not uncommon for companies in the tech sector.

Because of this, you had a couple of types of situation when it came to pharma's connectivity projects. One that was common in big pharma was that they would someone who had come up the management development track entirely within the industry and was going to stick around for a long time, and they'd assign them to a post in digital. This manager would learn some of the ropes and then move on up the career ladder or get poached for their insider knowledge by an external venture capital-backed company looking to break into pharma. That's largely what's been happening over the past five years or so.

Another situation was that, if a digital project got underway, it would start pulling in people from other sectors and, within a year, there'd start to be a cultural of misalignment. What would happen is the digital talent would look at the situation and see pharma treating their project as the lowest priority in the whole corporation, way down below what they saw as their actual business. So the digital talent would only remain for a time, before bouncing back out to an industry where they felt more valued.

That was a real issue – it's been hard for a pharma to retain the real top-flight talent. Those who it did retain weren't at all bad at what they do, quite the contrary, but they were not really those movers and shakers capable of shifting the paradigm.

However, things are changing. Over the last couple of years, other industries that were hyper-competitive for recruiting that top-flight talent have been offering fewer and fewer opportunities, and pharma has become more eager to, so pharma now has much more of a chance to pull these people in. Some of the big players like Roche, Genentech and AstraZeneca have really been making a push to attract and retain more of these very high-calibre people. It's expensive, but companies like these can see the how digital medicine and connectivity will grow in importance substantially in future, and their profitability and their core franchises allow them to make that push.

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It's worth noting that even within pharma there's competition for digital talent. One of the really interesting things going on inside pharma right now is the development of computational drug discovery. There's a lot of buzz about how generative AI might be applied in that area, and it's taking up a lot of focus internally. Unfortunately, this might come at the expense of connected drug delivery for now.

There's ample opportunity for digital talent in pharma, and it's increasing, but it's a very fragmented landscape at the moment – there's not really a cohesive community around connectivity just yet. Right now, pharma is leaning heavily on their drug delivery platform partners and other digital partners, which is where my company, EdgeOne Medical, is. We act as a central point that helps pharma compliantly develop these multi-component systems. Increasingly, pharma companies have their own people, but they need external expertise from trusted long-term partners like EdgeOne Medical to help them navigate the digital ecosystem, including all the additional regulation connectivity entails and the wide variety of solutions and technologies on offer.

I'm bullish that digital talent is increasingly going to come into pharma, but you have to be aware that the very best talent is going to be hard to hang on to. Big pharma companies must support their digital departments and really make them feel like a valued part of their businesses, rather than having a culture where digital is treated as optional, which still seems to be pervasive through some of the large companies.

Q How else do you think the pharma industry will need to adapt to bring about the significant changes embracing connectivity will require?

A Pharma has the lobbying power and clout to work with payers to make big changes but, generally speaking, pharma isn't all that interested in rushing towards any big change because the current system has been pretty successful. However, things do change. The world is changing. There are some legislative headwinds with the Inflation Reduction Act in the US, and some patents could be shortened. This means that we could see a permanent diminishing of some of the profit profile for traditional drug programmes. Increasingly, pharma companies are starting to understand that there is a real need to think differently.

There's a potential lesson from automotive here where, around 15 to 20 years ago, Volkswagen Group pioneered a shared playbook with associated brands to try to close the gap with Toyota. Volkswagen Group was able to close in on being the number one global manufacturer by units sold in large part due to four brands, Volkswagen, Audi, SEAT and Skoda, having a common shared architecture of certain components and so forth. So, one way I can see pharma changing

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to adapt to digital is that there could be a pharma company that develops common services or common architecture with its peers, which closes the gap on some of the big tech blockbusters.

This Volkswagen Group approach could allow a group of companies, possibly across different therapeutic areas, to share some common operations and reduce their individual operating costs. This is especially relevant for the lifecycle management and software side of digital development, which can be very difficult for traditional business models to pivot to. There may be some people who say that the various therapeutic areas are all very different, but I think there will still be common components that could benefit from this model, such as patient pathways, wet biomarkers and digital biomarkers, for example. It's a potential area of development I'm excited to keep my eye on.

Another important point I'd like to make here is about diagnostics. I've been hearing that companies that have developed capabilities in, or kept a hand in, diagnostics over the past ten years are going to have a noticeable advantage over other pharma companies both generally and, specifically, in adapting to digital. It's a matter of translation – how the different groups understand each other and work together; having internal diagnostics people who are able to effectively communicate and work with the molecule team, the drug delivery team and the therapeutic franchise, as well as the tech and digital side, is going to be a big benefit in getting digital programmes off the ground.

In an industry where outcomes-based therapeutics is rapidly coming to the fore, and precision medicine is emerging, it is self-evident when you think about it that the ability to analyse, measure and monitor patients, their disease metrics and their responses to treatments will be at the core. And that's diagnostics.

I've been an investor in some digital therapeutics and so forth, and something that really interests me is the applications around adherence and responsiveness to therapies. This is actually an area where some of the science is already proven, such as being able to use digital therapeutics to tell if a patient is a non-responder to a certain pain medication. Imagine if we were to look closely at some of the highest valued franchises in pain medication and it became clear that, for example, 20% of the prescribed users were unknowingly non-responsive. Payers are going to want to know that information. Doctors are going to want to know that information. When digital therapeutics take off in a more significant way, the data is going to start to show not only which patients adherent and compliant, but also who is getting the therapeutic benefit, which may or may not perfectly correlate.

Q **Can you offer any additional insights on why the process of developing connectivity is taking so long, and initiatives that might accelerate it?**

A We've already discussed the issues around bringing in and retaining digital talent, as well as the huge variety of stakeholders all with different opinions and priorities, and it's the latter I can elaborate on. In the US, there's something of a battle going on with everyone trying to push their own ideas, including pharma companies and academic institutions, who each have their own patents for digital and mechanical systems. These ideas don't necessarily amount to a complete solution

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on their own, but they're all jostling for a place in the overall care pathway. This is a process that takes time to play out.

There's an open question of how digital formularies can be established. Pharma has already been through an arduous struggle here with combination products, establishing pen injectors and autoinjectors in formularies alongside traditional therapeutics. And now we have a similar challenge ahead with digital formularies, which would codify how and in what circumstances digital therapeutics and digital diagnostics should be prescribed. Payers need to evaluate what's efficacious, what's safe and what they should add to their formularies. Of course, hospitals also have their own, and so they're exerting influence, and, sometimes, the big academic hospitals are also developing their own digital projects that they want to try out. It's a hypercompetitive landscape and, again, we're at the start of a process that will take time to play out. It will likely take years for a set of agreed-upon ways of prescribing these products to emerge.

As for initiatives that could accelerate the development of connected and digital therapeutics, in a few markets around the world, such as Scandinavia, Singapore and Germany, there are public health bodies conducting case studies that might conclude that digital approaches are really working – that is to say that digitisation and connectivity are lowering the cost of care and the overall public health burden – and that might push things forwards in those countries in a way that could strongly influence what happens elsewhere. It's going to be really interesting seeing how this unfolds over the next five to ten years.

Q Do you have any final thoughts that you'd like to share with our readers?

A The last point I'll make is for perhaps younger readers, or readers with digital experience outside pharma, who are considering a move into this industry.

You need to remember that most of the people at the top, the chief executives, have been in pharma for most of their careers – we're talking thirty-plus years here. All of that time, they've been working from essentially the same playbook, and it's done well for them for all that time. With that in mind, it's easy to understand why they might approach a huge shake-up like digital with hesitancy. There would have to be an immediate and very significant reason for them to take that kind of risk at that point in their careers. It's the next generation of top decision makers, those who are a couple of rungs down the ladder right now but will be C-Suite in five to ten years' time, who are going to be in the opposite situation, where not taking the plunge on digital will be the big risk. So I think it will be in the next five to ten years that we're really going to start to see some changes.

As I said before, the industry is highly fragmented, and with the widespread adoption of digital therapeutics there's scope for dozens of new classifications of drug delivery systems intersecting with data collection, processing and analysis, and they're going to be big markets. If you're starting out in your career, or have experience in another sector and are considering moving into digital pharma, the heterogenous nature of the industry means there's going to be a huge number of digital opportunities across a wide variety of sectors, from oncology to diabetes to mental health. You'll have unbelievable opportunities to affect global public health in the next ten years. So, I'm genuinely very excited for anyone considering getting into the industry. Whether you work at a drug delivery system provider or you're at a big pharma company or with another type of player, this is a wonderful place to be.

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ABOUT THE COMPANY

EdgeOne Medical is a global contract device development organisation that supports the compliant device development and testing of combination products. Since 2012, EdgeOne Medical has been elevating medical device and combination product development teams including in over half of the global top 20 biopharma companies.

EdgeOne Medical has a unique combination of multi-disciplinary product development experts combined with in-house ISO 13485 certified Testing Labs. These capabilities, known as Edgineering, and EdgeOne Labs provide clients with the peace of mind that they have complemented their teams with a partner with a successful track-record of de-risking, navigating, and accelerating device development programs.

EdgeOne Venture Partners provides more than device development and testing services. A device development team sometimes needs something extra, including access to emerging complex combination product and system development knowledge based on real development programmes; access to strategically interested big pharma, emerging pharma/biotech, medtech and digital health firms for partnerships and syndicates; access to funding opportunities for emerging firms and co-investment opportunities for larger firms; and the capacity and capability offered by adding a turbocharging best-in-class device/system development testing team and priority access to EdgeOne Labs. EdgeOne believes that nobody should have to develop complex combination products/systems by themselves.

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