ROUNDTABLE REPORT

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Scrip
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Can Parenteral Drug Delivery Devices Improve Patient Outcomes When Therapies Are Administered at Home?

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Julian Dixon, Human Factors Consulting Director, Team Consulting
Richard Johnson, President, Parenteral Drug Association
Tom Oakley, Director, Drug Delivery Device Development, Springboard
Mathias Romacker, Former Senior Director, Device Strategy, Pfizer
Alex Vasiev, Manager of Device Development, Oval Medical Technologies
Matthew Young, Founder and CTO, Oval Medical Technologies
Jo Shorthouse, Journalist and Healthcare Editor, Informa Pharma Intelligence (Moderator)

KEY TAKEAWAYS

- Multiple factors are driving increased demand for self-administered drugs and autoinjectors.
- As people manage their health more actively, drug companies are increasing their focus on patient-centered development.
- Successful adoption of parenteral drug delivery devices requires a 'journey to confidence' for patients.
- When pharmaceutical companies balance go-to-market time and risk, some defer the release of auto injectable drugs.
- Pharmaceutical leaders see value in adding connectivity to parenteral delivery devices, but it's not entirely clear how that value will be realized.

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OVERVIEW

As chronic conditions like diabetes, heart disease and COPD increase in prevalence, healthcare systems worldwide are feeling the strain. At the same time, medical care is shifting to the home and demand for specialized, targeted and personalized treatments is on the rise.

In response, many pharmaceutical companies are developing parenteral drug delivery devices, like autoinjectors, that patients can use to self-administer medications. This trend is creating various business challenges including the need for more patient research, the development of more sophisticated devices to accommodate new drug formulations and better training to increase end user confidence.

CONTEXT

This panel of industry experts discussed the options and challenges facing the future of novel treatments and how advances in parenteral drug delivery can improve patient outcomes outside traditional healthcare settings.

KEY TAKEAWAYS

Multiple factors are driving increased demand for self-administered drugs and autoinjectors.

When it comes to home administration of drugs, vials and prefilled syringes are the most basic delivery system. This approach has several disadvantages, however, and pre-filled syringes have become the standard of care. Unfortunately, challenges remain with pre-filled syringes. It is often difficult for people with conditions like Parkinson's disease or rheumatoid arthritis to manipulate the devices without hurting themselves. In addition, higher-volume and high-viscosity drugs require higher injection forces. Many people are unable to safely and effectively self-administer these medications using pre-filled syringes. In all of these situations, autoinjectors, or so-called large volume on-body-injectors, are a good solution.

In addition to the human factors-related advantages of such self-administration devices, the panelists discussed four reasons why these devices are outpacing other forms of home drug administration:

1. **Increasing use of biologics.** Over the last 10 to 20 years, most new drug therapies have been biologics. In fact, entire new categories of treatments – for example, dyslipidemia or anti-migraine – are now available in biologics. Most of these products cannot be administered orally and require injection.
2. **The cost of administering drugs in healthcare settings.** Many biologics are designed to treat chronic diseases on an ongoing basis. These drugs are costly and administering them in a healthcare setting over long periods makes the total cost of therapy even higher. As a result, many products targeted at chronic conditions are designed to be self-administered at home.

> Biologics are expensive compared to previous therapies. Part of the push for home administration is because it lowers the total cost of therapy. Although convenience is certainly a driver, another is cost.
>
> *Richard Johnson, Parenteral Drug Association*

3. **Growth in biosimilars and generics.** As biologics go off patent, the release of biosimilars and generics has generated additional demand for autoinjectors.
4. **Patient demand for convenience.** Society is moving to self-service models in many sectors, so the shift to autoinjectors in healthcare isn't surprising.

As people manage their health more actively, drug companies are increasing their focus on patient-centered development.

Historically, patients relied on doctors to manage their conditions and deferred to them. Today, many patients are taking an active role in managing their diseases. In response, drug development and life sciences companies want to make it easier for people to treat themselves at home. A more nuanced understanding of patient needs and expectations offers new opportunities for differentiation.

Session participants offered insights about patient-centered device development for parenteral drugs:

- **Demographic characteristics must be considered.** Advanced drugs like biologics are enabling patients to live longer with a higher quality of life. This places new demands on devices, as older patients may have visual impairments or cognitive disabilities that make self-administration more difficult.
- **User research is the only way to identify subtleties that are critical to good device design.** For example, some products use red/yellow/green color coding to indicate when a device is ready for use. This approach doesn't work, however, for individuals who are color blind.
- **Human factors is an important aspect of regulatory compliance.** Regulatory authorities expect drug and device companies to consider human factors when developing products. Over the last 10 years, good device design guides have emerged, ensuring that target patient populations can operate the device.
- **Although a strong de facto standard exists for autoinjectors, one device won't work for every patient.** Humans are all different, for example rheumatoid arthritis patients may have different issues to anti-migraine patients, so variation is the norm. In addition, companies must consider the physiological relationship between the autoinjector and the person. For instance, is the needle going to the right depth in the tissue? Also, injection speed varies from device to device. All of these factors may affect patient compliance.

> Until recently, the pharma industry has been fairly insulated from patients since clinicians have traditionally administered parenteral products. That's no longer the case with autoinjectors. We have an interest in understanding how patients relate to these devices.
>
> *Matthew Young, Oval Medical Technologies*

Successful adoption of parenteral drug delivery devices requires a 'journey to confidence' for patients.

Patients' emotional relationship with devices and treatments is very complex. Some are eager to use autoinjectors, while others are afraid of them. Pharmaceutical and life sciences companies must focus on how people relate to drug administration devices. This means supporting the journey to confidence.

Ideally, injections represent a small part of disease management. Unfortunately, for many patients today, they are far from that. The emotional journey to confidence is individualized and companies must identify what works and what doesn't.

> People want to be empowered to treat themselves, but they also need a sense of confidence that they're doing it right. Taking a patient-centric point of view and identifying the barriers to administering drugs is always at the forefront of our thinking.
>
> *Shawn Davis, AstraZeneca*

The patient journey with autoinjectors usually begins in the doctor's office during a stressful conversation about a serious health condition. This isn't a good forum for training patients. Once people leave the room, they often don't remember what they were told. The patient journey needs to include multiple touchpoints and different forms of learning. Training devices that administer mock injections, for instance, could be a useful tool.

> When people are confronted with something completely new, they don't learn in one try. With autoinjectors, one office visit and a leaflet full of dense text isn't a viable way forward for patients.
>
> *Tom Oakley, Springboard*

Another consideration on the journey to confidence is that autoinjector users may not be the same person as the patient. They could be a caregiver for an individual with dementia, a parent helping a child, or a family member administering an EpiPen to someone having an allergic reaction.

When pharmaceutical companies balance go-to-market time and risk, some defer the release of auto injectable drugs.

Autoinjectors can slow clinical trials and approvals. The regulatory risk often depends, in part, on the product formulation. Conventional autoinjectors are fine for drugs with a watery consistency. The risk increases for products that are high viscosity, high volume, or a non-Newtonian formulation, because platform devices won't work.

> There's little appetite to take on the risk of a device that would delay the regulatory filing. However, everything is becoming more competitive now. Offering devices that are more customized and tailor-made may become a dimension for differentiation.
>
> *Mathias Romacker, Parenteral Drug Association*

If pharmaceutical companies want a faster market launch, they may initially release a product with an IV formulation. This avoids development and approval of subcutaneous delivery devices. Within a year or

two, they may consider life cycle management and release a self-administered version of the product as a means of differentiation. Some believe that as the pharmaceutical industry becomes more competitive, companies may use more customized autoinjectors to create competitive advantage.

> Biologics and biosimilars are the technology push offering patients more targeted therapies with fewer side effects. These new molecules do not behave like the small molecule drugs that came before, creating technical challenges in manufacture and for parenteral delivery. As the market shifts to home use and less frequent administration the pressure falls on the device to adapt and deliver these therapies in ways that patients prefer.
>
> *Alex Vasiev, Oval Medical Technologies*

Pharmaceutical leaders see value in adding connectivity to parenteral delivery devices, but it's not entirely clear how that value will be realized.

The panelists shared thoughts about incorporating connectivity into parenteral drug delivery devices:

- **Some patients want connectivity, but technology can be a double-edged sword.** Patients have expressed interest in greater connectivity for drug delivery devices so they can track information, interface with diagnostic tests and communicate with providers. But integrating internet connectivity into devices can be complex. Technology can become a burden – rather than a benefit – if companies fail to implement it well. Consumers expect apps to be of the quality produced by Apple and Microsoft. Yet, software development isn't a core competency for many pharmaceutical firms.
- **Connectivity could be hugely useful during clinical trials.** Pharmaceutical companies see value in gathering data about whether trial participants have received their dose. The payback would easily justify the expense of adding sensors to drug delivery devices. Some participants felt this would be a great place for companies to begin their work with connectivity.
- **Patient needs should drive the journey to connected devices.** One participant suggested that pharmaceutical companies need to gather data in controlled ways to support the case for connectivity. The goal should be to deliver the greatest value to patients, rather than asking engineers to invent different ways to support end users.

> Connectivity is like a Swiss army knife for pharma. We can't resist opening up and inspecting all the different tools but the important question we face is this; which one is really useful right now?
>
> *Julian Dixon, Team Consulting*

ADDITIONAL INFORMATION

- 2021 PDA Universe of Pre-Filled Syringes and Injection Devices Conference. The Parenteral Drug Association is sponsoring this online conference on October 5 and 6, 2021. The theme of the conference is collaboration and simplification to accelerate device development and drug delivery.

BIOGRAPHIES

Shawn P. Davis, PhD

Senior Director, Head of Drug Delivery, AstraZeneca

Shawn Davis is a Senior Director at AstraZeneca (AZ) and leads the Drug Delivery team in Biopharmaceuticals Development. The team improves patients' lives by ensuring AZ's therapies are as safe, effective, and convenient as possible using technologies that target the delivery of medicines to the site of action and optimizing their effective half-life. This requires the evaluation, development, and commercialization of drug delivery technologies across a wide range of modalities in the biopharmaceutical space. Shawn also serves as a CMC leader balancing speed to market, commercial success drivers, and accelerated clinical timelines to deliver value to our patients and AstraZeneca.

Julian Dixon

Human Factors Consulting Director, Team Consulting

During his time at Team, Julian has worked on many drug delivery device development projects, particularly in the respiratory and parenteral sectors. He has fulfilled a range of consultancy roles for clients including facilitation, decision support, technical problem solving and, of course, user research/human factors. Julian joined Team in 1998 and has degrees in both Mechanical Engineering and Psychology. Prior to his current role, Julian worked as a design engineer and then as a consultant within an international innovation management practice. Julian has been a regular presenter at international conferences on topics related to HFE, particularly of combination products and with a regulatory focus.

Richard Johnson

President, Parenteral Drug Association

Richard has been president of the PDA since 2009. Formerly, he was Director, Corp. Quality Center of Excellence at Hospira/Abbott (2001 to 2003) and Director of QA at Sanofi Winthrop from 1992 to 1994.

Tom Oakley

Director of Drug Delivery Device Development, Springboard

Tom leads engineering and scientific teams developing new injection devices, pumps and inhalers. He has been the named inventor on dozens of patents throughout his 20 years' experience in industry. He is a regular speaker at various international conferences on innovation and medical device development, and mentors Engineering and MBA students on innovation and device development at the Cambridge University Engineering Department and the Judge Business School. He read Engineering at Cambridge University before becoming the Choate Fellow in Human Physiology and Pathology at Harvard University.

Mathias Romacker
Former Senior Director, Device Strategy, Pfizer

Mathias is the Principal of Romacker Injection Device Strategy, LLC. He brings over 30 years of industry experience on the supplier and pharma side to the table. Mathias retired from corporate life in December 2019. He stays connected to the industry through speaking engagements and in advisory roles. Furthermore, he joined the PDA Board of Directors in January 2020. Mathias was last Senior Director, Device Strategy at Pfizer HQ in New York City. He joined Pfizer in March 2015. In this role within Pfizer Global Supply he focused on the front end of device technology. He worked with multiple functions and sites across the organization to develop a device strategy for Pfizer pipeline and inline products.

Dr Alex Vasiev
Manager of Device Development, Oval Medical Technologies

Alex Vasiev, PhD, has a wide range of experience in medical and biomedical R&D, and is a passionate problem solver. Before joining Oval, he worked in academia and consultancy with a primary focus on the interface of engineering and biological systems. Dr Vasiev has been involved in the development of everything from smart stem cell microniches to patch pumps, inhalers and several high-viscosity autoinjectors. As a Manager of Device Development at Oval Medical, he has led various projects, guiding technical teams and device development programs. He graduated with an MEng in mechanical engineering with aeronautics, and a PhD in biomedical engineering from the University of Glasgow (UK).

Mathew Young
CTO, Oval Medical Technologies

Matthew Young founded Oval Medical in 2009. He has more than 10 years' experience working with a leading medical product development consultancy. Matthew's work has encompassed all aspects of industrial design. Matthew is recognized as a world–leader in the design and development of autoinjectors. He is a regular presenter at key industry conferences and has attended review meetings with the FDA in Washington and with the ISO committee to develop new standards in this area.

Jo Shorthouse (Moderator)
Journalist and Healthcare Editor, Informa Pharma Intelligence

Jo is a London-based journalist covering the commercial side of the pharmaceutical sector in Europe. She is often to be found at meetings and events, interviewing industry leaders. She also regularly turns her hand to creating infographics.