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# A New Purpose

## Drug repurposing is in vogue, but it's not always as easy as you think.

Geralt Williams | 06/18/2019 | Opinion

It is often said there is no such thing as an original idea – inspiration is always derived from something or someone else. And this is by no means a bad thing. As one example, consider drug repurposing for nasal delivery. This strategy became popular around the mid-nineties with companies wanting to leverage existing drug products through new routes of administration to give them a new lease of life. Nasal delivery was a popular option as its convenience was seen to improve patient compliance and allowed anyone – even a casual bystander – to administer drugs effectively in the event of an emergency. But existing drugs can be repurposed in many other ways as well.

Drug repurposing has recently seen a resurgence in the industry – mainly because of

economic drivers. The development and commercialization of new drug therapies requires up to 15 years of development work, and can represent around a $2.6 billion investment. Repurposing is cheaper and less complicated, although, as I will discuss later, it remains a complex exercise – and in my view, that complexity is often underestimated. But it is certainly an effective option to avoid extensive development work, and 54 percent of biologics launched or approved in the US in 2017 were for existing drugs repurposed for new disease indications, reformulations or combinations ('="">). For industry-newcomers and disruptors alike, there is space within the sector for them to make their mark. And with the recent approval of Spravato, an FDA-approved antidepressant adjunct, and Nazolam, a short-acting sedative drug, both repurposed for nasal drug delivery, the playing field is seemingly wide-open.

Repurposing presents a complex network of challenges that need to be addressed for the whole project to succeed. The correct choice of device is key – is it intuitive for the patient? Can it support adherence to the regimen? Consider the site of deposition – droplet and particle size, droplet velocity and the anatomy of the nasal cavity are all key considerations when repurposing a drug for nasal delivery. The impact of the epithelial membrane and mucus layer should also be clearly understood. Bottom line is that developers must understand three core objectives: deposition in the desired location; retention within the nasal cavity; and therapeutic effect. The strategy to achieve these objectives will depend on local versus systemic indications.

There can also be confusion about the regulatory process. First introduced in 1999, the FDA's 505(b)(2) pathway offers companies the opportunity to develop new formulations from existing products – so long as they will have a meaningful impact for patients. This registration pathway gives companies up to three years to develop and protect a repurposed product, as opposed to the 180 days available through other regulatory pathways, and the chance to pursue "innovation without duplicating existing work". While the benefits of this pathway are undeniably significant, the challenges that it presents are equally important. Some of the information required for approval through this pathway doesn't come from the

company developing the drug; rather, it is derived from previous studies not conducted by or for the applicant. This can often leave companies in a dilemma as they search for relevant studies to support their application. Most FDA guidance documents referring to New Drug Applications do, however, outline the steps required for a drug to be approved. With that being said, there is no specific

guidance on 505(b)(2) drug development programs from the FDA, which may overwhelm those unaccustomed to it.

And for a repurposed drug product for nasal delivery to be successful, it must employ an effective delivery system. We are witnessing a move to unit dose or bi-dose delivery devices for a number of reasons. For example, they can deliver powder or liquid drug formulations, are primeless, can be delivered 360°, are intuitive to use, and the protective chamber decreases the risk of misuse. They can also be administered by a third party in an emergency mode, are cost effective with minimal dead volume and, critically, have multiple market drug references already available in multiple regions, which means they are a proven technology.

For years, repurposing to nasal delivery seems has been a forgotten application, but I'm delighted by its resurgence. Many of us have short memories and there is a natural temptation to view it as new. This also leads us to assume that a new innovation is for trailblazers and that the risk can be as great as the reward. But nasal delivery is truly well established in the industry and, in my view, should be more widespread.

Let me restate: it is often said there is no such thing as an original idea, every idea is inspired by something or someone else. Repurposing isn't an original idea – it is decades old and the expertise is already well founded in the market. The challenge is that the complexity of the development process is significantly underestimated and people often do not take into account all of the key challenges involved.

## Reference

## About the Author

**Geralt Williams**

Director Scientific Affairs at Aptar Pharma.

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