

How Perrigo's global vice president of women's health, **Frédérique Welgryn**, brought true innovation to market via the **first over-the-counter birth control approved by the FDA.**

BY **KATERLIN LE FOLVAVEZ**

Perrigo's OTC GAME changer

**SPEED TO
VALUE:
A PLAYBOOK FOR
BOLD
RESULTS**



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- **FRÉDÉRIQUE WELGRYN**

No RX Required
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If the desire to have an outsized impact is a key motivator for executives the world over, perhaps no one understands that feeling better than Frédérique Welgryn, global vice president for Women's Health at Perrigo. For close to a decade, Ms. Welgryn's team of researchers, scientists and clinicians worked tirelessly on a groundbreaking campaign to develop the first over-the-counter (OTC) birth control contraceptive available to women in the U.S.

As a result of the passion and dedication from her team, the FDA approved Opill on July 13, 2023, the first ever daily oral contraceptive pill to become available over-the-counter without a prescription, soon to be available online and in stores in early 2024 to people of all ages.

Insigniam Quarterly recently had the opportunity to speak with Ms. Welgryn—named by *Fortune* as one of the top 13 innovators shaping the future of health—about this monumental achievement, lessons learned, and how to overcome challenges when people's lives literally depend on your success.

IQ: Congratulations on your success with Opill, which is truly an incredible achievement. What inspired Perrigo (and formerly, HRA Pharma) to develop Opill?

Ms. Welgryn: This is a groundbreaking achievement that was inspired by three key factors. First and foremost is the purpose of empowering women to have control over their sexual health journey. This innovation aims to provide easy access to safe and effective solutions for contraception in the U.S.

Second, the sobering facts in the U.S. revealed that nearly half of the

approximately 6 million pregnancies are unintended—and this is a clear public health issue. One-third of women face difficulties in obtaining or renewing contraceptive prescriptions, while 15 million women use the least effective contraceptive methods despite their desire not to become pregnant. The process of scheduling appointments and taking time off work for consultations adds to the challenges women face.

The third vital component is the company and team's determination and courage to address an issue that had previously gone unresolved. It takes guts to embark on a complex, long, and challenging journey for the greater good, embodying a spirit of entrepreneurship and risk-taking. This courage, determination, and pioneering attitude are what the team refers to as "gutsiness."

IQ: From what I understand, it sounds like Perrigo's researchers and scientists essentially had to reinvent the wheel in some respects to develop an over-the-counter solution that would be safe and effective. Can you describe the complexity this process entailed?

Ms. Welgryn: Although the ingredients used in prescription birth control were first approved in 1973, we had to engage in what we call a first-in-class prescription to OTC switch process, because we knew there was a massive need for more access to effective contraception in the U.S., and we wanted to tackle that challenge.

The process of making prescription drugs available over the counter involves several crucial steps. Firstly, we rewrote the patient leaflet to ensure it is easy for consumers to understand, removing any complex medical jargon. We then conduct extensive consumer studies to confirm

that women can easily interpret the drug information, including how to take the medication and when to use it.

Next, we perform self-selection studies with hundreds of patients, including those who might have contraindications. They must decide, based solely on the label, whether they can use the product. Any incorrect decision could affect the FDA's approval of the switch.

The most challenging step is probably the actual use trial, where we simulate real-life conditions for using an over-the-counter drug. Participants receive and use the product as they understand it, without external encouragement or incentives. They maintain an online diary to report their real-life usage. This approach mimics real-world scenarios, unlike traditional clinical trials that often involve patient compliance enforcement.

We also conduct an in-depth safety review, gathering data from previous clinical trials, pharmacovigilance databases, and registries to ensure that health authorities are aware of any potential safety concerns. Pharmacodynamic research was also conducted to bring modern data to our application about the window of intake.

Throughout the process, we maintained

close communication with the FDA, aligning with them on study endpoints, methodologies, and handling unexpected events. Ultimately, we presented a comprehensive benefit-risk analysis to demonstrate that the benefits of making the contraception available over the counter provides more access outweighed any potential risks.

All data was then presented to the FDA, precisely at a pivotal moment of the history of reproductive rights in the U.S. when the Roe v. Wade decision was overturned. Eight months later, this submission underwent a two-day advisory committee meeting with the FDA. This committee, consisting of experts from various fields, including contraception, statistics, clinical trials, and consumer representation, discussed and recommended approval for Opill to be sold over the counter without a prescription.

Our extensive preparations, including thousands of hours and numerous rehearsals, led to a unanimous vote of 17 to 0 in favor of approval by the panel. This was a momentous and emotional milestone in our journey to provide accessible contraception to women across the U.S. and widely covered by the media.

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—Frédérique Welgryn
 Global VP, Women's Health, Perrigo

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When The Work Pays Off

During their review process, the FDA's Nonprescription Drugs Advisory Committee (NDAC) and the Obstetrics, Reproductive, and Urologic Drugs Advisory Committee (ORUDAC) voted unanimously 17 to 0, with no abstentions, making Opill available for OTC use.

IQ: What were the most significant challenges you and your teams encountered while developing Opill—and how did you overcome them? Were there setbacks to contend with?

Ms. Welgryn: Throughout our journey, we faced numerous obstacles and encountered moments of difficulty, whether how to build this first-in-class switch program, or in our interactions with the FDA. We needed to prove ourselves at each step, which wasn't always easy. During that process, we tried to understand the FDA's expectations and maintain a collaborative and constructive approach. The FDA's primary goal is to protect consumers, and we needed to bring convincing data to show that consumers could use Opill safely and effectively without the intervention of a healthcare professional. Even in challenging times, we remained steadfast in pursuing this objective.

An example of a unique challenge was our quest for a no-age restriction for Opill.

To achieve this, we had to enroll young people in our clinical trials for contraception, which was a challenging endeavor, especially during the COVID-19 pandemic. Nevertheless, we believed that adolescents needed this product, and including them in the trials was essential to gain FDA approval without age restrictions.

Another aspect of our journey was our collaboration with advocacy groups. While not a challenge, it required mutual understanding. By remaining open, transparent, and clear about our respective roles, we established a productive relationship. Over time, these groups came to respect our expertise, and we adjusted our efforts to align with their support. Their instrumental role in our success was the result of significant efforts to explain our work and foster their understanding and endorsement.

Lastly, the political landscape added a unique dimension to our journey. Our submission coincided with the overturning of Roe v. Wade by the Supreme Court in the U.S. This further amplified the media

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attention and spotlight on our application. Yet, we were determined to base our application on science, data, and facts. We aimed to minimize the influence of politics as much as possible. We adhered to our strategy, maintained collaboration, and respected all stakeholders, even in frustrating situations. While acknowledging the political risks, we remained steadfast in our focus on delivering data and demonstrating that facts and science can ultimately prevail.

IQ: As a leader, how do you manage global teams toward a common vision and shared goal? How do you keep others enrolled in that vision through challenging times?

Ms. Welgryn: Leading a project of this magnitude demands a careful balance between organizing and motivating teams, maintaining their connection, and making well-informed decisions. A shared purpose, unwavering passion, clear governance and a talented, high-performing team were the driving forces behind our project's success. However, even in such teams, it's possible to lose momentum, succumb to distractions, or fall into minor conflicts. These setbacks can prove detrimental to the project's progress. To mitigate such issues, one must remain attuned to the team's dynamics and promptly address any emerging concerns, whether related to resources or competencies. Nipping these problems in the bud is essential to prevent them from escalating.

Staying connected goes beyond the team itself; it extends to understanding and navigating diverse personalities, egos, and cultures within the team. Frequent gatherings are necessary to ensure everyone remains aligned with the project's overarching purpose, organizational goals, and governance. In certain instances, coaching may be required to facilitate a collective step back, realign everyone with the project's significance, ensure cohesion, and boost team morale. Moreover, garnering support from the leadership team is vital, as it defines the project's priority within the company. Maintaining unanimous backing from the company's leadership ensures agility and preserves the freedom to make decisions without unnecessary bureaucratic hurdles.

Resource management is another critical

facet of the job. It involves safeguarding the essential resources vital for the project's success. This task often involves adapting to changes in leadership, such as CEO transitions and company acquisitions, which I experienced during this journey with HRA and Perrigo.

My role extended to communicating the project's importance to internal stakeholders, emphasizing its value for women and the company as a whole. Persuading CEOs and key executives to offer strong and unwavering support was essential. Fortunately, I found receptive leaders who recognized the unique opportunity and extended their steadfast commitment to our cause.

IQ: Personally speaking, what fueled your passion and helped you maintain your vision and dedication throughout this process?

Ms. Welgryn: Not often in your professional career do you get a chance to make a real difference, to impact society, to provide a bit of hope to millions of people. This project gave me the unique opportunity to influence society and offer hope to millions of individuals, particularly considering the complex landscape of reproductive rights in the U.S. over the past year.

As a woman, there's no greater aspiration than empowering fellow women to make choices about their reproductive lives. This endeavor not only impacts broader society, but it also holds deeply personal significance when you think about your family, your daughter, and the people around you. It becomes clear that this mission is of utmost importance, and the resolve not to falter in achieving it is unwavering. This project possesses a unique dimension with its societal and personal implications.

Furthermore, it prompted me to contemplate the broader landscape of women's health. Numerous reports have highlighted the neglect of women's health in terms of funding and projects in recent years. The desire was to make this initiative not only successful but also to serve as proof that doing the right thing can translate into a great business opportunity. The goal was to position women's health as a subject of positive news headlines and demonstrate its potential as a thriving business domain.



BIO: FREDERIQUE WELGRYN, GLOBAL VP, WOMEN'S HEALTH, PERRIGO

Frederique Welgryn is Global Vice President for the Women's Health Division recently created in Perrigo in January 2023. In her role, Ms. Welgryn leads a team of Global experts in marketing, digital, ecommerce, innovative Rx to OTC switches, regulatory and scientific affairs—all passionate about championing the right of women and people to determine their own sexual health journey. Ms. Welgryn has 25 years of experience in Pharma and OTC. She started her career in large pharma organizations such as Roche, AstraZeneca, and Sanofi, worked as a managing consultant for Cap Gemini Ernst and Young, and joined the executive leadership team of HRA Pharma in 2010. In that role, she led the teams obtaining the centralized EU Rx-to-OTC switch of emergency contraceptive ellaOne, the switch of oral contraceptive Hana in the UK, and the switch of daily birth control Opill in the U.S. Ms. Welgryn is a pharmacist by training with MS in business and management from Paris V University and HEC Paris.

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On a personal level, the journey has been profoundly fueled by the passion exhibited by the entire team, researchers, healthcare providers, advocates, and the women themselves. Engaging with various groups and consumers, listening to their experiences, and sharing their unwavering belief in the importance of providing women and people in the country with easier access and fewer barriers to reproductive health has been an inspiring and unifying force.

For leaders, it always commences with understanding the ‘why’—the purpose behind their endeavors. My motivation primarily stems from the collective purpose of the team, the consumers, and the individuals whose lives we are positively impacting.

Nonetheless, occasionally, leaders need to pause, reflect, and take a step back, even when deeply invested in a project. Even when you have a significant stake in the game, there are moments when taking a more distant perspective becomes necessary. This ability to step back, disengage momentarily from the team, and explore different perspectives has proven valuable in finding the right arguments and making critical decisions that resonate with all stakeholders.

IQ: The theme of this issue of *Insigniam Quarterly* is ‘speed to value.’ As a leader, how do you balance the need to be decisive and move the organization forward quickly while still ensuring that the product you’re developing is safe and effective?

Ms. Welgryn: When you are lucky enough to work in healthcare, there’s one fundamental principle that stands paramount, and that’s never compromising on safety and efficacy. This isn’t a matter of negotiation; it’s a matter of unwavering ethical responsibility. When considering innovation strategies, the welfare of patients is at the forefront, and there’s no room for compromise in this regard.

Maintaining this balance requires a clear and unwavering focus on our objectives. It’s not just about articulating our goals but consistently translating these objectives into actions, ensuring that the team lives up to these commitments. Leadership, in its essence, involves creating an environment where the team’s full potential is nurtured. It’s also about being receptive to the importance of active

listening and maintaining a willingness to challenge one’s own viewpoints and making clear and sometimes difficult decisions. Seeking external perspectives and advice can be invaluable, particularly when personal emotions and involvement cloud judgment.

One experience I’m reminded of occurred when we were actively engaged with two Insigniam partners, and we organized a team meeting to delve into the concept of responsibility. We aimed to foster a collective understanding of the term’s genuine purpose.

The objective was to eliminate any inclination to shift blame onto external factors or individuals. This was a pivotal moment where the team grasped the depth of their individual responsibilities and how these translated into our collective ability to drive change. Understanding and embracing this concept reinvigorated the team’s motivation, propelling us to surmount obstacles and maintain an accelerated pace toward our objectives. It fundamentally altered how we managed the program and approached the concept of ‘speed to value,’ ensuring that each team member comprehended their individual responsibilities and the impact they could make collectively.

IQ: Were there instances during the development of Opill where you faced any self-doubts or failures? If so, how did you overcome those challenges to stay effective and focused on the task at hand?

Ms. Welgryn: Of course, there were so many setbacks and challenges along the way. These moments of failure, as they are often labeled, carry an undeniable weight, and the typical narrative suggests the importance of learning from them. However, it’s worth noting that the introspective examination of past failures is not always a pleasant experience, and many individuals may shy away from it.

One particular instance comes to mind of a project that unequivocally met with failure. In this situation, our team made a deliberate choice to embark on a comprehensive review of the project, which was arduous and demanding, and we meticulously dissected everything that had gone awry. We acknowledged the existence of external factors beyond our control—an occasional occurrence in such undertakings. However, a substantial portion of the issues could be directly attributed to our internal



dynamics, including our leadership approach and the orchestration of our team.

As we navigated this introspective journey, we identified deficiencies within our team’s structure, which was a valuable lesson for our work on Opill. These shortcomings encompassed a lack of clarity in roles and responsibilities, leadership disparities, and instances where team members were disconnected from the overarching purpose.

Reflecting on this experience marked a pivotal moment, shaping my approach to the Opill journey. While perfection remained elusive, I was armed with insights drawn from past experiences, aiding us in our quest.

IQ: What advice would you share with other global executives leading large-scale projects with high levels of complexity?

Ms. Welgryn: Maintaining a sense of purpose is paramount in any significant undertaking. Ensuring that every individual involved comprehends the “why” behind their actions is vital. A strong organizational structure is equally critical—every team member should be acutely aware of their role and, notably, their

responsibilities. These responsibilities form the bedrock of a project.

Regardless of one’s position within the organization, staying connected to the team is of utmost importance. Even the most senior leaders should invest the time and effort to engage with their teams. In the realm of transformative and strategy-altering projects, proximity is essential. It allows for a visceral understanding of the ongoing developments, offering insights into the challenges team members encounter.

Lastly, adept stakeholder management is indispensable. This encompasses oversight from boards, CEOs, and various stakeholders who must remain closely aligned with the project’s objectives. It is a continuous endeavor to advocate for the project, create trust, and reaffirm its significance to the company and its broader impact on the world. This holistic approach ensures that the purpose remains in focus, the organization functions seamlessly, and the team operates harmoniously. **IQ**

Customer Devotion

For Ms. Welgryn, there is no greater aspiration than empowering fellow women to make choices about their reproductive lives. This endeavor, she says, not only impacts broader society, but it also holds deeply personal significance, “when you think about your family, your daughter, and the people around you.”