

10 Years of Follistim® Branded Products and Beyond

a report by

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Organon is a global leader in the development of innovative prescription products for reproductive medicine, anesthesia, mental health, and women's healthcare. Our company objective is to be a reliable partner to healthcare professionals and patients by providing products and services that improve the health and quality of human life.

In the field of reproductive medicine, Organon's commitment to providing top-quality products is evident by its continued development of safe and effective fertility medications, including the Follistim® brand, which was introduced in the US in 1997.

The constantly evolving field of reproductive medicine creates opportunities for knowledge sharing among healthcare professionals. As leaders in the field of fertility, Organon is dedicated to improving disease awareness through consumer and patient education and through its support for continuing professional education for those who strive to help couples succeed in having a child. We hope that '10 Years of Follistim® Branded Products and Beyond' will be an effective reference for those specialists.

This publication brings together contributions from experts across the field of reproductive medicine. Topics included relate to the diagnosis and treatment of the infertile couple. The opening chapter, authored by Zev Rosenwaks, MD, begins this discourse by addressing the challenges in identifying factors that predict a patient's response to ovarian stimulation and then using the information gleaned to optimize the treatment regimen and the chance of having a healthy child (see pages 5–8).

Women are now waiting well into their thirties and forties before making the important decision to have a child. Since 1982, there has been an

increase in the number of women having their first babies in their mid-thirties and later. Career choices often mean putting a hold on starting a family. While it is not completely unheard of for women in their fifties and

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beyond to achieve natural pregnancies, the odds are certainly not in their favor. Approximately 10% of women between the ages of 20 and 29 years report difficulty in conceiving; this figure jumps to 25% for women in their thirties and doubles to 50% for women more than 40 years of age. Egg quality and ovarian reserve decline with age and are the primary factors causing age-related female infertility, but there are also subtle shifts in hormonal patterns that make the endometrium less receptive with age. Studies are ongoing to determine whether aging eggs are to blame for infertility or if an aging uterus is a critical factor as well.

The chapter by Anuja Dokras, MD, provides a scientific review of the most common endocrine disorder affecting 6–7% of women of reproductive age: polycystic ovary syndrome (PCOS) (see pages 9–12). Dr Dokras describes the pathophysiology of the disorder and how its intertwining relationships with obesity and reproductive outcomes make it one of the main causes of infertility in women. She reports on the effectiveness of lifestyle modification and pharmacotherapy in treating infertility associated with PCOS.

Approximately two-thirds of Americans today are considered to be either overweight, defined as having a body mass index (BMI) between 25.5 and 29, or obese, defined as a BMI >30. Approximately one-third of the US population falls into the obese category. Studies have shown that a BMI >32 is associated with lower conception rates when using assisted reproductive technologies. Obesity results in a greater production of estrogen, which in turn results in a hormonal imbalance that interferes with ovulation. There is also a higher cancellation rate in obese women, and women who are overweight or obese are less likely to respond to fertility therapy. Egg retrieval is more difficult in this population as well, because the extra tissues and adipose layers make the ovaries harder to access.



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clinical research into the cellular regulation of pre-fertilization events and epididymal physiology in the non-human primate. She earned her doctorate from Old Dominion University in Norfolk, Virginia, and completed her post-doctoral studies at the Eastern Virginia Medical School.

Next, the pharmacotherapy of ovarian stimulation with follitropin beta is reviewed. In this chapter, authored by Henk Jan Out, MD, the development of recombinant follicle-stimulating hormone (rFSH) is discussed (see pages 13–16). Dr Out also highlights the benefits of rFSH, and offers a look forward into some of the genetic technologies that may contribute to treatment advances for infertile couples in the future.

In their chapter, Samuel Pang, MD, and Michael Kettel, MD, describe the simplification of infertility treatment processes through the use of technological advances—specifically the pen delivery system—for the administration of gonadotropins for patients undergoing controlled ovarian stimulation for *in vitro* fertilization (IVF) or ovulation induction (see pages 20–22). These two reproductive endocrinologists draw from their clinical experience as investigators in the two registration trials that examined ease of use and patient understanding when using a pen delivery system to self-administer follitropin beta. That experience, along with their subsequent clinical practice using the device, makes this an enlightening chapter, complemented by the following report of the results of patient and healthcare provider satisfaction surveys with the Follistim Pen in everyday clinical practice, written by myself and my co-authors Drew Moffitt, MD, and Ms Rochelle Orr (see pages 23–26).

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The next chapter, on single-embryo transfer (see pages 27–29), addresses one of the most important issues faced by reproductive medicine today:

that of maximizing treatment outcomes in assisted reproductive technologies while minimizing the risks associated with multiple pregnancies. Richard Scott, MD, identifies these risks and reviews the

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success rates of single-embryo transfer. He brings a scientific review as well as his clinical experience into the discussion to emphasize the need for individualized care and patient selection when considering this treatment option for infertile patients.

In the concluding chapter, we are honored to have Howard Jones, MD, share his views on the immediate and distant future of fertility treatment (see pages 30–32). First, though, Dr Jones takes us back to the start of assisted reproductive technology in the US, providing a rare look at the technological developments that have affected clinical practice and a glimpse of how patient demographics have changed since then. He then brings us beyond today to a future where he proposes a new era in reproductive medicine.

We are delighted to offer you '10 Years of Follistim® Branded Products and Beyond,' and sincerely hope that it imparts scientific fodder for consideration and discussion in this quickly evolving field. ■

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