

# From Birth Control to Menstrual Control

## The Launch of the Extended Oral Contraceptive, *Seasonale*

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*Cet article relate une discussion sur quelques implications et problèmes de la santé reproductrice des femmes et leur bien-être qui ont suivi le discours et le développement et le lancement en 2003 du contraceptif oral: Seasonale*

In September 2003, in a move much debated and discussed in the North American media, Barr Laboratories received U.S. FDA approval to release *Seasonale* on to the prescription drug market. *Seasonale* is a repackaging of low-dose birth control pills<sup>1</sup> in an extended regimen consisting of 84 straight days of use instead of the previously prescribed 21 days, followed by a seven day pill-free interval. Its release gave formal medical approval to the practice of long-term menstrual suppression achieved through continuous birth control pill use—much longer than 84 days in some cases—which has been quietly carried out by thousands of women, for a variety of reasons, for at least the last two decades. Some of the public discourse surrounding this event has been fuelled by the publication of a book in 1999 by Brazilian gynecologist, Dr. Elsimar Coutinho and population scientist, Dr. Sheldon Segal, entitled *Is Menstruation Obsolete?* Coutinho and Segal's main thesis is that menstruation is useless and harmful to women, their families, and to society. He argues that menstruation

is an evolutionary anomaly, which has become an inconvenience and a hassle for women and suggests that those who do not agree with him are misguided and out of date.

The extent of the discussion and debate that has accompanied these events is not a novel aspect of the hormonal contraception issue—there is an abundant body of literature and commentary on what has come to be known as the “Pill” (Marks). However there is a sense, which comes through in the discourse surrounding these recent events that the emphasis has shifted from a concern with birth control to one of menstrual control. Made explicit in Coutinho and Segal's book, this shift is also alluded to on the *Seasonale* website in the trademark slogan, “Fewer Periods. More Possibilities.<sup>TM</sup>” This can be read as a seemingly unintended ironic play on the promise of the Pill, marketed to millions of women on the implied assurance of “fewer possibilities” of pregnancy. And the issue of menstrual control forms the basis of a lively and intimately detailed discussion thread on the Museum of Menstruation website, which, since it started in December 2000, has received contributions from hundreds of women throughout North America and Europe, responding to museum curator, Harry Finley's question, “Would you stop menstruating if

you could?”

There is a significant body of feminist scholarship which explores the connection between the creation and development of reproductive technologies—of which *Seasonale* is one of many—and age-old beliefs and assumptions about “woman's nature” (Martin, Wajcman, Corea). Such beliefs and assumptions have been analyzed and deconstructed and feminist theorists and activists alike (Bordo) have exposed and delineated the social, political, and economic impact on women of the most central of these—the idea that women are inferior or less worthy as a result of their reproductive functions and capabilities. Cross-culturally and since ancient times, say these feminists, the so-called evidence for women's secondary status, manifest in their out of control, substance-exuding, form-changing bodies and their subservient sexual and familial roles, has been summoned up to deny, subjugate, and oppress them (Duden).

However, as part of her contribution to a series of articles on contraception, which ran in the national Canadian newspaper, the *Globe and Mail*, columnist Margaret Wentz put forward the argument that such conditions no longer exist for most women in contemporary Anglo-American and Western European society. This, she claims, is due in large part to the so-called sexual revo-

lution brought on by the introduction of the Pill in the early 1960s. Wente is obviously not alone in this analysis (see Tone). There is broad and popular acceptance of the idea that the introduction of the Pill has had a dramatic impact on these societies and on the lives of women in particular, as a result of the fact that the Pill, in all its various mutations, has provided them with the histori-

like the Pill itself, not something that has gained universal acceptance. Issues of morality, ideology, and family values, as well as immediate and long-term health effects that are both directly and indirectly related to Pill use, are, as the *Seasonale* story demonstrates, still very much matters of debate (Gordon and Gordon). And while, as a result of changing social values and technological advances,

duced on to the market was specifically formulated to mask these origins. Such a formulation was the outcome of the need for Rock and the Pill's co-creator, Gregory Pincus, to produce what Margaret Sanger—champion of the birth control movement in America (see Tone)—described as a safe, cheap, reliable, “magic pill” (208) that could be swallowed like an aspirin, and that would meet the demands of the Church and its social conservative allies for a birth control method that was “natural” and “God-given.” Rock and Pincus, believing they could promote the Pill to the Church leadership on the basis of it being a method similar to the Church-approved “Rhythm Method,” which simply uses and incorporates the “natural” hormonal cycling of the body to regulate the possibility of conception, “decided to cut the hormones off after three weeks and trigger a menstrual period” (Gladwell 4). This strategy of creating the impression of “business as usual” in women's bodies was also aimed at the prospective users, the women themselves, who Rock and Pincus felt would be reassured by a continuation of their monthly bleeding.

However, many women, as well as the Church leadership were to see through this ploy. Since the release of its 1968 encyclical outlawing the use of all forms of artificial birth control by its members, the Roman Catholic Church continues to maintain its ban on the use of the Pill, a position that is also supported by other contemporary religious and neo-conservative movements. As for the women, increasing numbers of them—80 per cent of American women born since 1945 have used oral contraceptives (Tone)—have rejected the edicts of traditional religious and conservative ideology and taken control of their fertility through the Pill. And as for Rock's and Pincus's attempt to give women the assurance of regular menstrual cycles while on the Pill, there are a numerous references in the literature to the so-called “honeymoon trick” (Rabin), whereby

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cally unprecedented ability to more or less effectively and safely control their fertility. In her recent book, Dr. Penny Le Couteur comments that in the last 40 years, in countries where the Pill and other similar hormonally-based contraceptives have become widely available,

the birth rate has dropped, and women have gained more education and have entered the workforce in unprecedented numbers: in politics, in business and in trade, women are no longer an exception. (Le Couteur and Burreson 221)

Le Couteur goes on to conclude that the Pill was more than just a fertility-controlling medication and that its introduction signaled a change in awareness. This was not just on issues of fertility and contraception, but also with regard to women's familial and sexual roles, allowing increasing numbers of them to speak out about and take significant steps to address the issues of broad-based gender inequality, violence, and poverty underpinning centuries of women's oppression.

This being said, the idea that the Pill has wrought only changes for the better, while popularly accepted, is,

the parameters of the debate have altered, it is interesting to consider that the concerns being raised by those involved in it have some of their sources in the conditions and circumstances surrounding the creation and marketing of the Pill some 50 years ago.

For instance, what is perhaps the central element of the current controversy—the issue of continuous use—has its origins in the particular characteristics of the development and testing phase of the initial versions of the Pill undertaken in the U.S. in the late '50s and early '60's (Oudshoorn). These were a consequence of the attempt to maneuver the prototype Pill through the conservative social climate and the obstacles raised by the leadership of the Catholic Church regarding the artificial, and therefore unacceptable, method of birth control presented by the Pill. Initially deriving from hormonal drugs and therapies that were created to treat fertility and menstrual problems through a program of short- to medium-term continuous use—this could be a interlude of a number of months to a number of years depending on the need and the problem—the version of the Pill that its main creator, the devoutly Catholic obstetrician, John Rock, intro-

women plan continuous pill taking around a special event, suggesting that the practice of continuous use was adopted by women not long after the Pill's introduction and has continued to grow since then.

Recently, attention has focused on the extent to which this latter practice is connected with the "marketing" and commercialization of disease prevention and control and how this relates to the use of the precursors of the Pill in the treatment of reproductive and menstrual disorders (Lippman). These disorders include a whole range of conditions from mild menstrual discomfort to dysmenorrhea, which involves severe pain and excessive bleeding. Possibly the most widespread contemporary use of the Pill in this area is in the treatment of a condition that has been described as one of the most common diseases on the face of the earth, endometriosis (see the Endocenter website). This statement, which is based on the contention that endometriosis afflicts over 80 million women world-wide is unfortunately not supported with references to any research data. Interestingly enough, a lack of supportive references and citations is far from the exception in this area of the literature. There is no supportive data cited for the other main therapeutic use of the Pill, the prevention of ovarian and endometrial cancer, which Malcolm Gladwell, for instance, claims are reduced in Pill users by 70 and 60 per cent respectively (7).

While acknowledging the documented beneficial effects of the Pill and other hormonal compounds in the treatment of reproductive system pathologies, I would like to suggest that this issue of unsubstantiated claims, which are widely quoted in the popular literature, is one among a number of issues that are part of a growing trend to promote drugs and therapies, including the Pill, for their preventive benefits. Women's health activist and McGill University Professor Abby Lippman has discussed this trend, coining the term "neo-

medicalization" to describe what she claims are two new variations, deriving from contemporary economic forces, on the historic and cross-cultural practice of medicalizing women's lives, in particular their reproductive lives. In the first place, she argues, the pharmaceutical industry is moving into the business of disease-creation, a role historically dominated by physicians. Lippman de-

hormonal deficiency or imbalance and was also labeled as the cause of other conditions such as heart disease and osteoporosis. She suggests that this framing of menopause as a cause of subsequent problems meant that even when the disease label fell out of favour, the treatment of menopause in the form of Estrogen Replacement Therapy (ERT) and combined Estrogen and Progesterone Replace-

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scribes an interrelated development, which involves the framing of normal bodily experiences less as diseases themselves, but as causes of future diseases. She claims that the phenomenon of neo-medicalization

fits seamlessly in the consumer-oriented society of North America today and to current views of disease—if not "pre-disease"—as a "market opportunity!" For example, this latest medicalization comes packaged as individual "choice" with the offer of multiple "options" to women. Thus, both neo-medicalization and consumerism construct health as a commodity, a resource needed for economic growth, and both emphasize increasing women's choices (via the creation of tests, screening exams, etc.). Further, by framing life experiences as "causes" of disease, neo-medicalization thereby generates a whole industry to create "pills for prevention. (9)

To illustrate this argument, Lippman looks at how the transitional state in women's lives known as menopause came to be understood and treated as a disease caused by

ment Therapy (HRT) continued to be recommended by the medical community because it was now seen as a measure preventing the onset of the diseases brought on by menopause. The negative consequences to women's health of such an approach have, argues Lippman, been recently revealed in the outcomes of the Women's Health Initiative (WHI) in which the two arms of a longitudinal, large-scale study looking at the effects of ERT and HRT on over 16,000 postmenopausal women in the U.S. were stopped three years earlier than the planned end date. The reasons given for the premature cancellation of the biggest trial of this type in drug trial history are outlined on the National Institutes of Health (NIH) website and include findings of an increased risk of invasive breast cancer as well as evidence that the overall health risks, in the form of increased susceptibility to heart attack and stroke, exceeded any benefits for the trial participants.

Menstruation is, Lippman suggests, being cast in the same way as menopause, as a problem of pathology that needs to be "fixed" or "eliminated" for not just its immediate undesirable and unwanted effects but also because of its disease-causing potential. The proponents of this

message include the persuasive—because difficult to refute—evolutionary arguments of Coutinho and Segal, who make a similar claim to Beverly Strassman, a U.S. anthropologist who has researched the link between breast cancer and menstruation. Strassman suggests that the much lower rate of pregnancy and postpartum amenorrhea in women in post-industrial society has given rise to a menstrual cycle rate that is 300 per cent greater than that of their pre-industrial foremothers (Strassman). This incessant ovulation in the form of an average of 400 menstrual cycles adds up to more than half of a life time's worth of monthly discomfort and distress for women of child-bearing age. In addition, there is the increased risk of developing some particularly aggressive types of cancers and a greater susceptibility to anemia, which, Coutinho and Segal argue, is one of the most serious health problems in the world.

Other proponents of this argument such as American MD, Patricia Sulak, demonstrate study evidence to support this theory about the ill-health effects of menstruation (Sulak *et al.*), and use it, as does Dr. Leslie Miller, the creator of the *NoPeriod* website, to make their case for the elimination of menstruation. Their message, which is framed in the language of choice and empowerment and aimed at all women of child-bearing age, emphasizes the benefits of not only minimizing the disease-causing potential of menstruation but of getting rid of the hassle and inconvenience of the monthly period. And this is where the Pill comes in. First with the years-old practice of off-label continuous use of the short-cycle oral contraceptives, which involves skipping the seven-day portion of placebos and continuous use of the 21 active pills in a Pill prescription. Then with the medically-approved version of this practice in the form of the extended cycle oral contraceptive, *Seasonale*, a package of 84 active pills and seven placebos, officially launched by the manufactur-

ers, Barr Laboratories at the end of 2003, and which is set for release in Canada within the next few months. And in the future, with the smaller dose, longer-use versions that are in the development pipelines of Barr and some of the other major pharmaceutical companies. With a potential target market of half the population combined with the high profit margin on birth control pills (Tone), as well as the greatly shortened research and development phase required for this incarnation of the Pill, it is not hard to see why the pharmaceutical companies seem to be staking out more space in an already lucrative market. Just as ERT and HRT was and is to menopause, so the Pill is and can be to menstruation, taking up center-stage with its dual roles in the processes of birth control and menstrual control.

Lippman's perspective is shared by other women's health advocates who believe that outcomes such as those that have come out of the Women's Health Initiative study should serve as a strong warning about the potential consequences of the neo-medicalization of menstruation. These include the members of the Society for Menstrual Cycle Research (SMCR), which is an organization comprised of reproductive health professionals, researchers, and activists from across North America, as well as Brazil and Australia. SMCR has, over the course of its 30-year history, been influential in raising questions about the risks to women's reproductive health of some of the mainstream approaches in this area. In a statement on the Society's website they have referenced findings from ongoing studies which were presented at the most recent SMCR conference in Pittsburgh in 2003 in order to articulate their concerns on the issue of menstrual suppression. Among these findings were ones that emerged from Alex Hoyt and Linda Andrist's 2003 study showing that women's negative attitudes toward the menstrual cycle were a better predictor of women's interest in menstrual sup-

pression than women's menstrual symptoms, suggesting the importance of psychosocial factors in women's decision-making about altering their menstruation. The possible source of some of these psychosocial factors was alluded to by Ingrid Johnston-Robledo and Jessica Barnack, whose study demonstrated a distinct bias in print-media coverage of menstrual suppression, whereby regular menstruation was portrayed as bothersome and even unhealthy and more space was given to the proponents of menstrual suppression and its benefits. Furthermore, a review of studies on extended cycle oral contraceptive use by Christine Hitchcock and Jerilynn Prior concluded that, as a result of a lack of well-designed, placebo-controlled, randomized trials, which examine women's experience, bone health and risks for blood clots and strokes, and which look at the particular risks faced by adolescents, there is not yet enough evidence to suggest that menstrual suppression is entirely safe and reversible. All this leads the SMCR membership to conclude that, as with many other health issues, women are not getting accurate, balanced information thus rendering an informed decision about this healthcare option difficult if not impossible.

Yet while there are potential learnings from the menopause and WHI study (see Lippman) there are also different concerns. Some of these are centered on the Pill's history as a safe and effective form of birth control and a harbinger of reproductive and sexual freedom for a generation of women as well as the role this will play in influencing women's response to, and acceptance of, the promotion of menstrual suppression. It is probably safe to say that the pharmaceutical companies are counting on this being an important factor in paving the way for the potential adoption of this practice among women who have the resources and ability to take advantage of it. Barr laboratories reported strong acceptance of menstrual suppression in results from their

clinical trials of Seasonale, in which over 1,400 women participated for a period of 12 months (Anderson and Hait). The strength of these results has since been called into question as closer analysis of the Barr data shows that of the 456 women who were in the Seasonale subgroup, 185 or 40 per cent, left before the end of the study with the majority of them citing the problem of break through or mid-cycle bleeding as the reason for quitting the trial prematurely (Rabin). However, in a press release issued in May 2004, Barr stated that initial sales of Seasonale had far exceeded their expectations and they were taking steps to triple their sales and support staff in order to keep up with demand (Hardy). An in-depth examination of these results and reports will be among the many tasks required in order to fully chart and analyze the Pill's makeover into a tool of menstrual control.

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<sup>1</sup>Active ingredients are 0.15mg of Levonorgestrel and 0.03mg of Ethinyl Estradiol.

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