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Preface

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FÜR KLINIK & PRAXIS

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Preface

Just over 50 years ago, on June 1, 1961 to be precise, the first contraceptive pill was launched by Schering/Berlin (now Bayer) on the European market under the brand name Anovlar. This preparation was initially approved only for the regulation of irregular menstrual bleeding in married women; at the time, no one could have imagined the influence it would have on women's lives. The introduction of the Pill throughout the world revolutionised family planning and fostered sexual freedom. Over the last 50 years, more than 300 million women worldwide have taken the Pill; there are probably about 150 million currently taking it. In Germany, more than 6 million women, i. e. 42% of the population in the reproductive age group, are protecting themselves from unwanted pregnancies by taking the Pill. In addition to its contraceptive action, however, in the last 20 years various so-called non-contraceptive benefits, such as a positive influence on skin and hair, in particular an improvement in acne vulgaris, regulation of heavy bleeding, less dysmenorrhoea and reduced frequency of ovarian cysts, plus a lower incidence of endometrial and ovarian carcinoma, have come to public attention. Some women take the Pill continuously, because they wish to be free of periods (so-called long-cycle contraception as an off-label recommendation).

The first reports of complications on the Pill were published as long ago as 1961 following its introduction, when a connection between thromboembolisms and use of the Pill was suspected.

Subsequently, it was soon realised that the initially too-highly dosed preparations did lead to an elevated risk of thromboembolism on the venous side of circulation, which was caused specifically by an excessive content of oestrogen (150 µg mestranol). On the arterial side a high dose of progestins (several times that needed to inhibit ovulation) caused a higher proportion of women with hypertension.

As consequence, both oestrogen and progestin dosages in oral contraceptives were reduced, and researchers looked for new progestins with the fewest and mildest side-effects possible. A further objective of new developments was to use substances, e.g. the group of progestins with such special partial actions as antiandrogenic properties, that would be suitable for treatment of women desiring contraception and in addition suffering from signs of hyperandrogenism. In the last years estrogen-free formulations either without ethinylestradiol or replacing ethinylestradiol by natural estradiol or its esters have been developed.

This further development of the Pill and other hormonal and non-hormonal methods of contraception has been paralleled by improved supervision of clinical trials with the introduction of Good Clinical Practice and the greater transparency afforded by central registration of clinical trials.

The Pill's history has been characterised by numerous highs, and also low points, such as the central question of whether the Pill causes cancer. In this connection, results obtained in beagles caused a lot of confusion at the beginning of the 1970s. It soon became apparent, however, that the steroid metabolism in beagle cannot be extrapolated to humans. The first epidemiological data on the subject of breast cancer and the Pill were published by Pike early in the 1990s. The discussion on steroid hormones and cancer that started at that time has never abated to this day. In recent years a further question has been raised, namely how the risk of cardiovascular disease can be minimised in healthy women taking the pill. The question of appropriate screening examinations based both on individual and family history and also on specific laboratory analyses has been mooted. With regard to cardiovascular disease, the family history has emerged as a clinically relevant parameter that can contribute to reducing the individual risk of venous thromboembolisms. New knowledge of the molecular genetic basics of the coagulation system has led to the characterisation of factors whose genetic traits are involved in determination of the individual risk of thrombophilia.

This special issue of *Journal of Reproductive Medicine and Endocrinology* intended to emphasise the most important developments in the history of the Pill, with reference to the advantages and disadvantages.

For many women the Pill was a liberating breakthrough; the Catholic Church, on the other hand, looked upon it as something that would endanger moral behaviour and decency and reacted with the encyclical "Humanae vitae", which Pope Paul VI published on July 25, 1968 and which clearly ex-



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pressed his Church's opposition to use of the Pill. Pope Benedikt XVI has supported this encyclical, again speaking up for "married love as a holistic process" that should not be made dependent on fleeting and dubious feelings – the Pill, he feels, has no place in this.

At the beginning of the 1970s the advantages that the upcoming generation of 1968 saw in the Pill led to a so-called pill-dependent slump in the birth rate – there was a substantial reduction in the number of births.

The Pill offers reliable protection from unwanted pregnancies and numerous non-contraceptive advantages with a relatively low risk profile. After 50 years, it is still not obvious, whether the pattern and the extent of possible psychic impressions – positive or negative – are influenced by it, possibly at least partly through the absence of cycle-dependent problems. While some women regard cycle-dependent mood swings as normal, others find them disturbing, especially when they suffer from premenstrual syndrome, which is itself another indication for the Pill.

In the opinion of former German Chancellor Helmut Schmidt, in the course of women's liberation the Pill has led to "the most striking evolution in German society." Throughout the world, however, it is not only the availability of contraceptives, but also the consistent implementation of women's rights, in the form of equal status, that is of key importance for an effective family planning policy.

The central point of this special issue is to pay tribute to **Carl Djerassi**, the steroid chemist who synthesised the first orally effective gestagen norethindrone all those years ago while working for Syntex at the end of the 1960s. This compound was first applied for oral contraception by the American group around **Gregory Pincus**. It is Carl Djerassi's trail-blazing innovation, the patent for which was the only chemical patent registered in the Hall of Fame in the USA, that we have to thank for the fact that we can now achieve effective contraception with steroid hormones.

The German Society for Gynaecology and Obstetrics (Deutsche Gesellschaft für Gynäkologie und Geburtshilfe) and the German Society for Gynaecological Endocrinology and Reproductive Medicine (Deutsche Gesellschaft für Gynäkologische Endokrinologie und Fortpflanzungsmedizin) have compiled this special issue with contributions from international authors in honour of Carl Djerassi and to commemorate the Pill's 50th birthday in Germany.

This would not have been possible without the support of numerous sponsors, such as the Federal Centre for Health Education, and industry through advertising: Bayer Vital, Contrel/Belgium and Gynsana GmbH, Gedeon Richter, HRA Pharma, Jenapharm, MSD Sharp & Dohme, Swiss Precision Diagnostics, Valley Electronics, and Kessel Marketing.

Dear Carl, without your inventive ambition and experimental skills, we would not be able to celebrate the 50th anniversary of the Pill in Germany. We are delighted that you enjoy the best of health and unstoppable creativity and will give a celebratory lecture in Heidelberg in October at the handover ceremony of this supplement.

We wish the Pill all the best on this special birthday
and you, dear Carl, we wish best for life, good health and lots more new ideas

Prof. Dr. med. Klaus Frieze

President, Deutsche Gesellschaft für Gynäkologie und Geburtshilfe

Prof. Dr. med. Thomas Rabe

President, Deutsche Gesellschaft für Gynäkologische Endokrinologie und Fortpflanzungsmedizin

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