

A hormonal male contraceptive: from wish to reality

The next decade may see the long-overdue development of an effective and widely desirable hormonal male contraceptive

IN A REJOINER to Benjamin Franklin's observation that nothing is certain in life bar death and taxes, people's fondest wishes seem to be to live forever and pay no tax. The timely and provocative study of Weston et al in this issue of the Journal (*page 208*),¹ reporting high acceptability of a hormonal male contraceptive among new fathers, prompts a reflection on wishful thinking, as such a new contraceptive remains unavailable. In some respects, contraception is closer to a consumer lifestyle choice than a conventional medical treatment, as illustrated by the impact of media-inspired contraceptive "scares" that have led to panic-driven abandonment of contraception and subsequent unwanted pregnancies.²

Creating a need for novel products is the *raison d'être* of advertising, and in the world of public relations presentation is the whole game. Responses to unfamiliar products or services are sensitive to how they are described, and almost any outcome may arise depending on how the access, convenience, safety and efficacy of hypothetical or existing contraceptive methods are described. At face value, however, the observations of Weston et al are consistent with recent findings from other cultures^{3,4} and earlier World Health Organization (WHO) studies,^{5,6} all of which similarly rely on forcing choices between hypothetical options. Even if the responses accurately reflect attitude, there is a vast gulf between human attitude and behaviour. This is the starting point for much of behavioural medicine, as illustrated by the failure of even low expectations of interventions that rely upon behavioural change (eg, interventions to deal with anger, smoking, drug addiction, obesity). Nevertheless, the strikingly positive attitudes reported by Weston et al herald major progress and the imminent availability of practical hormonal male contraceptives.

Arguably, the epitome of successful applied science in the 20th century was the development of reliable and reversible contraception. The universal availability of numerous highly effective female contraceptives fostered unprecedented social change extending well beyond medicine and science. At the start of the 21st century, it is a sad reflection that the previous century passed without the addition of a single new contraceptive method that men could use to share more equitably the burden of reliable family planning.⁷ Historically, all deliberate family planning methods (apart from abortion) were shared responsibilities requiring active male involvement. The phenomenal success of female-oriented contraceptive development in recent decades has shifted the burden of responsibility for family planning disproportionately onto women. Worldwide, however, male involvement in family planning remains remarkably high, considering the inadequate means available.⁸ The central dilemma for men in stable relationships seeking to share more responsibility for family planning is that the reversible methods are not

reliable and the reliable method (vasectomy) is not reversible. What is needed is a reversible male method as reliable as modern female methods.

The biologically unique processes of sperm development offer ever-increasing numbers of new ways for clever biotechnology to interrupt male fertility temporarily, notably by modification of sperm and male reproductive tract ion channels. However, these require full development as new drugs, whereas hormonal methods are close to practical realisation.

Although hormonal contraceptive methods were always equally feasible for men and women, during the decades when female contraceptive development flourished the development of analogous male methods languished, as it depended solely upon the limited resources available to academic researchers without pharmaceutical company product development. A decade ago, proof-of-concept for a hormonal male contraceptive was achieved jointly by the US Contraceptive Research and Development Agency and WHO's Male Task Force, which conducted the first efficacy studies for any chemical male contraceptive.^{9,10} These studies showed high reliability of a reversible prototype hormonal regimen, a crucial empirical finding about which the biggest surprise is that this finding lagged three decades behind the wide availability of analogous female hormonal methods. Continued impressive progress towards a practical product has been achieved. There is consensus that a combination progestin-plus-androgen approach is optimal, with several combinations approaching the ideal of universal azoospermia.⁷ Finally, some large pharmaceutical companies have recently upgraded their involvement from being spectators to participating in some active development of the well-advanced research produced by the academic community within the public sector.

New hormonal male contraceptives are needed for couples in stable relationships rather than for those with changing partners, among whom condom use prevents sexually transmitted disease as well as pregnancy. The survey of Weston et al highlights a likely niche for the use of a hormonal male contraceptive — the postpartum period. This period is ideal, because it focuses on a stable couple with a predictable timing of contraceptive need and a situation in which reliable female contraceptives are not well suited, particularly during lactation.

Other niche purposes for a hormonal male contraceptive include delaying vasectomy, offering an alternative to conventional female methods when they are not well tolerated, and replacing less reliable male methods. The finding that a hormonal male contraceptive is acceptable to an appropriate Australian target population is consistent with Australasian men having the highest rate of vasectomy

in the world.^{11,12} These observations highlight the substantial need and market for a hormonal male contraceptive.

Hopefully, this decade will see the long-overdue development of an eminently feasible and widely desirable product. The desultory response from multinational pharmaceutical companies, even after completion of much early-phase clinical research by the public sector, suggests implementation may be driven by populous countries such as China, Indonesia and India, whose family planning priorities value such developments more highly. In Western countries, development may require a more enterprising start-up company to capitalise on this opportunity, which eludes the imagination, or lurks beneath the commercial horizon, of the pharmaceutical industry behemoths.

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Public reporting of comparative information about quality of healthcare

A greater degree of public reporting of information about healthcare quality is an inevitable and desirable way forward

THE AUSTRALIAN COUNCIL for Safety and Quality in Health Care (ACSQHC) plans to publish data about the performance of the Australian healthcare system. It is probably inevitable that this kind of information, which is actively disseminated and reported in such a way as to encourage readers to draw comparisons, will be used in the near future by the media, the public and politicians to make public judgements about the relative performance of individual hospitals or even individual doctors or groups of doctors. Initiatives such as these will therefore be perceived as a threat by some health professionals and some organisations. Would this negative response be justified? What might be gained from public disclosure and how can the policy be implemented successfully?

We believe that a negative response to public disclosure in Australia would be counterproductive. Greater openness in healthcare is inevitable. Information is freely available about most areas of modern life and many believe that healthcare is one of the last bastions of protectionism. When millions of dollars are spent on healthcare, those who pay have a right to know that the money is being spent effectively, and the publication of comparative data sends a strong message about the willingness of health professionals and organisations to be accountable.

In addition, public disclosure appears to be an effective way of improving quality.¹ There is a growing body of evidence that the current level of quality of care is

unacceptable^{2,3} and that quality-improvement initiatives using confidential data have been largely ineffective at changing the behaviour of health professionals.⁴ When comparative data are released to the public, it appears to remind providers of the issues and refocuses them towards taking action.⁵

Arguments in support of the status quo — that the data are inadequate, the public won't understand them and the media will misuse them — are not sustainable if public disclosure is introduced properly. There are lessons that can be learnt from other countries to guide the process of disclosure in Australia. The United States has nearly 15 years' experience of publishing data in the form of "report cards", or "provider profiles". The initiative was launched by the federal government and the momentum has been maintained by a variety of public, private, commercial and not-for-profit organisations. Consumers and purchasers of healthcare were expected to play a key role by selecting high-performing providers, but recent evidence suggests that the providers themselves make greater use of the data than the service users.⁶

There are some notable examples of improvements in both the processes and outcomes of care associated with the publication of performance data.¹ Public reporting in Europe is less well established than in the United States, but hospital "league tables" have been published in the Netherlands for several years, and the UK government plans