

The Women's Health Research Program

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Compounded medicines, consumer beware

Increasingly, the community is turning to medicines prepared by pharmacists on individual prescriptions such that the compounding of medicines is now a multi-million-dollar industry. The prescribing and dispensing of compounded hormones and other products is wide spread across Australia and appears to be increasing exponentially. The FDA, which regulates medicines in the USA, and the Endocrine Society of North America have been quite vocal in their concerns. Although this is becoming a significant public health issue for Australians, the compounding of medicines falls between the gaps of Australian regulating bodies.

Australians need to be aware that in contrast to the pharmaceutical industry, which is tightly regulated by the Therapeutic Goods Administration (TGA) and Medicines Australia and physicians being required to comply with strict guidelines in the prescribing of TGA approved medications, the prescribing of compounded medicines for an individual is unregulated. Because these medicines are "dispensed" on individual prescriptions, the laws that would normally apply to the production of controlled substances, such as hormones, are not applicable.



Therefore,

- there are no requirements for studies to be conducted to show how well or poorly the compounded medicine is absorbed, what dose is best and what treatment side effects might occur.
- dosing is mostly a best guess based on past experience and not based on published trials of effectiveness and safety.
- there are no requirements for patient information leaflets and any warnings about safety to be included with the prescribed products.

There are no regulations governing what can be prescribed and compounded. Thus potent hormones like testosterone and DHEA which are categorised as restricted substances by the TGA can be prescribed in any dose regimen. Equally concerning is the common prescription of pig and cow thyroid extract, with no regulation of purity of source or dose prescribed. All things considered this is taking medicine back to the dark ages.

Women in particular are being duped into taking these unregistered and unregulated formulations by terms like 'bioidentical' and 'natural'. There is nothing natural about pig thyroid extract for a human or high dose



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hormone therapy for people who do not have a hormone deficiency. As a result, people are being overdosed with hormones they do not need. There is also the belief that because these medicines are 'natural' and compounded specifically for them, they must be safe.

In terms of the prescription of compounded hormones for menopausal women there is absolutely no evidence that the oestrogen or progesterone prescribed is any safer (in terms of breast cancer risk) than approved TGA oestrogen and progestin formulations.

Compounded hormones are being directly marketed to consumers via the internet and other means by Australian pharmacists "to restore balance" and "make you feel like yourself again". In contrast, direct consumer marketing by the pharmaceutical industry is illegal. There is clearly a need for the prescribing of compounded therapies to be regulated such that physicians prescribing these products are accountable to the community and for pharmacists to be regulated in their compounding activities in line with requirements imposed on the pharmaceutical industry. Patients must be informed that compounded medicines are not TGA approved. There should be a requirement for the inclusion of uniform information for patients, such as warnings and precautions, in packaging of compounded hormone products. The reporting by compounders and prescribers of treatment side effects should be mandatory.

What's new in the literature?

Sexual activity and satisfaction in any community-dwelling older women

Most medical practitioners still consider sexual activity to be the domain of the young, with elderly women rarely considered as having sexual needs or being sexually active. This recent publication of Trompeter and others¹ is an important addition to

the small body of literature about the sexuality of older women. 806 women with a mean age of 67 years responded to a questionnaire-based study of sexual activity. 50 per cent of the women reported sexual activity in the preceding four weeks. Although the likelihood of being sexually active declined with age, 40 per cent of women aged 68 to 79 years and 13 per cent of the women more than 79 years of age reported being sexually active within the last month. Furthermore, 23 per cent of the women aged over 79 years reported arousal almost always, and a similar pattern of satisfaction to that of younger women. Not surprisingly, being sexually active was associated with living with a spouse or partner, current HRT use and reporting better physical health.

Although aging per se interferes with the level of sexual activity, the improved health of older women and possibly altered expectations appear to have impacted on the sexual lives of older people over recent decades. A Swedish study reported that the proportion of 70-year-old married women reporting sexual intercourse increased from 38 per cent in 1971 to 56 per cent in 2000². The data from both of these studies re-affirm that sexual activity remains an important part of life for many older women. The recent study of Trompeter further indicates that the decline in sexual desire and frequency of sexual activity with age is not necessarily perceived as problematic. Although the proportion of women with low sexual desire increases with age, associated distress decreases with age³.

1. Trompeter SE, Bettencourt R, Barrett-Connor E. Sexual activity and satisfaction in any community-dwelling older women. *Am J Med* 2012;125:37-43.
2. Beckman N, Waern M, Gustafson D, Skoog I. Secular trends in self reported sexual activity and satisfaction in Swedish 70 year olds: cross sectional survey of four populations, 1971-2001. *BMJ* 2008;337:151-4.
3. Hayes RD, Dennerstein L, Bennett CM, Sidat M, Gurrin LC, Fairley CK. Risk factors for female sexual dysfunction in the general population: exploring factors associated with low sexual function and sexual distress. *The journal of sexual medicine* 2008;5:1681-93.

Get involved in research

Antidepressants ruining your sex drive?

Are you aged between 35–55 years, have been taking a stable dose of one of SSRIs (sertraline, citalopram, paroxetine, fluoxetine or fluvoxamine) or SNRIs (venlafaxine) for the past three months and are experiencing sexual difficulties and for which you would like to be treated.

If you would like more information, regarding this and other studies please visit our website: womenshealth.med.monash.edu or contact the Women's Health Research Program on 03 9903 0820 or by email on womens.health@monash.edu