

HEALTHY SCEPTICISM NZ

A second opinion on Drug Promotion for Doctors in NZ

June 2000, Vol. 3 No. 1

This edition

Does Direct-To-Consumer (DTC) promotion of Viagra risk lives?

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Summary

Most respondents were very satisfied with Healthy Scepticism.

Evaluation of drug promotion requires many skills.

In our opinion the DTC advertisement for Viagra overstates the problem, overstates the efficacy and understates the risks. Viagra has been presented as a simple solution for “restoring relationships” but reality is complex. DTC promotion of Viagra puts lives at risk.

Please let us know what you think of this edition.

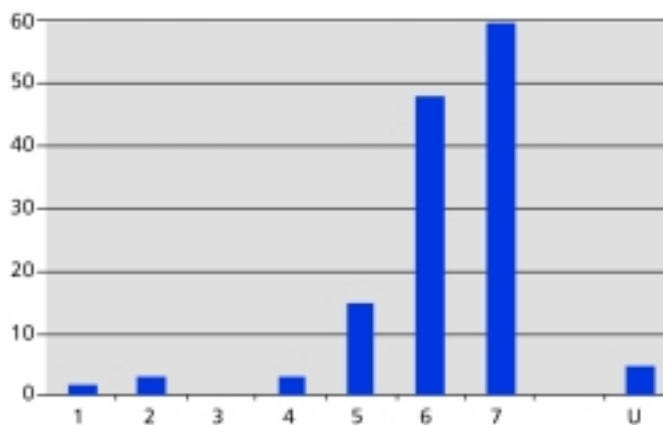
Healthy Scepticism NZ: Back by popular demand!

Healthy Scepticism NZ will continue because of the very positive response from most respondents during the initial trial (see Graph 1). We apologise for taking so long to start again. An important cause of the delay was that we took seriously the concerns of the few who expressed disapproval. A few readers expressed concern about Healthy Scepticism being funded by PHARMAC or incorrectly perceived MaLAM as being part of PHARMAC. This is understandable if readers are not aware of MaLAM’s 20 year track record as an independent international

organisation for health professionals. We took time trying to find an alternative source of funding. We failed. We then decided that it was better to continue with funding from PHARMAC than to cease providing a service that an increasing number of NZ doctors have found useful. The key to the concern appears to be understandable scepticism about whether or not our work could be independent of PHARMAC. We decided to test our relationship with PHARMAC by insisting that we start with a drug that is important for doctors but not for PHARMAC because they do not subsidise it: Viagra. We argued that our topics should be chosen according to medical importance and opportunity to make important points about promotion rather than cost cutting. PHARMAC accepted our arguments and agreed to fund this edition. We have agreed to produce 4 editions over the next 12 months.

A summary of feedback on the last edition during the trial, Vol 2 No 2, is now available on the Internet.¹ The challenge for Healthy Scepticism NZ is to provide a useful service that earns the respect of the majority of doctors who did not provide feedback during the trial. Please let us know what you think of this edition especially if you disagree.

Graph 1: Satisfaction with Healthy Scepticism about Antimicrobials Vol 2 No 2.



1 = Very Dissatisfied, 7 = Very Satisfied, U = Satisfaction Unspecified

Healthy Scepticism NZ is written by the MaLAM Secretariat and funded by PHARMAC. MaLAM aims to defend appropriate, compassionate, scientific medical care, health professionals and the public from marketing practices which may be detrimental to health. Please

address feedback to Dr Peter Mansfield, c/o PO Box 10-254, Wellington or E-Mail: peter.mansfield@flinders.edu.au.



MaLAM

MEDICAL LOBBY FOR APPROPRIATE MARKETING INC



Do you have all the skills required to evaluate drug promotion?

Some people believe that doctors are not adversely influenced by promotion because we are intelligent. It is just as helpful to say that we are all smart enough to pilot a space shuttle. We are intelligent enough for both tasks. However for both tasks what we need first is adequate training. Our ability to evaluate promotion depends on our understanding of Pharmacology, Epidemiology, Public Health, Evidence Based Medicine, Drug Evaluation, Pharmacovigilance, Statistics, Psychology, Economics, Sociology, Anthropology, Management, History, Politics, Communication/Media Studies, Logic, Rhetoric, Epistemology, Linguistics, Evaluation of Literature and Art, and various sub disciplines of Marketing including Product Management, Advertising Account Planning and Public Relations. Clearly doctors have more training in many of those fields than many members of the general public. However we all have more to learn. After decades of studying promotion the MaLAM team have found that (as with other areas of science) the more we learn the more we realise how little we know.

New methods

We have decided to vary our methods depending on the topic. In this edition we will ask three key questions for analysis of promotion:

- 1 Does it overstate the problem to expand the market?
- 2 Does it overstate efficacy?
- 3 Does it understate the risks?

We will also identify and explain promotional fallacies. There are over 100 errors of logic that can lead even the most intelligent to unjustified conclusions. Knowledge of fallacies can make evaluation of promotion easier.

A second opinion on DTC promotion of Viagra (sildenafil)

Many people will benefit from sildenafil. Some will die.² This edition examines a large Direct-To-Consumer (DTC) newspaper advertisement for Viagra produced by the distributor, Douglas, with the approval of the manufacturer, Pfizer.³ It appeared in the Dominion on 17 February, 1999 and elsewhere. We have placed a copy for study purposes on our web site.⁴ Unlike most advertisements targeting doctors, this advertisement is a “long copy ad.” (It has 610 words, not counting the fine print.) Long copy is used to give the impression of providing enough information to precipitate decisions to take action without the reader feeling the need for information from other sources.⁵ In other countries people have obtained sildenafil from friends, dealers, sex shops and

the Internet without consulting a doctor^{6,7} and suffered adverse effects.⁸ Consequently we are concerned that this advertisement may harm men in New Zealand.

Does the advertisement overstate the problem to expand the market?

Douglas/Pfizer claim “About 52% of men aged 40 to 70 are affected by ‘Erectile dysfunction’.
...it strikes at the very essence of what it means to be a man and can affect your confidence, self esteem, health and happiness...
Erectile problems do not just affect men. They can have a profound effect on their partners as well.”

Members of the general public may interpret this claim to mean that 52% of New Zealand men aged 40 to 70 need sildenafil. The 52% statistic comes from the Massachusetts Male Aging Study⁹ and was inflated by the inclusion of many men with “minimal” dysfunction for which sildenafil is not appropriate. An Australian study found that the 95% confidence intervals for the prevalence of “erections inadequate for intercourse” was between 50-78% in 70-79 year old men but only between 0-6% in 40-49 year old men.¹⁰

What impact will such claims have on men with confidence problems? What will be the impact on couples who had previously come to terms with their situation? Will these claims harm those for whom sildenafil is not effective, too expensive or too dangerous by making their disability seem worse than it was before?

Exaggerating the severity and/or frequency of conditions to expand markets has been described as “disease mongering”.¹¹

Does the advertisement overstate the efficacy of sildenafil?

Douglas/Pfizer claim “In clinical trials 78% of men reported improvements in their erections. So Viagra will work in about 4 out of 5 men.”

Ambiguity?

If members of the general public interpret “will work” to mean “will work well enough to enable successful sex” they will be disappointed. The “success rate” will be lower than the 78% “improvement rate” because “improvement” is not always enough to enable penetration. For example, a before-and-after study of sildenafil in clinical practice found that for complete erectile dysfunction after prostatectomy “improvements” occurred but were not enough to enable successful sex.¹² In the best designed trial of sildenafil published so far, intercourse was reported successful in 59% of patients taking sildenafil compared to 15% of patients taking placebo so the success rate attributable to sildenafil was 44%.¹³ Furthermore *effectiveness* in general use in the



“real world” is often less than *efficacy* in the “ideal world” of clinical trials where enthusiastic specialists provide new therapies for selected patients. The claim uses terms that may be taken to mean the same thing but really have very different meanings. “Men in clinical trials” is very different from all “men”. “Improvements” is very different from “will work”. The claim is an example of a fallacy of ambiguity. It is just as logical as claiming that A causes B therefore C causes D.¹⁴

Oversimplification?

The claim is also an example of a fallacy of oversimplification. The claim of a 78% “improvement” rate does not convey the fact that improvement rates vary dramatically depending on the cause of the erectile dysfunction. The claim is just as helpful as saying that the average adult has one breast and one testicle! The “improvement” rates with sildenafil that Pfizer claim for key diagnoses are presented in Table 2. However there is yet more complexity. Firstly, in clinical practice sildenafil is less successful for more severe dysfunction of any cause than for mild dysfunction of any cause.¹⁵ Secondly, cardiac failure and complicated diabetes are two important causes of erectile dysfunction where the success rates for sildenafil may be lower but are not known because men with those conditions were excluded from Pfizer’s pre-marketing trials.¹⁶

Does the DTC advertisement for Viagra understate the risks?

The headlines and copy do not mention any risks. Some risks are mentioned in a smaller, less readable font. However the following three sentences are in bold.

“You must not take Viagra if you are using any nitrate

medication including amyl nitrate (poppers). It may lead to a severe drop in your blood pressure, that may be difficult to treat. As sexual activity may be a strain on your heart your doctor will need to check whether you are fit enough to use Viagra.”

The problems with those statements include:

- 1 Readers may not realise that drugs with names like Ismo 20 or Corangin are nitrates.
- 2 Readers may not realise that the “severe drop in blood pressure” may be a euphemism for death.
- 3 It is understandable that Douglas and Pfizer want to shift the blame for deaths from their drug to the effort of sex. However, sex is rarely fatal.^{19,20} In one case sildenafil 50 mg consumption was followed within 30 minutes by a non fatal acute myocardial infarction in a man with no risk factors even before any attempt at sex²¹. However that could have been a coincidence.

A more helpful set of warnings could include:

If you have heart disease you could die after taking Viagra. Even men who do not seem to be at risk may rarely have severe adverse effects after taking Viagra. The severe adverse effects have included heart attacks, strokes and deaths. That is only one of the reasons why it is important to consult a doctor before trying Viagra.

If you take therapy for chest pain (nitrates for angina) or if you use poppers (amyl nitrate) within 24 hours before or after taking Viagra then you may have a heart attack or die before you can get medical help. Medical help will probably not make any difference anyway because the combination of Viagra with nitrates is very difficult to treat. The list of

Table 2: “Improvement rates” claimed by Pfizer with our comments

(NB “Success rates” will be lower. We would have used them here if we had been able to get access to them.)

Category	Improvement with placebo	Improvement with sildenafil	Improvement attributable to sildenafil	Comments
Spinal cord injury	12%	83%	71%	This is an important but relatively rare cause of erectile dysfunction.
Diabetes	16%	59%	43%	This applies to uncomplicated diabetes in clinical trials. ¹⁷ Success rates in complicated diabetes in clinical practice will be lower. Complicated diabetes is a common cause of erectile dysfunction but we were not able to locate any relevant studies.
Radical prostatectomy	15%	43%	28%	Success rates for complete erectile dysfunction after prostatectomy may be very much lower. ¹⁸



therapies for chest pain that should not be taken within 24 hours before or after taking Viagra include: Anginine, Carvasin, Corangin, Coronex, Duride, Imdur, Imtrate, Ismo 20, Minitran, NitroCor, Nitrobid Ointment, Nitroderm TTS, Nitrolingual Spray, Nitronal Injection.

The safety and effectiveness of sildenafil for people with the following conditions is not known because they were excluded from the pre-marketing studies: blood pressure above 170/100, on anticoagulants, aspirin or NSAIDs, diabetic retinopathy (which is often the first complication of diabetes), cardiac failure and unstable angina.²² Consequently for many of the people who have erectile dysfunction we have no directly relevant information with which to make decisions about risk benefit ratios.

Is sildenafil a simple solution for dysfunctional relationships?

Douglas hired BGA Marketing to develop the promotional campaign for Viagra using some material from Sudler & Hennessy in Australia all under “tight control” from Pfizer. BGA Marketing described their aims as: “*We have to do two things with Viagra. We have to say look, there is this big problem with erectile dysfunction and then we have to say ‘here, this is a simple and effective solution’.*”²³

The advertisement uses a photograph of a heterosexual couple in bed with the woman kissing the man who looks satisfied. A spokesperson for BGA Marketing explained the image thus: “*Research shows that using a couple has good cut-through [wins attention against competition] and good appeal [emotional motivation] and gets the message across about restoring relationships... This concept has strong appeal for GPs, who are consumers too, and I can see it having a similar appeal to the public.*” The advertisement uses the slogan: “*Viagra (sildenafil/Pfizer) Helping to restore relationships.*”

Sexuality is not simple.²⁴ Proper medical assessment of erectile dysfunction is not simple.²⁵ Restoring dysfunctional relationships is not simple.²⁶ Many couples will benefit from sildenafil. However prescribing sildenafil without understanding the complexities may damage vulnerable relationships.^{27, 28} Erectile dysfunction may be a consequence rather than a cause of relationship dysfunction in which case the “pill for every ill” approach won’t work. Implementing the advice in the book ‘*Why marriages succeed or fail*’²⁹ and/or ‘*Mind over mood*’³⁰ is not simple but will often be more effective for “restoring relationships” than treating erectile dysfunction. Those books cost less than a pack of 4 sildenafil tablets, last longer and can be shared with others.

By contrast there is a simple way to prevent erectile dysfunction that has not been promoted enough: exercise.³¹

¹ www.camtech.net.au/malam/NZ/healthy.htm

² Viva Viagra. Four Corners. Australian Broadcasting Corporation. 1998 November. www.abc.net.au/4corners/stories/s22482.htm

³ Floyd K. Viagra ad campaign targets doctors, deflates hype. The Independent 1998: 11 November:28

⁴ www.camtech.net.au/malam/NZ/healthy.htm

⁵ Ogilvy D. Ogilvy on advertising. London: Pan 1983, Prion 1995

⁶ Aldridge J, Fiona Measham F. Sildenafil (Viagra) is used as a recreational drug in England. BMJ 1999;318:669 www.bmj.com/cgi/content/full/318/7184/669

⁷ For example see <http://viagra.au.com/Australia/oz.htm>

⁸ 33 ADRs with Viagra in Japan. Scrip 1999;2468/9:25

⁹ Feldman HA, et al. Impotence and its medical and psychosocial correlates: results of the Massachusetts Male Aging Study. J Urol. 1994;151:1:54-61

¹⁰ Pinnock C, et al. Erectile dysfunction in the community. MJA 1999;171:353-7

¹¹ Moynihan R. Too much medicine? Sydney: ABC Books 1998

¹² Marks LS, et al. Treatment of erectile dysfunction with sildenafil. Urology 1999;53:19-24

¹³ Padma-Nathan H, et al for the Sildenafil Study Group. Efficacy and safety of oral sildenafil in the treatment of erectile dysfunction. Int J Clin Pract. 1998; 52:6:375-380.

¹⁴ Copi IM, Cohen C. Introduction to logic. 9th Ed. New York: Macmillan 1994

¹⁵ Marks LS, et al. Treatment of erectile dysfunction with sildenafil. Urology 1999;53:19-24

¹⁶ Wolfe SM, Sasich L. Petition to add important information about Viagra’s dangers to the drug’s label. Public Citizen 1998; 1 July. www.citizen.org/hrg/PUBLICATIONS/1445.htm

¹⁷ Rendell M, et al. Sildenafil for treatment of erectile dysfunction in men with diabetes. JAMA 1999;281:5:421-6

¹⁸ Marks LS, et al. Treatment of erectile dysfunction with sildenafil. Urology 1999;53:19-24

¹⁹ Smith DS, et al. Sex and death: are they related? BMJ 1997; 7123, 315(7123):1641-1644.

²⁰ Muller JE, et al. Triggering myocardial infarction by sexual activity. Low absolute risk and prevention by regular physical exertion. JAMA 1996; 275, 18:1405-9 and editorial, 1447-8

²¹ Feenstra J, et al. Acute myocardial infarction associated with sildenafil. Lancet 1998;352:9132:

²² Wolfe SM, Sasich L. Petition to add important information about Viagra’s dangers to the drug’s label. Public Citizen 1998; 1 July. www.citizen.org/hrg/PUBLICATIONS/1445.htm

²³ Floyd K. Viagra ad campaign targets doctors, deflates hype. The Independent 1998: 11 November:28

²⁴ Gregoire A. Male sexual problems. BMJ 1999;318:245-7

²⁵ Garg RK, et al. Is management of impotence with sildenafil changing clinical practice? Lancet 1999;353:9150:375-6

²⁶ Gottman J. Why marriages succeed or fail. New York: Simon & Schuster 1994, London: Bloomsbury 1997

²⁷ Wise TN. Psychosocial side effects of sildenafil therapy for erectile dysfunction. J Sex & Marital Therap 1999;25:145-50

²⁸ Ivy ME, et al. Complication of Viagra- stab wound. J Trauma. 1999 Feb;46:2:357

²⁹ Gottman J. Why marriages succeed or fail. New York: Simon & Schuster 1994, London: Bloomsbury 1997

³⁰ Greenburger D, Padesky C. Mind over mood. New York: Guilford 1995

³¹ Pinnock C, et al. Erectile dysfunction in the community. MJA 1999;171:353-7

Acknowledgments

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Feedback on *Healthy Scepticism NZ* about Viagra

Please send your feedback to Peter Mansfield, c/o PO Box 10-254, Wellington. Feel free to attach a sheet of paper if you want to write more comments.

Regarding MaLAM's decision to continue *Healthy Scepticism NZ* with funding from PHARMAC rather than discontinue *Healthy Scepticism NZ* I feel:

VERY DISSATISFIED 1 2 3 4 5 6 7 VERY SATISFIED

COMMENTS:

Regarding this edition of *Healthy Scepticism NZ* I feel:

VERY DISSATISFIED 1 2 3 4 5 6 7 VERY SATISFIED

COMMENTS:

As a result of reading this edition of *Healthy Scepticism NZ* my understanding of the risks and benefits of sildenafil has changed:

NOT AT ALL 1 2 3 4 5 6 7 SIGNIFICANTLY

As a result of reading this edition of *Healthy Scepticism NZ* I intend to change the information I provide to patients about therapy for erectile dysfunction:

NOT AT ALL 1 2 3 4 5 6 7 SIGNIFICANTLY

COMMENTS:

Feedback to Douglas and Pfizer about the DTC advertisement for Viagra

(Please comment on the *advertisement* regardless of your assessment of the drug. If you want to look at the advertisement a copy is available for study at www.camtech.net.au/malam/NZ/healthy.htm)

Regarding the DTC advertisement for Viagra (sildenafil) I feel:

VERY DISSATISFIED 1 2 3 4 5 6 7 VERY SATISFIED

COMMENTS:

Healthy Scepticism NZ?

If you would like to give us constructive criticism of drafts for future editions of *Healthy Scepticism NZ* prior to publication then please write an e-mail address that we can use to contact you below:

