www.nature.com/clinicalpractice/uro

The urologist as a gatekeeper

Philip Hanno

Urologists have, in many respects, become the primary care providers for male patients. This trend is partly related to the chronic nature of many urologic disorders and the need for regular prostate cancer screening. I discuss here three situations in which the goal to do what is in the patient's best interest might not be as straightforward as it first seems.

The use of herbal supplements and complementary therapies for medical problems raises both clinical and ethical issues. The 1994 Dietary Supplement Health Education Act, passed by Congress and approved by President Clinton, enabled the usage of such therapies to increase. The Act allows anyone to create and sell a supplement provided they do not make a specific health claim. There is no requirement as to the safety, efficacy, or potency of the ingredients. While the FDA can intervene, their resources to do so are limited. Many companies that manufacture or market supplements have followed the guidelines only loosely, and have frequently made health claims, whether implied or specified (DeAngelis CD and Fonatanarosa PB [2003] *JAMA* 290: 1519–1520). In February this year, Mark Moyad estimated that 10–15% of urologists currently sell or promote a brand of supplements in their offices for personal profit. In some cases the patients have no idea that there is a conflict of interest.

Off-label prescribing is another area where caution is required. In 2001, 21% of all medications prescribed in the US were for off-label indications. This approach was most common for cardiac medications, but the two specific medicines with the highest off-label use were gabapentin (83%) and amitriptyline (81%). While off-label prescribing provides a pathway to innovation in clinical practice, it also raises key concerns about risks to patients and costs to the health-care system (Radley DC *et al*. [2006] *Arch Intern Med* 166: 1021–1026). In fact, this use of gabapentin and amitriptyline illustrates the problems and benefits quite vividly. Gabapentin drew substantial media attention when Warner-Lambert was found guilty of promoting Neurontin off-label for a variety of disorders. Amitriptyline has been available in generic form for many years, and its off-label use for neuropathic pain is well substantiated. Amitriptyline will never be promoted by the pharmaceutical industry, and clinical studies depend on funding from private or government sources since there is little financial gain to be made. The primary responsibility for safety and efficacy of off-label prescription falls to the physician and his or her experience and knowledge of the literature and mechanisms, rather than the FDA. While off-label prescribing can raise the cost to patients, wise use of generic agents such as amitriptyline can also reduce them.

Urologists have a duty to educate and fill in the gaps for consumers

Finally, a few words on direct-to-consumer advertising, revenue from which rose from US$654 million in 2001 to $1.19 billion for television advertising alone in 2005. While 82% of television advertisements make some factual claims and rational arguments for product use, only around 25% describe causes, risk factors, or prevalence of conditions. Emotional appeals are widespread and products are frequently portrayed as medical breakthroughs (Frosch DL *et al*. [2007] *Ann Fam Med* 5: 6–13). Urologists have a duty to educate and fill in the gaps for consumers and make suggestions based on efficacy and cost, rather than simply giving the patient what they ask for. Correction of the misconceptions that patients gather from direct-to-consumer advertising has, unfortunately, become a major part of the outpatient practice of medicine.

P Hanno is Professor of Urology, University of Pennsylvania Health System, Philadelphia, PA, USA.

Competing interests
The author declared he has no competing interests.

www.nature.com/clinicalpractice
doi:10.1038/ncpuro0818