

Introduction

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This Special Report supplement of *The American Journal of Managed Care* features the proceedings of a roundtable discussion of erectile dysfunction (ED) titled "Clinical and Therapeutic Advances in the Treatment of Sexual Dysfunction: A Paradigm for Managed Care," which was held September 11-12, 1998, in Chicago, Illinois.

Participants in the 11-member discussion, which was co-moderated by Jonathan P. Jarow, MD, of Johns Hopkins University School of Medicine, and Culley C. Carson, III, MD, of the University of North Carolina, included four urologists, two managed care executives, a health economist, and representatives within the fields of cardiology, primary care, pharmacy, and psychology.

The discussion took place less than 6 months after the introduction of the drug sildenafil (Viagra), at a time when almost 4 million prescriptions had been written for a medication that has already revolutionized the treatment of sexual dysfunction in The United States.

Sildenafil's entry into the market marks a turning point in the treatment of ED, a disorder that is estimated to affect some 20 to 30 million

American men, including 5% of men by age 45 and as many as 70% by age 70.¹ By definition, ED is considered to be present if a man consistently fails to attain or maintain a penile-erection or the rigidity needed for satisfactory sexual performance.²

Available by prescription only and relatively costly at \$8 to \$10 a tablet, sildenafil promises to replace a variety of erection aids, ranging from other previously available oral medications and vacuum erection devices, to counseling, self-injection therapy, and penile implants.

Widespread access to sildenafil is creating a major shift in the delivery of treatment for ED, moving it from the traditional domain of urologists to that of general medicine. Specifically, primary care physicians and family practitioners are currently writing 55% of all prescriptions for sildenafil compared with 35% written by urologists, and 10% written by others (unpublished data, JPJ).

The medical community is concerned that serious underlying medical conditions, such as vascular disease, diabetes, hyperlipidemia, cardiac disease, or hypertension—diseases for which ED can be a symptom—may be overlooked as millions of men inun-

date family practitioners with requests for this new "miracle" drug.

Within the medical community, questions about the safety of sildenafil have arisen, especially when the drug is used by older sexually and physically inactive men and/or prescribed to men with whom the primary care physician has had little or no previous contact.

Concern about the potentially serious consequences of the use of sildenafil by such men has led to recommendations that it be prescribed only after a thorough evaluation by a urologist, cardiologist, and in some cases by a psychologist as well. Such caution is warranted, proponents argue, especially for hypertensive men who have underlying vascular disease.

In the brief time it has been available, sildenafil itself has been associated with some 69 deaths, most of which were linked to vascular and cardiac causes.³

In today's climate of managed care, the demand for and ready availability of sildenafil raises a critical question that is itself a social issue: "Who will pay?"

Annual sales of sildenafil have been projected to reach \$1 billion a year. (Pfizer Dn 4%; Morgan Stanley cuts Viagra sales outlook. Dow Jones Newswires 1998; September 4.) much of which would come from insurers or managed care groups. As a result, the question becomes not only one of who will pay for the drug but who is "entitled" to it.

Part and parcel of the "entitlement" dimension are the complex issues of whether the problem of ED is one of "lifestyle," that is, sex as an enjoyable pursuit, versus "quality of life," that is, satisfactory sexual activity as integral to a man's overall physical and mental well-being.

Value judgments inescapably enter the picture when the "lifestyle" interpretation is accepted, but if the more

sobering characterization of ED as a "quality of life" issue is accepted, it raises questions about whether it is harmful to deny access to sexual satisfaction by withholding sildenafil from a man who wants it.

Although there is no consensus among clinicians and managed care executives regarding the validity of arguments for and against the "lifestyle" versus "quality of life" characterizations, those on whom the financial responsibility of paying for sildenafil falls predict that coverage for the drug will either be denied, available with significant limitations,

ACRONYM LIST

The following acronyms appear in this Special Report:

ACC/AHA	American College of Cardiology/American Heart Association
ACE	Angiotensin-converting enzyme
ATP	Adenosine triphosphate
cAMP	Cyclic adenosine monophosphate
CEA	Cost-effectiveness analysis
cGMP	Cyclic guanosine monophosphate
DSM-III	<i>Diagnostic and Statistical Manual of Mental Disorders, Volume 3</i>
ED	Erectile dysfunction
FDA	Food and Drug Administration
HDL	High-density lipoprotein (cholesterol)
ICI	Intracavernosal injection
MI	Myocardial infarction
MUSE	Medicated urethral suppository for erection
NIH	National Institutes of Health
NO	Nitric oxide
PBPI	Penile blood pressure index
PDE	Phosphodiesterase
PHS	Public Health Service

or require sizable copayments from the men who will benefit from it.

... REFERENCES ...

1. Feldman HA, Goldstein I, Hatzichristou DG, Krane RJ, McKinlay JB. Impotence and

its medical and psychosocial correlates: Results of the Massachusetts Male Aging Study. *J Urol* 1994;151:54-61.

2. NIH Consensus Development Panel on Impotence. NIH Consensus Conference. *JAMA* 1993;270:83-90.

3. 1998 *Heart and Stroke: Statistical Update*. Dallas, Texas: American Heart Association. 1998.