A Brief Rationale for *NOT* Scheduling Viagra and Other PDE5 Inhibitors as Controlled Substances

Charles A. Moser, PhD, MD

Dr. Klausner presents a very interesting argument for scheduling sildenafil, vardenafil and tadalafil, the three phosphodiesterase type 5 (PDE5) inhibitors currently available for the treatment of erectile dysfunction. I disagree with his position, and here is a point-by-point response with my rationale for not changing the status of this drug class.

Dr. Klausner suggests that an association exists between participation in unsafe sex and the use of these drugs, leading to a rise in STIs. The studies he cites do show correlation, but not causation, between PDE5 inhibitors and unsafe sex. Dr. Klausner admits that the use (and abuse) of other recreational or disinhibiting substances taken in combination with the PDE5 inhibitors is the real problem. Those other drugs are already scheduled, which does not seem to have diminished access to them. We doubt that scheduling the PDE5 inhibitors will diminish access for those individuals who apparently have little problem in obtaining other scheduled substances. We believe that the effect on STI rates from scheduling these drugs would be minuscule at best.

Dr. Klausner is also concerned about the medical consequences of illicit PDE5 inhibitor use. Although all drugs can have negative effects, there is no indication that individuals using these drugs are clogging the emergency departments or local physician offices with complications from their illicit PDE5 inhibitor use. Although I do not support the use of these drugs without medical supervision, I doubt that the direct negative medical consequences are significant. The problems that arise from the other illicit drug use are much more serious. The desire for PDE5 inhibitors in this population presents another opportunity to reach out to these individuals and should not be ignored.

A positive response from a "friend's" use of a PDE5 inhibitor could lead a patient to request evaluation for his own prescription. At that time, the physician may uncover other medical conditions, psychiatric concerns, as well as use the opportunity to counsel the patient on the dangers of unsafe sex and illicit drugs. Scheduling the drug, thus increasing the penalties for its illicit use, would probably decrease the likelihood that the patient will consult the physician.

Inherent in Dr. Klausner's article is the belief that young men do not have problems with erections. Actually 7 percent of the men between 18 and 29 years of age report difficulty obtaining or maintaining an erection.[1] Erectile dysfunction in younger men should not be ignored and can be a significant problem for these men. There is also some evidence that one reason that substance abusers use illicit drugs is to self-medicate their own sexual dysfunction.[2,3] There is no way of knowing how many men with sexual dysfunction self-medicate with illicit drugs and, consequently, how many would avoid illicit drugs if their sexual concerns were treated in a timely factor.

There is a concern that younger men are using these drugs for enhancement—not to treat a "true" dysfunction. In fact, PDE5 inhibitors have little effect on normal men.[4,6] In reality, the definition of erectile dysfunction is a patient's complaint of difficulty with getting or maintaining an erection. Physicians should not impose their beliefs of what constitutes an acceptable sexual response or what is acceptable sexual behavior on their patients; we have come a long way from denying contraception to unmarried women. In addition, we do not deny weekend athletes NSAIDs, just because they are more functional than someone who is crippled by arthritis.

We are trying to foster an atmosphere where all patients can feel comfortable discussing their sexual concerns. If

Continued on page 12

Yes to PDE5 Inhibitors as Scheduled Drugs

Continued from page 10

medications and other substance use can be assessed. Use of phosphodiesterase type 5 inhibitors with other substances that may increase untoward effects—like nitrites, either prescribed or recreational, and inhibitors of enzymatic function like protease inhibitors—can be avoided.

The successful scheduling of this class of drugs requires consent of the Department of Health and Human Services. That will not be easy but it is a rational response to reduce the unforeseen public health consequences associated with their abuse while preserving their availability to those in need.

Dr. Klausner is the Deputy Health Officer and Director of the STD Prevention and Control Services at the San Francisco Department of Public Health. The views of Dr. Klausner on this subject are not necessarily the policy views of the SFDPH.

REFERENCES

1. Aldridge J, Measham F. Sildenafil (Viagra) is used as a recreational drug in England. *British Medical Journal.* 1999;318:669.
2. Chu PL, McFarland W, Gibson S, Weide D, Henne J, Miller P, Partridge T, Schwarcz S. Viagra use in a community-recruited sample of men who have sex with men, San Francisco. *Journal of Acquired Immune Deficiency Syndrome* 2003, 33:191-3.
3. Kim AA, Kent CK, and Klausner JD. Increased risk of HIV and sexually transmitted disease transmission among gay or bisexual men who use Viagra, San Francisco 2000-2001. *AIDS* 2002, 16:1425-8.
4. Sherr L, Bolding G, Maguire M, Elford J. Viagra use and sexual risk behaviour among gay men in London. *AIDS* 2000, 14:2051-2053.
5. Mansergh G, Colfax G, Marks G, Rader M, Guzman R, Buchbinder S. The Circuit Men's Health Survey: Findings and Implications for Gay and Bisexual Men. *American Journal of Public Health* 2001, 91:953-958.
6. Purcell D, Wolitski R, Bailey C, et al. Viagra® use and sexual risk among HIV-seropositive men who have sex with men. XIII International AIDS Conference; July 7-12, 2002; Barcelona, Spain.
7. Cachay E, Mar-Tang M, Mathews W. Screening for potentially transmitting sexual risk behaviors, urethral sexually transmitted infection, and sildenafil use among males entering care for HIV infection. *AIDS Patient Care and STDs.* 2004;18:349-354.
8. Delate T, Simmons VA, Motheral BR. Patterns of use of sildenafil among commercially insured adults in the United States:1998-2002. *International Journal of Impotence Research.* 2004;16:313-318.
9. Loeb L, Kellogg T, Nelson K, Dilley J, Klausner J, McFarland W. Recreational use of Viagra is associated with HIV seroconversion in San Francisco. XV International AIDS Conference; July 11-16, 2004; Bangkok, Thailand.
10. Hirshfield S, Chiasson MA, Remien RH, Humberstone M. Substance use and high-risk sex among men who have sex with men (MSM) recruited through the Internet: a national survey. AIDS Care. 2004 Nov;16(8):1036-47.
11. Brewer DD, Golden MR, Handsfield HH. Factors associated with potential exposure to and transmission of HIV in a probability sample of men who have sex with men. 2004 National STD Prevention Conference; March 8-11, 2004; Philadelphia, PA; pg A.73.
12. Chiliade P, Brown AS, Steinfeld R, Bautista J. Predictors of high risk behavior at a gay men's clinic. 2004 National STD Prevention Conference; March 8-11, 2004; Philadelphia, PA; pg A.167.
13. Federal Controlled Substances Act. United States Code of Federal Regulation: 21 C.F.R. § Section 812 (1996).

No to PDE5 Inhibitors as Scheduled Drugs

Continued from page 11

patients sense reticence to prescribe these drugs, they may not discuss their sexual concerns with their physicians; we could miss the clinically significant diagnoses associated with sexual dysfunction and the chance to connect with our patients on a deeper level.

Some physicians resist prescribing scheduled drugs, which is the basis for the current campaign to improve the treatment of pain. The scheduling of these drugs may create analogous problems. Concerns about drug-seeking behavior are always an issue with patients taking scheduled drugs. These concerns can add to resistance to prescribing PDE5 inhibitors.

Both physicians and patients have resisted discussing sexual concerns, and these drugs (and sex therapy) are actually underutilized. Scheduling these drugs would be a further impediment to the appropriate treatment of erectile dysfunction. We need to foster an atmosphere of frank and open communication.

Although any drug can be misused or abused, there are at least some men who use the PDE5 inhibitors to maintain erections while using condoms. These men may not technically suffer from erectile dysfunction, because they can function quite well without a condom.

Continued on page 13

These drugs, then, can increase adherence to safer sex guidelines and decrease the spread of STIs.

I am sure that Dr. Klausner would agree that we need to prevent the Internet sales of these drugs, limit the self-medication with these drugs, and assure that physicians are diagnosing and treating these problems. The solution to this problem is better education of both physicians and patients, rather than limitations imposed by scheduling these drugs.

REFERENCES

1. Laumann EO, Paik A, Rosen RC. Sexual dysfunction in the United States: Prevalence and predictors. JAMA, 1999 Feb 10;281(6):537-544.
2. Smith, D, Apter-Marsh, M, Buffum J, Moser C, Wesson D. Sociosexual issues in the using and recovering alcoholic. *Alcohol Treat Quar*, 1984 fall;1(3):17-31.
3. Smith D, Moser C, Wesson D, Apter M, Buxton M, Davison J, Orgel M, Buffum J. A clinical guide to the diagnosis and treatment of heroin-related sexual dysfunction. *J Psychoactive Drugs*, 1982;14(1-2):91-99.
4. Aversa A, Mazzilli F, Rossi T, Delfino M, Isidori AM, Fabbri A. Effects of sildenafil (Viagra) administration on seminal parameters and post-ejaculatory refractory time in normal males. *Hum Reprod*, 2000 Jan; 15(1):131-134.
5. Mondaini N, Ponchietti R, Muir GH, Montorsi F, Di Loro F, Lombardi G, Rizzo M. Sildenafil does not improve sexual function in men without erectile dysfunction but does reduce the postorgasmic refractory time. *Int J Impot Res*. 2003 Jun;15(3):225-8.
6. Moser, C. The effect of sildenafil citrate on middle-aged "normal" men. *Elect. J. Human Sexuality*, 2001 Mar 9;4: www.ejhs.org/volume4/Moser/body.htm.

Guest Editorial; Introducing Sexual Medicine

Continued from page 9

Sexual health is being recognized as an integral part of overall health (see http://www.paho.org/English/HCP/HCA/PromotionSexualHealth.pdf and http://www.surgeongeneral.gov/library/sexualhealth), and the concept of sexual rights as human rights is being advanced[3]. See an excellent example of a Declaration of Sexual Rights adopted by the World Association of Sexology at http://www.worldsexology.org about_sexualrights.asp.

Physicians are at the forefront of finding new, active and preventive treatments for a variety of sexual concerns. New vaccines for HSV and HPV are in development. We are defining the mechanisms of erection and the pathophysiology of erectile dysfunction, as well as other sexual concerns. We are learning the molecular intricacies of how various sexually transmitted infections are actually transmitted. We are exploring the special health concerns of various sexual lifestyles and how sexuality changes through the lifespan.

The standard of care has progressed so that the sexual concerns of our patients can no longer be ignored. *San Francisco Medicine* has taken up the challenge to assist physicians to educate themselves and provide the resources for that education. I am proud to be part of that process.

REFERENCES

1. Smith GD, Frankel S, Yarnell J. Sex and death: are they related? Findings from the Caerphilly cohort study BMJ 1997;315:1641-1644 (20 December).
2. Wylie, KR. Becoming a sexologist in the United Kingdom. *BMJ* 2005;330 (January 15):23-24. [Available online at: http://careerfocus.bmjjournals.com/content/vol330/issue7483].
3. Tiefer, L. The emerging global discourse of sexual rights. *J SexMar Ther* 2002;28:439-444.

Young Physicians Mixer
Thursday, March 31, 2005
1409 Sutter Mansion
San Francisco
6:30 p.m.

Young Physician Section socials are the perfect way to meet and network with colleagues who are also at the beginning of their careers. Watch for more details in upcoming fax bulletins. The events are fun and free. For more information contact SFMS Membership Director Thomas Young at tyoung@sfms.org.
The San Francisco Medical