

POLICY & PRACTICE

Plan B Investigation

Two Democratic senators are calling on the Government Accountability Office (GAO) to investigate the Food and Drug Administration's decision to hire a private contractor to collect and review comments submitted on the Plan B emergency contraception application for over-the-counter marketing status for women aged 16 years and older. Sen. Hillary Rodham Clinton (D-N.Y.) and Sen. Patty Murray (D-Wash.) recently sent a letter to the GAO asking officials there to look into the contract FDA has entered into with Booz Allen Hamilton and report back as soon as possible. Last fall, the FDA announced that it would accept public comments on the Plan B application. Sen. Clinton and Sen. Murray said they want to know why the FDA outsourced the work, the cost of the contracts, and whether there are any other contracts related to Plan B. "Outsourcing public comments on Plan B is yet another warning sign that the FDA is not taking seriously its responsibility to make a decision on Plan B, yes or no," the senators said in a joint statement.

HIV Postexposure Prophylaxis

There is low adherence to postexposure HIV prophylaxis by adolescents who have been victims of sexual assault, according to a study published in the July issue of the Archives of Pediatrics and Adolescent Medicine. The researchers found that only about 15% of patients who were referred for follow-up to an academic medical center and provided with a 28-day course of antiretroviral medications actually completed the full course of treatment. Researchers at two Boston academic medical centers performed a chart review of all adolescent sexual assault victims who visited their two pediatric emergency departments between July 1, 2001, and June 30, 2003. They included charts from adolescents aged 12-22 years who were examined within 72 hours of a penetrating sexual assault. Of 145, 129 (89%) were offered a course of antiretroviral medications for postexposure prophylaxis and 110 (76%) agreed to take them. There were follow-up data available for 86 of the 110 patients who agreed to take the medication. Of those 86 patients, 13 (15%) completed the full course of prophylaxis.

Support for Contraception

More than 80% of Americans polled in a recent survey said they tend to agree that providing access to birth control is a good way to prevent abortions. While the results of the Wall Street Journal Online/Harris Interactive Health Care Poll show that a majority of respondents (89%) tend to agree that there should be more access to information about birth control options, respondents were split when it came to teenagers accessing birth control. About two-thirds of respondents said they tend to agree that abstinence is the best option for protecting teens from unwanted pregnancies. On the issue of whether teenagers should be allowed to access birth control without their parents' knowledge, 46% tended to agree, 41% tended to disagree, and 13% were unsure. The online survey included 2,689 adults in the United States.

Postmarketing Study Failure

The Food and Drug Administration is doing a poor job of ensuring that pharmaceutical companies live up to postmarketing study commitments, according to a new report by the Department of Health and Human Services' Office of Inspector General. The OIG reviewed new drug applications from 1990 to 2004; 48% of those applications had at least one postmarketing study commitment. Drugmakers are required to submit annual status reports. The OIG found that 35% of the reports that should have been submitted in fiscal

2004 were missing or had no information on the study commitments. The OIG noted that the FDA has limited enforcement power in this area, but suggested that the agency require more, and more relevant, information from drugmakers. In response, the FDA said it could not do that without additional regulations, but agreed that it needed to do more to improve its monitoring and to ensure that commitments are honored and that annual reports are thorough.

In-Office AIDS Test, Please

Americans would much prefer to be tested for AIDS in a physician's office or clinic,

instead of performing a home test, according to a survey of 2,500 adults by the Kaiser Family Foundation. Overall, 62% of respondents preferred a doctor's office or clinic, compared with 26% who preferred home testing; only 10% said the location did not matter. However, respondents did think home tests should be an option; 65% said home tests help people who otherwise would not learn their HIV status. On the other hand, 27% agreed with the statement that home tests are "a bad idea" because people need counseling that is available only in a physician's office or clinic.

—Mary Ellen Schneider

Vitamin D—both its importance and the amount needed—cannot be underestimated for proper calcium absorption AND OPTIMAL BONE HEALTH

How much proof is there that vitamin D is essential to bone health?

Volumes.

Vitamin D is critical

To help maintain normal blood levels of calcium and absorb the calcium needed to form and help maintain strong bones, vitamin D is essential.¹ Most calcium absorption occurs in the small intestine.² Without vitamin D, the small intestine absorbs only a fraction of dietary calcium. In a study by Heaney et al, vitamin D increased calcium absorption by as much as 65%.³

Vitamin D insufficiency is becoming an epidemic problem, especially for older Americans^{4,5}

The majority of Americans do not achieve adequate vitamin D levels.^{6,7} 90% of older adults aged 51 to 70 (and 98% of those over 70) are not getting adequate vitamin D from their diet.^{6,7} But inadequate intake isn't limited to just postmenopausal women and the elderly. More than two thirds of adolescent and adult women do not meet the adequate intake of vitamin D from their diet.^{6,7} Clearly, something needs to be done.

"...[current] recommendations are totally inadequate..."⁴

Current recommendations for daily vitamin D intake were established almost a decade ago. Many experts now agree that the daily recommended intake is too low.^{4,8-12} The response to vitamin D supplementation in clinical trials is further evidence that patients can benefit from higher levels of vitamin D. Emerging research suggests that getting at least 750-800 IU of vitamin D daily is associated with improved bone and muscle health in the elderly.^{8,13} Furthermore, a meta-analysis by Papadimitropoulos et al suggests, "Vitamin D decreases vertebral fractures and may decrease nonvertebral fractures."¹³ Zittermann states, "Current estimations for an adequate oral intake are obviously much too low to achieve an optimal vitamin D status..."¹⁰

Many experts agree: *the lowest daily dietary intake for vitamin D for adults should be at least 750-800 IU per day.*^{4,8,11,12}

Why Rx osteoporosis therapy still requires calcium and vitamin D

Rx treatments, including bisphosphonates, uniformly require sufficient calcium intake. However, as the use of these drugs has risen, a simultaneous decrease in the use of calcium supplements has occurred.¹⁴ This may be a result of patients believing that their Rx drug replaces their need for calcium. In addition, the majority of this population fails to consume the minimum recommended dietary intake of calcium, making calcium supplementation more critical.

Adequate vitamin D intake must also be taken into consideration.¹⁵ As noted in FDA's official magazine, for those receiving osteoporosis treatments, calcium and vitamin D supplements can be essential.¹⁶ Yet, more than half of North American women receiving therapy to treat or prevent osteoporosis have inadequate levels of vitamin D.¹⁷ This population needs to understand the importance of getting the right amount of calcium and vitamin D every day.

When patients need more D, you need to recommend a supplement

Very few foods are natural sources of vitamin D. And while sunlight is an excellent source of vitamin D, many individuals limit sun exposure or use sunscreen, which interferes with vitamin D synthesis of the skin, putting them at increased risk of inadequate vitamin D levels. In addition, as many people age, their ability to produce vitamin D decreases. Calcium supplements with added vitamin D are an excellent way to help ensure patients get the D they need daily for optimal bone health. It's never too soon to improve bone health. And it's never too late. The US Surgeon General states, "...[for those] not getting enough calcium and vitamin D in your diet, supplements can be bone savers."¹⁸

Together, calcium and vitamin D can transform the future of bone health

References: 1. National Institutes of Health. Office of Dietary Supplements. Available at: <http://ods.od.nih.gov/factsheets/vitaminD.asp>. Accessed April 6, 2006. 2. Wasserman RH. *J Nutr*. 2004;134:3137-3139. 3. Heaney RP et al. *J Am Coll Nutr*. 2003;22:142-146. 4. Holick MF. *Am J Clin Nutr*. 2004;79:362-371. 5. Holick MF. *J Nutr*. 2005;135:2739S-2748S. 6. Moore C et al. *J Am Diet Assoc*. 2004;104:980-983. 7. 2005 Dietary Guidelines Advisory Committee Report. Available at: www.health.gov/dietaryguidelines/dga2005/report/html/DI_adequacy.htm. Accessed March 22, 2006. 8. Hanley DA, Davison KS. *J Nutr*. 2005;135:332-337. 9. Pick M. Available at: <http://www.womentowomen.com/nutritionandweightloss/vitaminD.asp>. Accessed March 8, 2006. 10. Zittermann A. *Br J Nutr*. 2003;89:552-572. 11. Hollis BW. *J Nutr*. 2005;135:317-322. 12. Dawson-Hughes B et al. *Osteoporos Int*. 2005;16:713-716. 13. Papadimitropoulos E et al. *Endocr Rev*. 2002;23:560-569. 14. Stafford RS et al. *Arch Intern Med*. 2004;164:1525-1530. 15. Sunyecz JA, Weisman SM. *J Womens Health*. 2005;14:180-192. 16. US Food and Drug Administration. Available at: http://www.fda.gov/fdac/features/796_bone.html. Accessed March 28, 2006. 17. Holick MF et al. *J Clin Endocrinol Metab*. 2005;90:3215-3224. 18. US Department of Health and Human Services. *The 2004 Surgeon General's Report on Bone Health and Osteoporosis: What It Means To You*. Office of the Surgeon General; 2004.

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