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January 18, 2006

Andrew C. von Eschenbach, M.D.
Acting Commissioner
U. S. Food and Drug Administration
5600 Fishers Lane
Rockville MD 20857-0001

Dear Dr. von Eschenbach:

I commend the efforts of the Food and Drug Administration to protect Americans from "bogus" remedies and unapproved drug products. A recent example of the FDA's vigilance against unapproved and fraudulent therapies is the FDA's action against companies marketing "bogus" flu products.[1]

The FDA issued warning letters to companies marketing "bogus flu products," and stated in its press release that "FDA is not aware of **any scientific evidence that demonstrates the safety or effectiveness of these products** for treating or preventing avian flu and **the agency is concerned that the use of these products could harm consumers** or interfere with conventional treatments"[2] (emphasis added).

In light of this vigilance to protect Americans from the deceptive and fraudulent claims of unproven and dangerous drugs, I am exasperated at FDA's failure to act against the fraudulent claims about "medical" marijuana. Since September of 2003, I have repeatedly asked the Food and Drug Administration to add to its extensive website information about dangers of smoking marijuana, and the fact that the FDA has not approved marijuana for *any* indication.

As you are no doubt aware, marijuana is the most widely-abused drug in this country. Far from being shown as "safe and effective" for treating any disease, marijuana is linked to serious, dangerous physical and mental side effects including increased risk of heart disease, lung cancer, bronchitis, emphysema, depression, schizophrenia, and thoughts of suicide.[3] Comprised of nearly 400 chemicals, marijuana can affect almost

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[1] FDA News, "FDA Acts to Protect Public from Fraudulent Avian Flu Therapies," December 13, 2005. Available at http://www.fda.gov/bbs/topics/NEWS/2005/NEW01274.html (last visited January 13, 2006).
[2] Id.
[3] Letter from John P. Walters, Director, Office of National Drug Control Policy, and Karen P. Tandy, Administrator, Drug Enforcement Administration, to Hon. Frank Wolf, Chairman, Subcommittee on

every organ in the human body, from the central nervous system to the cardiovascular, endocrine, respiratory/pulmonary, and immune systems.[4] Moreover, early exposure to marijuana is linked to the likelihood of lifetime subsequent drug problems.[5]

Thirteen states now allow doctors to recommend marijuana as "medicine," Rhode Island being the most recent addition to this list. The FDA, having failed to assert its statutory authority as the sole agency authorized to approve drugs as "safe and effective," appears unconcerned that such a harmful substance—unapproved for treating any indication and linked to so many deleterious effects—is being used as "medicine."

FDA's absurd failure to act undermines significantly the FDA's statutory authority under the Food Drug and Cosmetic Act, and its credibility for protecting the public health. The conditions for which marijuana is "prescribed" in those states that allow doctors to recommend the drug as medicine are equally absurd, ranging from headaches to "restless leg syndrome."[6]

A section on the FDA's website is the most minimal gesture for the agency to inform the public about various public health dangers. The FDA has deemed that unprotected handling of a similarly unprotected iguana or touching tiny turtles merits this minimal warning, posting information about these obscure dangers on its website.[7] However, there is nothing on the FDA's *own* site to warn the public about the misleading, fraudulent medical claims of smoking marijuana.[8] This is inexcusable.

I introduced a bill at the end of the last Congress, requiring the FDA to disseminate a meta-analysis on the available scientific data regarding the health risks of smoking marijuana; it was introduced as a shot across FDA's bow to act voluntarily. I am prepared to reintroduce this or a similar bill to compel the agency to act, should appropriate measures addressing the effects and claims of "medical" marijuana not be forthcoming.

Science, the Departments of State, Justice, and Commerce, and Related Agencies, Committee on Appropriations (June 7, 2005) (on file with this Subcommittee).

[4] *Marijuana and Medicine: The Need for a Science-Based Approach: Hearing Before the Subcommittee on Criminal Justice, Drug Policy and Human Resources, Committee on Government Reform*, 108th Cong. (2004) (statement of Nora D. Volkow, Director, National Institute on Drug Abuse.

[5] Id.

[6] Brief of Amici Curiae U.S. Representative Mark E. Souder et al. at 25, Ashcroft v. Raich, 545 U.S. ___ (2005) (No. 03-1454).

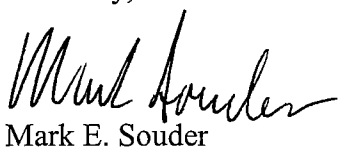
[7] "The Fright of the Iguana: Pet Reptiles Post Risk of Salmonella Infection for their Owners," available at http://www.fda.gov/fdac/features/1997/797_rept.html (last visited January 13, 2006); "Alert to Parents: Pet Turtle May be Harmful to Your Children's Health," http://www.fda.gov/cvm/documents/turtlesflier.pdf (last visited January 13, 2006).

[8] A link on FDA's site to another agency's warnings against marijuana would be insulting, and an additional failure of the FDA to forthrightly address the issue.

Dr. von Eschenbach, I want to take you at your word when you say, "I consider it a public health hazard when people are lured into using bogus treatments based on deceptive or fraudulent medical claims."[9] It is long past time that the FDA post accurate information about the claims of "medical" marijuana on its website. As is the case with the bogus flu remedies, there is not "any scientific evidence that demonstrates the safety or effectiveness" of marijuana for treating a single disease, and the agency should most definitely be "concerned that the use of these products could harm consumers."

I hope to hear a positive response to this letter by February 10, 2006.

Sincerely,



Mark E. Souder
Chairman
Subcommittee on Criminal Justice, Drug Policy and Human Resources
Government Reform Committee

CC: Hon. Mike Leavitt, Secretary, Health and Human Services
Joshua Bolten, Director, Office of Management and Budget
John Walters, Director, Office of National Drug Control Policy

[9] FDA News, *supra* note 1.