

April 25, 2003

BY FAX; FEDERAL EXPRESS

Craig Jackson, R.Ph., Director
Division of Occupational and Professional Licensing
Utah Department of Commerce
160 East 300 South—P.O. Box 14671
Heber M. Wells Building (1st Floor)
Salt Lake City, UT 84102

Re: **In the Matter of: PCM Venture I., LLC**
Stipulation and Consent Order
Case No. DOPL-2002-317.

Dear Mr. Jackson:

This is submitted on behalf of Pfizer Inc. (“Pfizer”). Pfizer discovers, develops, manufactures, and markets leading prescription medicines, including Viagra® (sildenafil citrate) and Celebrex® (celecoxib).

Pfizer requests that the Utah Division of Occupational and Professional Licensing (“DOPL”), in accordance with any applicable procedural requirements, reopen this matter and set aside the above-captioned Stipulation and Consent Order (“the Agreement”). The Agreement is at odds with FDA policy and Federal law, and is well outside of mainstream medical board thinking on internet “pseudo-prescribing”. Most important of all, however, the Agreement seriously compromises the public health. If that in itself was not enough, the Agreement may well authorize behavior that is now being specifically prosecuted by the United States Government via a 198 count criminal Indictment filed in the United States District Court for the District of Arizona on October 1, 2002. See *United States vs. Kwikmed, Inc., et al.* (copy of Indictment and Press Release enclosed collectively as Exhibit A).

DOPL need go no further than the nearby State of California to see where the mainstream is on these issues. For example, the Medical Board of California, on its Services for Consumers web page, publishes a Bulletin called “*Internet Prescribing: Ordering Prescriptions Through the Internet? Buyer Beware!*” See <http://www.medbd.ca.gov/buyerbeaware.htm> (visited April 24, 2003). In the Bulletin, the California Board makes a number of key points that the DOPL may not have reflected on completely when it entered into the Agreement. Some of these points bear repeating here:

"Few people like to go to the doctor to be examined. It's human nature to avoid discussion about conditions that cause embarrassment, and sometimes shame. While it's human nature, the avoidance of the doctor's office, in some instances, can be dangerous and even life threatening.

Recently, on-line ordering of prescription medication has become very popular with the public and profitable for the sellers. Selling Viagra and Xenical on the Internet has particularly preyed on consumers' desire to stay out of the doctor's office and maintain anonymity. Is that a good idea? Probably not. Many of the conditions which you may be attempting to treat have underlying medical causes that should be evaluated by your physician during an actual examination. If contemplating obtaining prescriptions through the Internet, consumers should consider the following:

- Ordering drugs without a relationship with a physician is potentially dangerous. By law, prescription drugs must be prescribed by a physician. There is good reason for this, as drugs should only be prescribed after an examination is performed and the cause of the problem or condition is diagnosed. On-line "consultations" cannot, with any certainty, provide enough information to make a verifiable diagnosis.
 - Many of the sites offering prescriptions for drugs are operating illegally. In California, the law requires that physicians and pharmacists be licensed, and that physicians perform a physical exam prior to prescribing drugs. It is generally impossible for consumers to determine the licensing status of the physician or pharmacist by the information on Internet pharmacy Web sites. In addition, many sites only require a questionnaire and do not verify the most basic facts needed for physicians to prescribe pharmaceuticals safely.
 - Self-diagnosing can be dangerous, and treating a symptom without determining the underlying cause may mask symptoms that will prevent appropriate treatment of a serious, and maybe life-threatening, disease or condition.
 - All drugs, particularly prescription drugs, have the potential for dangerous side effects. After the prescription is sold, it is likely that the prescribing on-line physician will not be available to help you. Patients

need a physician with whom they have a relationship to monitor and treat their conditions for a number of very good reasons. In the event of side effects, if the condition worsens, or if there is an interaction with other drugs, each patient needs a physician who is aware of his or her condition and the medications.”

(Emphasis supplied).

In addition, the Agreement departs from the mainstream views on the subject articulated by the Federation of State Medical Boards. The Federation's membership comprises the medical boards of each of the states of the United States, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, and 13 state boards of osteopathic medicine. In this respect, it represents the consensus view of the United States medical board community. According to the Federation's *Model Guidelines for the Appropriate Use of the Internet in Medical Practice*, adopted in April 2002 (see <http://www.fsmb.org/> (Policy Documents)): "Treatment, including a prescription, based solely on an online questionnaire or consultation does not constitute an acceptable standard of care." Further, "[s]tate medical boards should consider it unprofessional conduct for a physician to provide treatment and consultation recommendations, including issuing a prescription, via electronic or other means, unless the physician has obtained a history and physical examination of the patient adequate to establish diagnoses and identify underlying conditions and/or contraindications to the treatment recommended/provided".

FDA is likewise seriously concerned. The Agency has devoted substantial time, energy, and resources to combating the kind of "pseudo-prescribing" that the Agreement would sanction. See FDA "*Buying Medicines and Medical Products Online*", <http://www.fda.gov/oc/buyonline/default.htm> (visited April 24, 2003). The 198 count Indictment against Kwikmed charges the company with numerous violations of the Federal Food, Drug, and Cosmetic Act ("Federal Act") that FDA is responsible for administering. It is quite apparent that dispensing a prescription drug based on self-"diagnosed" and self-"reported" responses to an on-line questionnaire amounts to dispensing the drug based on a "sham" script in violation, among other things, of the rigid controls on prescription drug dispensing imposed under §503(b) of the Federal Act, 21 U.S.C. §353(b). Compare *United States vs. Moore*, 423 U.S. 122 (1975) (dispensing "controlled substance" based on what effectively amounts to a sham prescription without any valid underlying doctor/patient relationship or examination, even when written by a physician otherwise licensed to practice medicine, still violates Federal Controlled Substances Act).

Last, for present purposes anyway, is the self-evident and empirically validated proposition that, as the California Medical Board put it in its "*Buyer Beware*" Bulletin on buying prescription drugs on the internet: "Self-diagnosing can be dangerous, and treating a symptom without determining the underlying cause may mask symptoms that

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will prevent appropriate treatment of a serious, and maybe life-threatening, disease or condition.” This is validated by empirical evidence. Let’s just take the example of Viagra. Erectile dysfunction (ED) is a common complaint among men. It is highly correlated with cardiovascular disease and other serious co-morbid conditions such as dyslipidemia, depression, renal failure, prostate cancer and benign prostatic disease. ED is often the only presenting complaint in men who have very serious cardiovascular or urologic disease. Several recent studies, reviewed in the attached paper by Dale Glasser, Ph.D., Medical Director, Pfizer Sexual Health (July 16, 2001) (originally prepared for submission to FDA and the Federal Trade Commission) (Exhibit B), demonstrate that substantial numbers of men are being diagnosed with serious co-morbid illnesses, either vascular or otherwise, following visits to physicians with a sole complaint of ED. These diagnoses, and the consequent public health benefit, could not have occurred based on the kind of “pseudo-prescribing” that DOPL is effectively sanctioning in the Agreement.

For reasons of the public health, as well as all of the other foregoing reasons, DOPL should reopen this matter, and thereafter, set the Agreement aside. We are happy to discuss this matter with you by phone or in person, and we look forward to participating in the proceeding when the matter is reopened.

Respectfully submitted,

PFIZER, INC.

By: _____
Arnold I. Friede