

28 June 2009

Kent A. Shaw
Assistant Chief
California Office of the Attorney General
Department of Justice, Bureau of Narcotics Enforcement

VIA FAX: 916-319-9444

Dear Mr. Shaw,

I am a physician who has worked for 15 years in both primary and specialty care in Pediatrics. In addition, I have Board certification in Addiction Medicine and for 18 years I have provided treatment to drug addicts and alcoholics. Through our federally funded research on methamphetamine addiction, I have gained insight into the dynamics that perpetuate the epidemic use of methamphetamine in California.

I have reviewed the provisions of SB 484, which proposes to restrict sales of pseudoephedrine-containing pharmaceuticals to those persons with a valid prescription. I am in support of this measure, and encourage the Assembly to favorably consider it. As I understand it, SB 484 aims to reduce availability of pseudoephedrine to illicit manufacturers of methamphetamine (meth cookers). This drug has been a scourge in California, particularly in rural areas, which have been adversely affected by the proliferation of clandestine methamphetamine labs, which, in turn, increase local supplies of the drug, and pose a direct health and environmental threat due to the toxic processes involved in methamphetamine manufacture. The previous legislation that restricted pseudoephedrine sales was initially very effective, but via the ploy of "smurfing" meth cookers have effectively exploited this loophole. In the past two years we have seen a dramatic re-emergence of methamphetamine labs and all of the misery that ensues.

In making medical decisions, the discipline of medicine is to weigh the expected benefits of prescribing a medication versus its risks. When used as a treatment for nasal congestion, the FDA has found pseudoephedrine to be somewhat effective for this indication. The drug releases norepinephrine (nor-adrenaline) from nerve endings throughout the body, which causes the blood vessels in the nose (as well as elsewhere) to constrict, hence reducing the degree of nasal congestion that accompanies respiratory infections or allergy. Though marginally effective in symptom reduction, the drug comes with considerable risks: since norepinephrine is the principal mediator of the sympathetic nervous system, it has very widespread effects on structures besides the lining of the nose. Well-known, major adverse drug reactions are hypertension, heart rhythm disturbances (sometimes fatal), stroke, and myocardial infarction. For persons with certain diagnoses, such as hypertension, cardiovascular disease, diabetes mellitus, smokers, and pregnant women, pseudoephedrine is a particular hazard and may produce serious or fatal outcomes in these patients. Persons prescribed antidepressants, beta-blockers, MAO inhibitors, and heart medications can similarly be adversely affected.

S. Alex Stalcup, MD

Currently, because pseudoephedrine is available over-the-counter, persons for whom this medication is contraindicated, frequently obtain it and use it to bad effect, presumably unaware of the danger to them, in part because they did not consult a physician. SB 484 will increase the safe use of pseudoephedrine by requiring physician consultation before it is prescribed. This is a distinct benefit of SB 484. I have personally seen several patients who misused pseudoephedrine, and became toxic with anxiety, insomnia, hypertension, and weight loss.

Though SB 484 increases public safety by requiring a physician prescription for pseudoephedrine, ready access to its' use will be restricted, possibly meaning that someone who wants to use it may be prevented from obtaining it, or be required to see a physician. The argument made against this legislation—that it unfairly restricts access to the medication for those with limited access to physician assessment—cuts both ways. In rural areas where lengthy distances are required to see a physician, for poor and underserved populations, and for families with an ill child, a family member may purchase over-the-counter medications to avoid having to see a physician. Unfortunately, this means that these populations are at disproportionately higher risk of exposure to adverse drug reactions related to pseudoephedrine use. Similarly, these families are more susceptible to the impact of drug marketing, because looser standards of proof of efficacy are required for over-the-counter (OTC) medications. Fortunately, pseudoephedrine is not an essential drug for any purpose. The benefits on nasal function are marginal and other safer preparations are available (some containing phenylephrine, PE) to meet this need. At worst, the main adverse consequence of SB 484 might be an outbreak of stuffy noses.

In sum, the risks of pseudoephedrine in a non-prescription OTC preparation are well documented, and substantial, where it is only somewhat effective for the intended use. However, the benefits of restricting the illicit use of pseudoephedrine in methamphetamine manufacture are substantial.

Sincerely,

S. Alex Stalcup, MD, Medical Director
New Leaf Treatment Center
Diplomate, American Board of Addiction Medicine