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VIA e-mail and 1st Class Mail
St-medicine@state.pa.us
Teresa Lazo, Assistant Counsel
Department of State
P.O. Box 2649
Harrisburg, PA 17105-2649

Re: Proposed Rulemaking No. 16A-4933 (Prescribing)

Dear Ms. Lazo:

This office represents Levan Drugs No.3 LLC d/b/a/ Troy Pharmacy located at 1612 Lowrie Street, Pittsburgh, PA 15212 (hereinafter "Levan Drugs").

OBJECTION

Levan Drugs is filing this Objection to the proposed amendment to Title 49 of the Pennsylvania Code, Section 16.92, and specifically (a) (3) and (4), for the reasons that follow.

Background

The State Board of Medicine has supported it efforts to indirectly classify certain drug substances as controlled substances based upon unverified statistics and conclusions from the Federation of State Medical boards and the National Association of Boards of Pharmacy. *See* Pennsylvania Bulletin, Vol. 42, No. 9, March 3, 2012, p. 1122.

Certain of these drugs identified in the proposed regulations are not classified as controlled substances under federal law and there is no evidence that these drugs have been studied by the Drug Enforcement Administration or any other federal agency.

Argument

I. Lack of Authority

The proposed rulemaking by the PA State Board of Medicine to amend Title 49 of the Pennsylvania Code 16.92 is outside of the authority of the PA State Board of Medicine (Board). The Board should not take over the functions of the Administrator of the Drug Enforcement Administration (DEA), in attempting to decide which non controlled drugs should be designated as controlled substances in Pennsylvania.

The DEA is the agency within the Department of Justice responsible for carrying out the functions assigned to the Attorney General under Title 21 United States Code (USC) Controlled Substances Act (CSA). 21 U.S.C. 871(a); 28 CFR 0.100. These functions include enforcing and administering the CSA provisions governing the prescribing, administering, and dispensing of controlled substances. Thus, the scope of DEA's authority is delineated by the extent to which Congress itself regulated controlled substances through the enactment of the CSA and assigned certain functions under the Act to the Attorney General.

The CSA regulates that portion of the practice of medicine that involves the use of controlled substances. The DEA is correspondingly responsible for ensuring that controlled substances are prescribed in compliance with Federal law.

Congress expressly intended that there would be a dual system of Federal-state regulation of controlled substances by including in the CSA a preemption provision, 21 U.S.C. 903, which reflects that this field of regulation was to be shared by the Federal and state governments. Section 903 states: "No provision of this subchapter shall be construed as indicating an intent on the part of Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State. At the same time, this provision reiterates what is inherent in the supremacy clause of the United States Constitution, that no state may enact a law relating to controlled substances that presents a "positive conflict" with the CSA.

On October 15, 2008, Congress passed the Ryan Haight Act on October 15, 2008 ("Act"). The Act amended the Controlled Substances Act (CSA) and Controlled Substances Import and Export Act (CSIEA) by adding various provisions to prevent the illegal distribution and dispensing of controlled substances by means of the Internet. The Act relates solely to controlled substances. Controlled substances are those psychoactive drugs and other substances—including narcotics, stimulants, depressants, hallucinogens, and anabolic steroids—that are placed in one of the five schedules of the CSA due to their potential for abuse and likelihood that they may cause psychological or physical dependence when abused.

Approximately 10 percent of all drug prescriptions written in the United States are for controlled substances, with the remaining approximately 90 percent of prescriptions being written for non controlled substances.

The Act contains various provisions that call upon the Attorney General to issue regulations to implement the Act. The Attorney General may promulgate and enforce any rules, regulations, and procedures which may be necessary and appropriate for the efficient execution of functions under this Act or the amendments made by this Act, and, with the concurrence of the Secretary of Health and Human Services where this Act or the amendments made by this Act so provide, promulgate any interim rules necessary for the implementation of this Act or the amendments made by this Act, prior to its effective date. This regulatory authority of the Attorney General has been delegated to the Administrator of DEA.

There are two important points should be taken from this Act:

a) If Congress had intended to include all prescription drugs within the Act, then it would have taken that action. Controlled substances are designated in terms of the current official list of controlled substances in section 1308 of the most recent issue of Title 21 Code of Federal Regulations (CFR) Part 1300 to end (21 CFR §1308)
b) The Administrator of the DEA has sole authority to administer this Controlled Substance List. This authority is not designated to any state legislative authority

Proceedings to add, delete, or change the schedule of a drug or other substance may be initiated by the Drug Enforcement Administration(DEA), the Department of Health and Human Services (HHS), or by petition from any interested party, including the manufacturer of a drug, a medical society or association, a pharmacy association, a public interest group concerned with drug abuse, a state or local government agency, or an individual citizen. When a *petition* is received by the DEA, the agency begins its own investigation of the drug. There has been no showing that the Pennsylvania State Board of Medicine has filed such a petition.

The DEA also may begin an investigation of a drug at any time based upon information received from laboratories, state and local law enforcement and regulatory agencies, or other sources of information. Once the DEA has collected the necessary data, the Deputy Administrator of DEA, requests from HHS a scientific and medical evaluation and recommendation as to whether the drug or other substance should be controlled or removed from control.

This request is sent to the Assistant Secretary of Health of HHS and HHS solicits information from the Commissioner of the Food and Drug Administration and evaluations and recommendations from the National Institute on Drug Abuse and, on occasion, from the scientific and medical community at large. The Assistant Secretary, by authority of the Secretary,

compiles the information and transmits back to the DEA a medical and scientific evaluation regarding the drug or other substance, a recommendation as to whether the drug should be controlled, and in what schedule it should be placed.

Once the DEA has received the scientific and medical evaluation from HHS, the DEA Administrator will evaluate all available data and make a final decision whether to propose that a drug or other substance be controlled and into which schedule it should be placed.

The PA State Board of Medicine is attempting to by-pass this important peer review system for adding or deleting controlled substances. Following such a thoughtful process, the Administrator of the DEA has taken action to add Carisoprodol as a Schedule IV controlled substance effective January 11th, 2012. Therefore, there is no need to adopt subsection (a)(2). Levan Drugs feels that it is improper for the Board to seek to regulate Tramadol Hydrochloride or Butalbital when an appropriate mechanism for study, analysis and recommendation is available through the federal government. As a result of the foregoing, the Board lacks authority to indirectly designate Tramadol Hydrochloride or Butalbital as controlled substances and the attempt to do so is in conflict with federal law.

II. Commerce Clause Violation

The Commerce Clause expressly grants Congress the power to regulate commerce "among the several states." This grant of power implies that a state is prohibited from passing rules that improperly burden or discriminate against interstate commerce. The restriction is self-executing and applies even in the absence of a conflicting federal statute.

In order to determine whether a law violates this so-called "dormant" aspect of the Commerce Clause, the court first asks whether it discriminates on its face against interstate commerce. In this context, "discrimination" simply means differential treatment of in-state and out-of-state economic interests that benefits the former and burdens the latter. If the state activity constitutes "regulation" of interstate commerce, then there is a second inquiry: whether the activity regulates even handedly with only "incidental" effects on interstate commerce, or discriminates against interstate commerce.

The proposed amendment by the Board to designate Tramadol Hydrochloride and Butalbital as controlled substances, thereby forcing non PA licensed medical practitioners to follow onerous "controlled drug" procedures to prescribe these drugs, rather than prescribing them as non controlled drugs which is permitted in their home state, is clearly discriminatory in that it discriminates against out of state licensed physicians prescriptions being dispensed by a PA licensed pharmacy. Similarly PA licensed physicians, who are obliged to follow these onerous controlled drug prescribing procedures, are discriminated against as they are unable to prescribe to out of state residents

This proposed regulation has a much greater effect on interstate commerce than "incidental" in that it precludes the prescribing and dispensing of these non controlled drugs to any out of state resident. The percentage of out of state dispensing of these two drugs on mail order is far greater than in state dispensing.

III. Conclusion

Troy Pharmacy requests that the PA State Board of Medicine withdraw the above-described sections of the proposed regulation. Should the Board fail to do so, Troy Pharmacy reserves the right to seek relief in the appropriate Court to strike down any final regulation.

Very truly yours,

David R. Dearden