



U.S. Department of Justice

Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

July 28, 2009

The Honorable Patrick J. Leahy
Chairman
Committee on the Judiciary
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

This letter provides the Department of Justice's views in support of S. 1292, the "Secure and Responsible Drug Disposal Act of 2009". S. 1292 would amend the Controlled Substances Act (CSA) to allow ultimate users of unused or unwanted pharmaceutical controlled substances to dispose of these drugs in a safe and controlled manner in accordance with the CSA. Consistent with the existing scope of the CSA, S. 1292 would not mandate any specific methods of disposal of controlled substances. Rather, the bill would allow for the development of methods of drug disposal that both minimize the contamination to the nation's water supplies and maintain effective controls against diversion of controlled substances into illicit channels for the purposes of abuse.

Current Statutory Requirements

Under the CSA, Congress established a "closed system" of distribution designed to prevent the diversion of controlled substances.¹ As part of this closed system, all persons who lawfully handle controlled substances must be registered with the Drug Enforcement Administration (DEA) or exempt from registration by the CSA or DEA regulations. Another central element of this closed system is that DEA registrants must maintain strict records of all transactions in controlled substances. Consistent with the CSA requirements, current DEA regulations employ a system to account for all controlled substances received, stored, distributed, dispensed, or otherwise disposed. Under this system, all controlled substances used in legitimate commerce may be transferred only between persons or entities who are DEA registrants or who are exempted from the requirement of registration.

With certain specified exceptions, the CSA requires every person who distributes any controlled substance, or who proposes to engage in the distribution of any controlled substance, to obtain from DEA a registration authorizing such activity. 21 U.S.C. § 822(a). "The term 'distribute' means to deliver (other than by administering or dispensing) a controlled substance . . ." 21 U.S.C. § 802(11). "The terms 'deliver' or 'delivery' mean the actual, constructive, or attempted transfer of a controlled substance . . ., whether or not there exists an agency relationship." 21 U.S.C. § 802(8).

¹ H.R. Rep. No. 91-1444 at 3 (1970).

“The term ‘ultimate user’ means a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household” (21 U.S.C. § 802(27)). The CSA exempts ultimate users from the requirement of registration if the ultimate user possesses the controlled substance for that person’s own use or for the use of a member of the person’s household or for an animal owned by the person or by a member of the person’s household (21 U.S.C. § 822(c)(3)). However, this exception does not allow a patient to distribute the controlled substance to another entity, including a long-term care facility, for any purpose, including the purpose of disposal of the drug.

Thus, because the CSA’s definitions of the terms “deliver” and “distribute” encompass all methods of delivery and distribution of controlled substances, and because the CSA allows ultimate users to obtain and possess controlled substances solely for purposes of use, an ultimate user may not deliver or distribute controlled substances for purposes of disposal. As a result, the distribution of a controlled substance by an ultimate user, regardless of the purpose, is illegal.

Purpose of Legislation

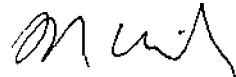
The Secure and Responsible Drug Disposal Act of 2009 amends the CSA to provide a means by which ultimate users may distribute controlled substances to other persons for disposal. Specifically, the Act amends section 302 of the CSA (21 U.S.C. § 822) so that an ultimate user who has lawfully obtained a controlled substance may, without being registered, deliver the controlled substance to certain specified persons for the purpose of disposal of the controlled substance. The person receiving the controlled substance must be authorized under the CSA to engage in such activity. The disposal must take place in accordance with regulations issued by the Attorney General to prevent diversion of controlled substances.

The Act will also amend section 302 of the CSA to add a new provision (section 302(g)(2)) authorizing the Attorney General to promulgate regulations that will permit “long-term care facilities” to dispose of controlled substances on behalf of ultimate users. (The Act adopts, by reference, the definition of “long term care facility” contained in the DEA regulations, 21 CFR 1300.01(b)(25), which includes a nursing home or other facility that provides extended health care to resident patients.) This new provision is necessary because long-term care facilities sometimes gain possession of controlled substances that are no longer needed by patients, but the CSA currently does not allow such facilities, which are usually not registered under the CSA, to deliver controlled substances to others for the purposes of disposal. The regulation will permit disposal in a manner that the Attorney General determines to provide effective controls against diversion, and to be consistent with the public health and safety.

Finally, for consistency with the foregoing amendments, the legislation also amends section 308(b) of the CSA (21 U.S.C. § 828(b)) to make clear that the written order form requirement, which is generally a prerequisite under the CSA for distributing a schedule I or II controlled substance, does not apply to the delivery of a controlled substance for the purpose of disposal by an ultimate user or long-term care facility acting in accordance with new section 302(g) of the CSA.

Thank you for the opportunity to present our views. The Office of Management and Budget has advised us that from the perspective of the Administration's program, there is no objection to the submission of this letter.

Sincerely,



Ronald Weich
Assistant Attorney General

cc: The Honorable Jeff Sessions
Ranking Member