

certificate, or a Custom's inspection after regular duty hours).

However, the IOAA applies "only when there is no independent statutory source for the charging of a fee or where a fee statute fails to define fee-setting criteria" *AMA v. Reno*, 857 F. Supp. at 84 (D.D.C. 1994). Accordingly, the controlled substances registration fees that are the subject of this rulemaking *do not constitute user fees* because other statutory authority (as described above) set specific criteria and funding guidelines. Moreover, in the 1993 Appropriations Act, Congress mandated fulfillment of the requirements of the Act "(n)otwithstanding (a)ny (o)ther (p)rovision of (l)aw," thus making its provisions supersede all other provisions of law that would otherwise prevent or impede DEA's recovery of the full costs of the DCP through registration fees. H.R. 5678, 102nd Cong., 2d Sess. 111 (1992).

However, with that said, registrants who pay the fees *do* receive special benefits not conveyed on the general public. Specifically by registering with the DEA, registrants are able to handle controlled substances, an immediate "gain or value" not provided to the general public. Because of the closed system of drug distribution and the diversion control activities of the DCP, there are some tangential public benefits as well, much in the same way that the system of driver's licenses (by which individual drivers receive a specific benefit not conveyed on the public at large) increases the general safety on public roads thus also conveying an ancillary public benefit.

Because Congress specified in the 1993 Appropriations Act (with collection and spending criteria established by prior law (21 U.S.C. 821 and 958(f)), that "(f)ees charged by the Drug Enforcement Administration under its Diversion Control Program shall be set at a level that ensures the recovery of the full costs of operating the various aspects of that program" and funds from the Drug Diversion Control Fee Account (DDCFA) to fund the DCP will be raised "in accordance with estimates made in the budget request of the Attorney General" (21 U.S.C. 886a(3) and (4)), the registration fees charged by DEA pursuant to this act are not user fees subject to the IOAA because the Appropriations Act and related statutory authorities constitute independent statutory sources for charging the fee and define fee-setting criteria, *i.e.*, to cover the full costs of the DCP. *AMA v. Reno*, 857 F. Supp. 80 (D.D.C. 1994).

Thus, the appropriate test for fee-funding DCP activities is not whether

they convey a special benefit to registrants but whether the fees are "reasonable" and "relat(e) to the registration and control of the manufacture, distribution, and dispensing of controlled substances" or relate to the registration of importers and exporters, and are set "at a level that ensures the recovery of the full costs of operating the various aspects of (the Diversion Control) program." 21 U.S.C. 821, 958(f) and 886a(3). DEA has concluded that the fees meet both of these criteria.

#### V. Diversion Control Programmatic and Operational Costs

Several commenters wrote that DEA had not provided adequate justification for the fee raise with some requesting detailed descriptions of the costs and expenditures made by the DCP. Commenters questioned the programmatic and operational costs of the DCP and raised concern about the rising costs of DCP activities over the past ten years that necessitated the fee increase.

This section describes fee-fundable activities that constitute the DCP, the budget justification for the fee increase, and how the fees were calculated and addresses related comments regarding the operation of the DCP.

##### A. Fee-Fundable Activities

DEA's mission with respect to licit controlled pharmaceuticals is to prevent, detect and eliminate the diversion of controlled pharmaceuticals from legitimate channels to illegal use, while at the same time ensuring their availability for legitimate medical and scientific purposes. To facilitate these goals, Congress, through the Controlled Substances Act, established a closed system of controlled substance distribution encompassing manufacturers, distributors, pharmacies and practitioners; that is, within this closed system a controlled substance can be traced from the time it is manufactured to the time it is dispensed to the ultimate user. This system has proven effective in reducing the diversion of these substances from legitimate channels to the illicit market. Components of this closed system include scheduling of all controlled substances, registration of all controlled substance handlers, recordkeeping for accountability, security, and manufacturing quotas, all under the oversight of the DCP. (The DCP also possesses similar chemical control responsibilities pursuant to the Chemical Diversion and Trafficking Act (CDTA) and subsequent legislation. The chemical diversion control program

and/or its registration and reregistration fees are outside the domain of this rulemaking and therefore are not affected by this rulemaking.)

The plain language of the 1993 Appropriations Act requires DEA to set and collect registration fees to cover the full costs of operating the DCP. In its 1993 final rule publication setting new registration fees, DEA examined all activities that relate to the registration and control of the manufacture, distribution and dispensing of controlled substances and to the registration (and control) of importers and exporters. DEA determined that "activities contained in the [diversion] program which give rise to the fees consist of diversion investigators, analysts, technicians, and clerical personnel salaries and expenses; and travel, rent, utilities, supplies, equipment and services associated with these positions for the registration and control of the manufacture, distribution and dispensing of controlled substances" (58 FR 15273). DEA determined that it would not fee-fund costs associated with chemical control efforts (see below), clandestine laboratory efforts, overseas staff (specifically diversion investigators assigned to foreign posts), DEA's Office of Chief Counsel or executive direction (58 FR 15273). DEA concluded that these activities were excluded from the Attorney General's budget delineation for the category of "Diversion Control" and thus not included in the determination of the fees. *Id.*

At the time this initial rule was published on March 22, 1993, 21 U.S.C. 821 did not extend to chemical control activities ("regulated transactions"). Accordingly, there were no registration or fee requirements for handlers of List I chemicals, and chemical control activities were not included among those to be supported by controlled substances fees. Congress amended 21 U.S.C. 821 on December 17, 1993 to require reasonable fees relating to "the registration and control of regulated persons and of regulated transactions." Domestic Chemical Diversion Control Act of 1993, 3(a), Pub. L. 103-200, 107 Stat. 2333. Despite this amendment, to date DEA's chemical control activities have continued to be supported by appropriated funds and *not* by the controlled substances fees through the Drug Diversion Control Fee Account (DDCFA). Again, DEA's chemical control activities are not the subject of this rulemaking.

In its December 1996 **Federal Register** notice, DEA further excluded from fee-funding those activities that incidentally support the DCP but are funded