

Following publication in the **Federal Register** of the fee adjustment in 1993, the American Medical Association (AMA) and others filed a complaint in the United States District Court for the District of Columbia objecting to the new fees. The district court issued its final order granting the government's motion for summary judgment and disposing of all claims on July 5, 1994. *AMA v. Reno*, 857 F. Supp. 80 (D.D.C. 1994). The AMA appealed, and on July 27, 1995 the United States Court of Appeals for the District of Columbia Circuit remanded, without vacating, the rule to DEA. Specifically, the court required DEA "to identify the components of the fee-funded diversion control program and provide a brief explanation of why it deemed each component to be a part of that program." *AMA v. Reno*, 57 F.3d 1129, 1135 (D.C. Cir. 1995).

DEA responded to the remand requirement through a notice in the **Federal Register** on December 30, 1996, describing the fee-funded components and activities of the DCP with an explanation of how each satisfies the statutory requirements for fee-funding. 61 FR 68624–32. DEA accepted comments on this final rule and, based on these comments, published its final rule on the Drug Diversion Control Fee Account (DDCFA) in the **Federal Register** on August 9, 2002. This rule contains information on the Specific DCP activities funded by the DDCFA. Copies of both the December 30, 1996 and August 9, 2002 rulemakings may be found on the Diversion Control Program Web site: <http://www.dea diversion.usdoj.gov>.

This announcement establishes the fee structure under the existing registration system to fully support the operations of the Diversion Control Program for Fiscal Year 2004 through Fiscal Year 2006. Since the last published rule in 1993, the Diversion Control Program has experienced significant growth without any associated increase in registrant fees to support the growth and increased funding needs. DEA is required by law (see below) to collect the full costs of the Diversion Control Program. The amount to be recovered is established by the Congressional appropriations process. The projected amount required to be recovered for Fiscal Year 2004, based on the President's Budget Request, will be \$133.6 million; the estimated amount required to be recovered for Fiscal Year 2005 will be \$157.3 million. The estimated amount required to be recovered for Fiscal Year 2006 will be \$160.3 million. These figures include required program growth

and the mandatory annual \$15 million transfer to the U.S. Treasury.

#### Statutory Authority to Collect Fees

DEA's authority to collect registration fees derives from three statutory provisions. DEA is authorized by 21 U.S.C. 821 to collect "reasonable fees relating to the registration and control of the manufacture, distribution and dispensing of controlled substances and to the registration and control of regulated persons and of regulated transactions." Secondly, 21 U.S.C. 958(f) permits DEA to collect "reasonable fees relating to the registration of importers and exporters of controlled substances or List I chemicals." Lastly, the 1993 Appropriations Act added a provision requiring DEA to set a fee schedule "that ensures the recovery of the full costs of operating the various aspects of that program." 21 U.S.C. 886a(3). The United States Court of Appeals for the District of Columbia Circuit noted that in establishing the DDCFA, Congress left intact the fee collection requirements of 21 U.S.C. 821, confirming boundaries of the DCP that DEA can fund by registration fees. *AMA v. Reno*, 57 F.3d 1129, 1135 (D.C. Cir. 1995). Although the court made no specific mention of 21 U.S.C. 958(f), those same boundaries remain intact as well. The court found that the current statutory scheme thus requires DEA to set registration fees to recover the full costs of the DCP, while requiring DEA to charge "reasonable" fees relating to the registration and control of the manufacture, distribution and dispensing of controlled substances and the registration and control of regulated persons and of regulated transactions.

DEA, therefore, must examine DCP activities in conjunction with the nexus requirements of 21 U.S.C. 821 and 958(f) to determine whether it can properly fee-fund them while setting fees that recover the full cost of these activities.

#### Diversion Control Program and Responsibilities

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 CSA, 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 DEA DCP oversight. (The DCP also possesses similar chemical control responsibilities pursuant to the Chemical Diversion and Trafficking Act (CDTA) and subsequent legislation.)

The plain language of the 1993 Appropriations Act requires DEA to set and collect registration fees to cover the full costs of operating its Diversion Control Program. 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 the DDCFA. 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.