

SUPPLEMENTARY INFORMATION:**I. Introduction and Statutory Authority**

The Drug Enforcement Administration (DEA) published a notice of proposed rulemaking in the **Federal Register** on February 18, 2003 (68 FR 7728) to adjust the registration and reregistration fees for controlled substances handlers. 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."

Thirdly and importantly, the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act of 1993 (Pub. L. 102-395) requires that DEA collect fees to ensure the recovery of the full costs of operating the Diversion Control Program (DCP). Section 111(b)(3) of the act, codified at 21 U.S.C. 886a(3), requires that "fees 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." Section 111(b)(1) of the act also requires that "there shall be deposited as offsetting receipts into that account all fees collected by the Drug Enforcement Administration, in excess of \$15,000,000, for the operation of its Diversion Control Program."

Following an adjustment in registration fees 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. After the district court issued its final order granting the government's motion for summary judgment and disposing of all claims, the AMA appealed. In the ensuing case, *AMA v. Reno*, the United States Court of Appeals for the District of Columbia Circuit found DEA's rulemaking to be inadequate and remanded, without vacating, the rule to DEA, requiring the agency to provide an opportunity for meaningful notice and comment on the fee-funded components of the Diversion Control Program (DCP). In doing so, however, the court also confirmed the boundaries of the DCP that DEA can fund by registration fees

(*AMA v. Reno*, 57 F.3d 1129, 1135 (D.C. Cir. 1995)). More specifically, the court found that the current statutory scheme 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 responded to the remand requirement through a notice in the **Federal Register** on December 30, 1996 (61 FR 68624), describing the fee-funded components and activities of the DCP with an explanation of how each satisfies the statutory requirements for fee-funding. A final rule was subsequently published on August 9, 2002 (67 FR 51988).

DEA, therefore, is bound by the above-referenced statutory requirements in setting fees that recover the full cost of the Diversion Control Program and its activities. DEA has developed its rulemaking according to these legislative mandates.

II. Comments Received

Following publication of the Notice of Proposed Rulemaking on February 18, 2003, DEA received 36 comments to the notice, objecting to the fee schedule contained in the proposed rule. Twenty-seven comments were received from physicians (5 comments) and veterinary (22 comments); two comments were received from pharmacists, and seven comments were received from national or state associations representing different registrant groups. Late comments were also sent by another national group after the close of the comment period. Its comments were already raised by other commenters and, therefore, are addressed accordingly in this final rule.

Most commenters objected to the proposed increase in registration and reregistration fees, most noting that the increase was "too much" despite the ten-year period since fees were last adjusted; one commenter wrote that he had no problem with the proposed fee increase for practitioners from \$70 to \$131. One commenter also raised concern that the proposed fees were based on estimated budgets for Fiscal Years 2004-2006 and that, because the fee schedule would extend only to Fiscal Year 2006, DEA could raise the fees again at that time. Several commenters inaccurately characterized the proposed registration fee as either a "tax" or as a "user fee."

Four commenters expressed concern about the programmatic and operational

costs of the DCP that necessitated the proposed increase in fees. Commenters specifically addressed why the DCP budget authority has doubled since Fiscal Year 1994 and what activities, including what new initiatives, would be supported through registration fees.

Three commenters expressed concern about the potential effect of the proposed increase in fees on small businesses, particularly in the current economy.

Three comments were received regarding individual registrations. One commenter wrote that the ability of residents and hospital- and clinic-based physicians to use their employer's registration number instead of being required by DEA to maintain individual registrations causes confusion with pharmacies. Another commenter argued that veterinarians unfairly support a disproportionate share of DCP costs because veterinary clinics as free-standing hospitals must purchase separate DEA registrations unlike physicians and other practitioners affiliated with human hospitals that may work under the hospital's registration under certain circumstances. Comments also noted that a fee increase would encourage practices, especially large practices, to forego licensure of all practitioners in the practice. Similarly, two commenters requested that registration fees be calculated based on the volume of controlled substances used, as usage differs by type of registrant.

Four commenters expressed concern that Internet pharmaceutical companies selling veterinary products at discounted prices are undermining veterinarian revenue. Other areas addressed by commenters included eliminating the mandatory annual \$15 million transfer to the U.S. Treasury; finding alternative sources for funding the Diversion Control Program such as fines to violators of controlled substances laws, fines to insurance companies and health care providers that use DEA registrations for identification purposes, "taxes" on Internet pharmacies, fees to large drug companies that "have billions of dollars," and Congressional appropriations; and the provision of additional time beyond the 30 days following publication of the final rule for the new fees to go into effect.

Each of the points raised by commenters is addressed below.

III. Objections to Fee Increase

All but one of the commenters objected to the increase in registration and reregistration fees, many characterizing them as "arbitrary" and