Legal Backgrounder

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DEA'S REVIEW OF DRUG APPROVALS COULD LIMIT ACCESS TO VITAL MEDICINES

by

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The Food and Drug Administration (FDA) has a new partner in the drug approval process: the Drug Enforcement Administration (DEA). As a result of an amendment included in the DEA's budget under the 2005 Appropriations Act, (the Act) the DEA may not use any of its appropriated funds for fiscal year 2005 to "establish a procurement quota" for drugs following FDA approval for marketing *until* DEA "has reviewed and provided public comments on labeling, promotion, risk management plans, and any other documents" related to that drug.[1]

The amendment was inserted without being reviewed by authorizing committees, without debate, and without the benefit of any true understanding of its impact or benefit to either patients or law enforcement. It creates an ambiguous process that could delay drug approvals, deemphasize medical need as the basis for determining the number of dosage forms to be manufactured in a given year, and worse, could interrupt the supply of medicines to patients.

The Controlled Substances Act (CSA) requires that DEA establish quotas to regulate and control the manufacture of Schedule I and II controlled substances. The DEA assigns an annual procurement quota to manufacturers which authorizes them to obtain quantities of the basic classes of Schedule I or II drugs, such as oxycodone, hydrocodone, morphine and codeine, to make dosage forms of approved drugs.[2] Companies may not purchase source materials or conduct dosage form manufacturing without a procurement quota. This includes not only the manufacture of Schedule II drugs, but also combination drugs controlled in Schedules III and IV, such as Tylenol with Codeine, where the manufacturer must obtain a Schedule II drug, such as codeine, to manufacture the medicine.

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[1]Consolidated Appropriations Act, 2005, Pub. Law 108-447, Div. B., §§ 110-111 (Dec. 8, 2004).

[2]21 C.F.R. § 1303.12(a).

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The CSA provides the framework for DEA to determine the appropriate quota to be assigned for each supplier and manufacturer of Schedule I and II controlled substances to ensure an uninterrupted and adequate supply of these important medicines. Procurement quotas are critical; they must be calculated to match the overall medical need for a substance in the United States. Manufacturers may not exceed their assigned procurement quota so a delay in approval of a quota can cause a disruption in the manufacturing process and, ultimately, the availability of medicines.

The quota amendment is bad public health policy. This restriction inappropriately permits DEA to tread in FDA's business and will compromise the needs of patients who depend on the medicines that FDA approves.

The Act Creates an Ambiguous Process. The Act is rife with ambiguities: it fails to describe how and when the DEA review process is to be done; the manner of the public comment is not stated; the time in which review and comment will be completed is not prescribed; and no definition is provided for the term "any other documents." The quota amendment is certain to disrupt FDA's approval process. It does not say that DEA performs an approval function, only that it must review and provide public comment *before* any procurement quotas can issue. However, the effect of this ambiguous "review and public comment" authority is to make DEA the judge of FDA-approved labels, promotional materials, risk management plans, and "any other documents." It gives DEA the power to require or modify risk management plans that the expert agency, FDA, deems appropriate. By withholding its "review and public comment," DEA can effectively block the marketing of drugs that FDA has approved.

Because labels and promotional materials are typically not made final until the end of FDA's review process, it is certain that DEA's participation will add substantial time before useful drugs can be made available. The amendment also raises serious concerns about the approval and availability of important medicines, such as:

- How will DEA's participation affect the congressionally mandated Prescription Drug User Fee Assessment (PDUFA) time frames for approvals?

- Will it be necessary to integrate DEA personnel at FDA, in order to make it possible to review the voluminous and confidential data submissions?

- How is confidential data submitted under a New Drug Application (NDA) (which, by law FDA must keep confidential) to be protected from public disclosure, if they must now be submitted to DEA, which currently is not subject to the same confidentiality restrictions under the NDA and Abbreviated New Drug Application (ANDA) process?

- How will DEA be capable of conducting a timely review of the numerous drugs that are subject to procurement quotas?

- What will be the substance of DEA's public comment, and will it alter public perceptions on drug safety and efficacy?

- Will this process have any impact on lessening diversion, misuse, or overall abuse of drugs?

It is expected that DEA would express criticism in its commentary to risk management plans and "any other documents," but to what end? Because the amendment fails to define the nature of DEA's review and public comment, there is the potential that adverse statements by DEA could

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affect public perception on safety and efficacy. Such comments may become a basis for product liability lawsuits. This result would be tragic, particularly given DEA's lack of a mandate and limited expertise on science and medical issues.

Quotas Should Be Determined Based on Medical Need. The assignment of procurement quotas is supposed to ensure an uninterrupted and adequate supply of drugs to patients. DEA has continuously emphasized the importance of timely and adequate quotas, but there have been occasions where procurement-related shortages have caused serious health concerns. For example, in 1988, the DEA Administrator had to issue a final order requiring an increase in the quota for methylphenidate.[3] The DEA Administrator noted that the quota system is intended to "assure that sufficient quantities of the drug will be available for patients having a legitimate need for it" and that "a therapeutic drug should be available to patients when they need it."[4] To accomplish this a smooth flow of distribution is required. Actual drug shortages or even threatened drug shortages can seriously interfere with patients' lives.[5]

The quota amendment ignores the fact that FDA already provides DEA with substantial data on sales of controlled substances that are factored into each quota determination. The result of DEA's review and comment could lead to inevitable delays in availability of medicines for millions of patients, with no apparent benefit to improving DEA's role in limiting the illegal diversion and misuse of these important medicines. Finally, the reviews mandated by the quota amendment will delay the FDA's drug approval process.

The amendment will also delay DEA's work. Absent timely approval of a procurement quota, manufacturers could be unable to provide an adequate supply of medicines necessary to meet medical needs for a given year.

The Quota Amendment Supercedes FDA Authority. The CSA is not to "be construed as in any way affecting, modifying, repealing, or superceding the provisions of the Federal Food, Drug, and Cosmetic Act."[6] The CSA recognizes that scientific and medical evaluations of the nation's drug supply are the responsibility of FDA, while DEA is responsible for preventing and investigating the diversion of controlled substances. Labeling, promotion and risk management are inherently related to the evaluation of a drug's safety and efficacy for its intended use — FDA's responsibility.

FDA has specific statutory authority to regulate the labeling that accompanies a product and the advertising used to promote the product. Under § 505(a) of the FD&C Act, all "new drugs" must be the subject of pre-market approval for their labeled uses. FDA's authority includes the oversight of promotional labeling for all drugs and advertising for prescription drugs.[7] The review and evaluation of drug labels, promotion, and risk management plans are part of the drug approval process delegated to FDA under the FD&C Act. FDA is uniquely qualified to provide medical and

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[3]Ciba-Geigy Corp. and MD Pharmaceutical, Inc.; 1986 Aggregate Production Quota; 1986 Individual Manufacturing Quotas, and 1986 Disposal Allocations for Methylphenidate, 53 Fed. Reg. 50,591 (Dec. 16, 1988).

[4]*Id*. at 50,593.

[5]*Id.*

[6]21 U.S.C. § 902.

[7]*Id*. § 355(b).

scientific determinations on the appropriate labeling, promotion and risk management plan for an NDA or ANDA.

The quota amendment has changed that. It implicitly modifies or repeals FDA authority on labeling, promotion, and risk management by empowering DEA to use its procurement quota authority to block the manufacture of these medicines, unless or until all FDA documents relating to the approval of a controlled substance meet the satisfaction of the DEA.

Granted, there is a need for a certain level of FDA-DEA cooperation on drug approvals and setting quotas, but that is adequately met under the current, pre-quota amendment setup. The quota amendment thrusts DEA into an area where it has no expertise, and the inevitable disputes that will arise between the agencies will surely take considerable time to resolve, and will lead to an increase in litigation. Where the disputes center on medical and scientific judgments, DEA will be thrust into an arena where it lacks sufficient expertise or a legitimate mandate.

Conclusion. The quota amendment is unwise as a matter of policy. It is inconsistent with the system of regulation that Congress thoughtfully devised by providing FDA with the authority to approve medicines, while providing DEA with the authority to prevent the diversion and illegal use of these medicines. The amendment does not promote health or safety, nor is there any evidence that it will have a positive effect on law enforcement. It is a mistake that should be quickly rectified.

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