July 11, 2011

OLP Regulatory Docket Clerk
Attention: FDMS Docket No. DOJ-LA-2011-0016
Department of Justice
950 Pennsylvania Ave. NW
Room 4250
Washington, D.C. 20530

Re: FDMS Docket No. DOJ-LA-2011-0016, *Preliminary Plan for Retrospective Review under E.O. 13563*

Dear OLP Regulatory Docket Clerk,

The undersigned organizations and companies welcome the opportunity to comment on the Department of Justice's (DOJ) proposed rule: *Preliminary Plan for Retrospective Review under E.O. 13563* that was published in the *Federal Register* on June 10, 2011. **We firmly support the Department's plan to evaluate regulations that apply to quotas to registered manufacturers of Schedule I and II controlled substances and certain List I chemicals found in *21 C.F.R. §§ 1303, 1315*.** We believe the current regulations of controlled substances, and in particular the quota system, have negatively impacted patients across America by contributing to the number and duration of drug shortages.

In recent years, the number of drug shortages has dramatically increased leading to adverse outcomes for patients and increased costs to the healthcare system. Many of the drugs in shortage contain controlled substances and are considered "medically necessary" by the Food and Drug Administration (FDA). We believe processes and resources should be afforded to ensure the Drug Enforcement Agency (DEA) expeditiously modifies or transfers quotas among manufacturers when one ceases production of a drug containing a controlled substance. Preventing administrative delays relative to quotas will allow manufacturers to quickly increase production to meet the needs of patients for medically necessary drugs. Otherwise we will be left with our current situation where patients are suffering, and medical costs are increasing.

We are encouraged by the DOJ's willingness to review this regulation. As new regulations are crafted, we hope to be able to work with DOJ to address some of the limits to the current system that have resulted in increased costs and implications for patient access and care across the United States.

Sincerely,
American Hospital Association (AHA)
American Society of Anesthesiologists (ASA)
American Society of Clinical Oncology (ASCO)
American Society of Health-System Pharmacists (ASHP)
Generic Pharmaceutical Association (GPhA)

Hospira
Premier Inc.
Teva Pharmaceutical Industries Ltd.

Cc: Eric H. Holder, J.D.
Attorney General of the United States