United States Senate
COMMITTEE ON THE JUDICIARY
WASHINGTON, DC 20510-6275

May 3, 2012

The Honorable Gene Dodaro
Comptroller General
U.S. Government Accountability Office
441 G Street, N.W.
Washington, D.C. 20548

We write to request that the Government Accountability Office (GAO) conduct a study of the extent to which Drug Enforcement Administration (DEA) policies and regulations may contribute to the growing drug shortage crisis with regard to controlled substances prescribed by physicians.

We are concerned that patients with medical needs lack access to a number of controlled substances (as defined by The Controlled Substances Act codified at 21 U.S.C. § 801 et. seq.) in short supply. Accordingly, we would like to better understand any impediments to production or distribution of such drugs and, if so, how such impediments can be ameliorated to ensure a sufficient supply of controlled substances for lawful patient care purposes. More specifically, we would like to better understand the impact of DEA quotas on patients with emergency medical and critical care conditions and traumatic injuries, and the extent to which DEA policies and regulations may impede the ability of physicians and health care providers to mitigate a shortage of a drug on any of the applicable schedules.

In responding to our specific questions below, we request that the GAO conduct this study and report on its work within one year of the date of our letter. Further, we request that you consult with relevant stakeholders such as manufacturers of brand and generic pharmaceuticals, patient advocacy groups, physician organizations, health care providers such as hospitals, pharmacies, fire, EMS and CCT agencies and national organizations representing them, relevant state agencies, and others as deemed necessary.

In researching and writing this report, we request that the GAO examine the following issues:

1. With respect to *annual* quota requests: the timeliness of responses from the DEA to drug manufacturer initial annual quota requests; the proximity to the subsequent calendar year that the DEA responds to such requests; the data that manufacturers provide and the data the DEA uses in granting quota requests; the processes, methodology, and data used by the DEA to determine whether and to what extent to grant a manufacturer's initial annual quota request; whether drug manufacturer annual quota requests accurately predict lawful

market demand for the product in a subsequent year; and whether allowing manufacturers to provide annual quota requests later in the calendar year would improve the accuracy of such requests.

2. With respect to *supplemental* quota requests: the timeliness of responses from the DEA to drug manufacturer supplemental quota requests; the data that manufacturers provide to the DEA and the data the DEA uses in granting quota requests; and the processes, methodology and data used by the DEA to determine whether to grant the manufacturer's supplemental quota request and how much to grant.

3. With respect to related issues: whether an appeals process for manufacturers that disagree with the quota granted by DEA would help alleviate drug shortages; whether the DEA includes inventory allowance requirements when providing an annual quota, and provides manufacturers increased inventory allowances if necessary to mitigate the risk of drug shortages; whether processes exist for manufacturers to obtain increases in quotas to respond to emergencies or unforeseen circumstances; and any other issues deemed necessary by the GAO related to quotas.

4. With respect to the impact on patients: identification of patient populations at serious risk of death, disability, or medical errors due to lack of access to essential drugs; identification of patient safety risks such as substantial alterations of drug formulation and concentration; the potential for increased risk of drug administration errors, including in the transport environment; tools for mitigating drug shortages such as sharing products between agencies or among stations within agencies or the utilization of expired drugs when no other alternative is available; and the amount or prevalence of unnecessary waste and whether repackaging drugs in short supply and implementing shelf-life extension programs are viable options for mitigating shortages.

5. Whether DEA regulations and policies and the application and enforcement thereof adversely impact or exacerbate the shortage of drugs used to treat patients with emergency and critical conditions and traumatic injuries, or otherwise impede the ability of emergency physicians, and EMS and CCT physician medical directors and agencies to maximize access to a limited supply of controlled substances for their patients.

6. Whether access for patients with emergency and critical conditions and traumatic injuries to controlled substances needed for their treatment would be improved by: i) improving DEA regulatory applicability to the field EMS/CCT setting; ii) addressing potential inconsistencies in enforcement of DEA rules in the field EMS/CCT transport environment to ensure clear and consistent application nationwide; and iii) removing any impediments that GAO may identify regarding mitigation of drug shortages for patients with emergency and critical conditions and traumatic injuries.

Thank you for your cooperation and attention in this matter. We would appreciate a response by May 14, 2012. If you have any questions, please do not hesitate to contact Erika Smith for Senator Grassley at (202) 224-5225 or Justin Florence for Senator Whitehouse at (202) 224-2921.

Sincerely,

Charles E. Grassley
Ranking Member
Judiciary Committee

Sheldon Whitehouse
Chairman
Crime and Terrorism Subcommittee