November 6, 2011

Drug Enforcement Administration  
Attention: DEA Federal Register Representative/OD  
8701 Morrissette Drive  
Springfield, VA 22152

RE: Docket No. DEA-358  
Controlled Substances: Proposed Aggregate Production Quotas for 2012

On behalf of Advocates for the Reform of Prescription Opioids, Inc. (ARPO), I offer these comments on the DEA’s proposed aggregate production quotas for Schedule II opioids in 2012. ARPO formed earlier this year with the goal of ending the epidemic of death and addiction caused by prescription opioid drugs by ensuring that opioids are regulated, marketed, prescribed and used in an evidence-based manner. Many of our members are bereaved parents who lost a child to prescription opioids. In my case, I lost my eighteen year-old daughter Emily after she consumed one OxyContin pill given to her by a relative. Others in our group are struggling with an addicted family member; the majority of these cases began due to an injury that led to an opioid prescription.

The United States and other developed countries around the world are currently in what has been termed a prescription drug epidemic. The term, “epidemic”, has been used by Office of National Drug Control Policy Director Gil Kerlikowske, the Centers for Disease Control, National Institute on Drug Abuse Director Nora Volkow, SAMHSA, coroners and others to refer to the prescription drug crisis we are currently facing. In her remarks before a Congressional subcommittee earlier this year, DEA Administrator Michele Leonhart stated that “Prescription drug abuse is a serious problem. Reducing prescription drug abuse is vital to the health and welfare of the American people.” (Leonhart 2011). Of some 35,450 deaths in the United States in 2008, more than 20,000 of these deaths were attributed to prescription drugs, and of those 14,800 deaths were attributed to prescription opioids (CDC 2011).

According to the DEA website, the mission of the Drug Enforcement Administration (DEA) is to enforce the controlled substances laws and regulations of the United States. In fulfillment of this mission, DEA establishes production quotas for Schedule I and II drugs every year. In her Congressional remarks earlier this year, Administrator Leonhart stated that “DEA establishes manufacturing and procurement quotas each year for schedule I and II controlled substances in order to avoid the overproduction of these substances, for the purpose of reducing the risk of diversion to illicit traffic. Accordingly, the quota system serves the vital purpose of reducing the risk of diversion” (Leonhart 2011). If this is indeed the objective of the quota system, the

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following information casts serious doubt on the effectiveness of DEA’s administration of its quota system.

Here is a graph showing the steady increase in DEA production quotas for most Schedule II opioids:

![Graph of DEA Production Quotas for Schedule II Opioids, 1996-2009 (kg). Includes quotas for codeine, fentanyl, hydrocodone, hydromorphone, meperidine, methadone, morphine, opium, oxycodone, oxymorphone and thebaine. Source: DEA website.]

In the United States during roughly this same time period, deaths from prescription opioids have risen in parallel with the increase in supply:

![Graph of Annual deaths from opioid analgesics, United States, 1999-2008. Source: CDC.]


Annual deaths from opioid analgesics, United States, 1999-2008. Source: CDC.
These two trend lines are clearly very highly correlated (Pearson correlation coefficient = 0.94 for years 1999-2008), providing evidence of the close relationship between the supply of prescription opioids, as represented by the DEA quotas, and deaths from these same drugs.

Following is a graph from the Centers for Disease Control that shows that the rate of deaths and treatment admissions attributed to prescription opioids have steadily risen in lock step with sales of prescription opioids in the United States:

Rates of prescription painkiller sales, deaths and substance abuse treatment admissions (1999-2010).


These graphics vividly establish that deaths and addictions from prescription opioids have continued to rise unabated as DEA production quotas have been increased. It is abundantly clear that the steadily increasing supply of opioids that is made possible through DEA’s production quotas is driving the prescription opioid epidemic.

The time has come for DEA to finally recognize that its production quotas enable the production of drugs that kill and addict thousands of Americans and other citizens throughout the world each year. Thus, **DEA is directly responsible for enabling the American drug production system to mass produce huge quantities of narcotics that are killing people and destroying lives.** To consider only the benefits that these medications provide is to ignore a major public health problem that is being driven by DEA’s drug quota policies. With all of the problems brought on by the mass production of oxycodone in this country, a 2012 proposal to allow the production of 103,600 kg (114 tons), a 1,747% increase over the amount produced in 1996, the year OxyContin first came on the market, is unconscionable and reflects a complete disregard for the loss of life that this drug has caused.
According to CDC, in 2010 about 12 million Americans aged 12 or older (about one in twenty) reported using prescription opioids nonmedically, enough to medicate every American adult around the clock for a month (CDC 2011). This constitutes proof that these powerful and deadly narcotics have over-saturated our society. The DEA has approved these massive increases in the legal supply of prescription opioids without evidence that these narcotics are safe or effective for chronic noncancer pain. Rather than taking the drug companies’ or FDA’s word for it, why does DEA not conduct its own investigation on the efficacy of these drugs and how the drug companies propose to use them? A good place to begin your investigation is the website of Physicians for Responsible Opioid Prescribing (PROP) at: http://www.responsibleopioidprescribing.org/. Our own website also provides up to date medical research on prescription opioids: http://www.rxreform.org/.

The time has come for DEA to do the right thing – it must **roll back the production quotas** to save lives.

Sincerely,

Peter W. Jackson, President
Advocates for the Reform of Prescription Opioids
www.rxreform.org

References:

