

The Reflex Sympathetic Dystrophy Syndrome Association (RSDSA) opposes the petition to re-label opioid analgesics, submitted to the FDA by Physicians for Responsible Opioid Prescribing (PROP). RSDSA is a national not-for-profit organization with 6,000 members. RSDSA's mission is to promote greater awareness and earlier recognition of Complex Regional Pain Syndrome (CRPS), to fund critical research, and to provide support to people with CRPS and to their loved ones. RSDSA, in the name of its membership, urges the FDA to reject PROP's petition. In its opposition, RSDSA endorses the scholarship and arguments of Bob Twillman, PhD, FAPM, Director of Policy & Advocacy, American Academy of Pain Management¹, and that of Martin Grabojs, MD, President, American Academy of Pain Medicine.

CRPS is a neuropathic pain disorder of uncommon severity. It has a US prevalence of between 65,000 and 1.3 million individuals. The mechanism of disease is unknown, but the best theory proposes that it is an immune-mediated disease that causes central neuroinflammation of the nociceptive apparatus, including, but not limited to spino-thalamic and thalamo-cortical circuits.² It is difficult to treat. In the absence of disease control, symptom control is all that is available to people who suffer cruelly. RSDSA declares that the effect of PROP's petition, if implemented, will be to significantly limit access and availability of opioid pain medications for patients who need them for chronic pain management.

RSDSA has no objection to labeling opioid medication for "severe" pain, since among people with CRPS the average pain score is 7.9 out of 10.³ RSDSA strongly objects, however, to any arbitrary limit to the duration of opioid prescribing. The average duration of disease among subjects in the Johns Hopkins study was greater than 3 years. Among 513 respondents to RSDSA's 2008 Internet survey of people with CRPS, 422 (82%) used opioid medications for their pain, and 49% of this group took a sustained-release opioid to manage their pain⁴.

¹ Pain-topics.org ,News/Research Updates, Sept. 26,2012

² Banati RB. Visualising Microglial Activation In Vivo. *Glia*, 2002;40:206–217.

Cooper MS, Moskowitz PA. Activated Glia: Targets for the Treatment of Neuropathic Pain - Report from a recent translational research workshop that included clinicians, scientists, patient advocates, and industry representatives interested in the study and treatment of painful conditions. *Practical Pain Management*, 2010;9:78-84.

Watkins L, Maier SF. Beyond Neurons: Evidence that Immune and Glial Cells Contribute to Pathological Pain States. *Physiol Rev*, 2003;82:981-1011.

³ In 2005, RSDSA conducted a web-based survey of people with CRPS in conjunction with Johns Hopkins School of Medicine (an abstract of the survey and journal article, *Reg Anesth Pain Med*. 2009; 34(2):110-115 are published on our website at www.rsds.org). 1359 individuals completed the survey and 888 satisfied the diagnostic criteria for CRPS and were included for data analysis).

⁴ 2008 Internet survey conducted by RSDSA. (www.rsds.org)

⁵ Personal communication from Jeffrey Janata, PhD, based, in part, on Sharma A, Agarwal S, Broatch J, Raja SN. A Web-Based Cross-Sectional Epidemiological Survey of Complex Regional Pain Syndrome. *Reg Anesth Pain Med*. 2009;34(2):110-115

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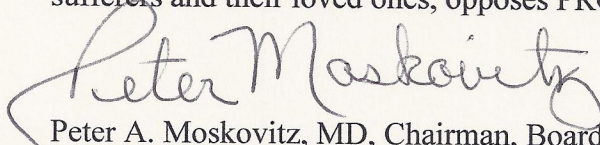
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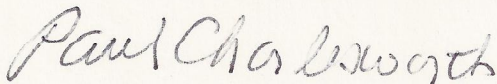
The severity of the disease is represented in the findings of the Johns Hopkins study: 60% of subjects rated themselves as disabled, 47% had suicidal thoughts, and 15% reported suicidal behavior, two times, on average. In describing the pain of CRPS, a pain psychologist observed, "There are no [other] pain conditions so associated with desperation that amputations in an attempt to relieve pain are not unheard of."⁵

RSDSA will gladly partner with the FDA in efforts to educate physicians and pharmacists in appropriate patient and opioid selection and in careful follow-up, to improve compliance with existing statutory and regulatory requirements, and to work with industry to promote responsible advertising and representation of its opioid products. RSDSA acknowledges that abuse, diversion, accidental overdose, and post-opioid hyperalgesia are serious problems. Nonetheless, until the science, pharmacology and technology to solve these problems are available, The FDA must not withhold symptom control from patients in need.

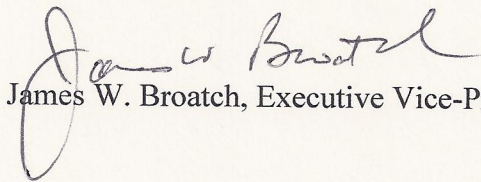
There exists an argument that because FDA regulation does not limit off-label prescribing, FDA relabeling of opioids will not limit worthy patient access. This argument is false, since insurance payers' denial of coverage for off-label prescriptions effectively denies access to treatment. Such an outcome would create an abhorrent two-tiered system of healthcare, segregating rich and poor. PROP's ill-conceived petition will not enhance the prevention of adverse effects of opioids. It can only increase the suffering of people with CRPS. RSDSA, on behalf of CRPS sufferers and their loved ones, opposes PROP's petition.



Peter A. Moskovitz, MD, Chairman, Board of Directors



Paul Charlesworth, President



James W. Broatch, Executive Vice-President

⁵ Personal communication from Jeffrey Janata, PhD, based, in part, on Sharma A, Agarwal S, Broatch J, Raja SN. A Web-Based Cross-Sectional Epidemiological Survey of Complex Regional Pain Syndrome. Reg Anesth Pain Med. 2009;34(2):110-115