

Washington, DC
16 July 2010

A. Thomas McLellan, PhD
Deputy Director,
White House Office of National
Drug Control Policy
Executive Office of the President
750 17th St, NW
Washington, DC 20503

Dear Dr. McLellan:

On behalf of all the organizations comprising the Pain Care Forum, it was a distinct pleasure to have you and Ms. LaBelle attend our meeting last Thursday, July 8 to share the Administration's approach to controlling nonmedical use of pharmaceutical opioids and other medicines, and the resulting harm, while ensuring access to these medicines for legitimate medical purposes.

You had requested that we write you to comment on our mutual interests. As we mentioned, the Forum's purpose is to create an environment in which diverse groups, including pharmaceutical manufacturers and distributors, health care professional organizations, groups who advocate for people in pain, palliative care organizations, State regulators, and drug abuse prevention groups to air views on topics of concern to our organizations, to foster consensus development when possible, and to articulate issues of concern, so that individual organizations or groups of organizations can take policy positions. The Forum itself, does not take stances on any issues, preferring to act as a convener for those interested parties who may decide to support a view on a particular subject.

Among the organizations attending in person and by teleconference, there was broad agreement with the elements you reviewed to address reducing demand for illicit substances and for pharmaceuticals for nonmedical purposes. The undersigned organizations share your concern about:

- The need for increased attention to help create an informed public about these medications, their potential harms and benefits
- Overdoses from pharmaceutical opioids and other medicines
- The insufficient number of healthcare professionals trained to adequately treat pain, compared to the need in the populace
- The confusion of physical dependence with addiction, as one example of the need for better training
- The sources of diverted medicines
- Your planned focus on prescribers and other health care professionals, the pharmaceutical industry, and families and the communities in which they live.

We are encouraged that you are seeking to facilitate the coming together of pain-oriented professional organizations with those representing primary care prescribers to jointly re-evaluate the delivery of pain care and to agree on acceptable protocols and other guidance to improve prescribing and ongoing care practices. We strongly suggest that ONDCP consider writing groups that participate in the Forum, like the American Academy of Pain Medicine, the American Academy of Pain Management, the American Society of Anesthesiologists, the American Headache Society, the American Pain Society, the American Society for Pain Management Nursing, the Federation of State Medical Boards, the National Hospice and Palliative Care Organization, and others, such as the Hospice and Palliative Care Nurses Association, the American Academy of Family Physicians, the Society for General Internal Medicine, the American Medical Association, the American Osteopathic Association, the American College of Physicians, the American Academy of Nurse Practitioners, and the American Academy of Physician Assistants to name a few, to urge them to work together to improve the effectiveness and safety of pain care with opioid

analgesics. We believe that a call from the executive branch would do much to catalyze a coordinated effort.

There was also broad support for your call for more regular use of State Prescription Drug Monitoring Programs (PDMPs) as a tool to improve clinical care, to identify persons with early problematic use of these medicines and to reduce diversion from “doctor shopping.” Two major hurdles to be overcome, however, are a) interoperability between States (e.g., uniform sets of data fields, integrity of data collected, accessibility by practitioners across State lines) and b) in what part of the State governmental structure such programs reside. As you pointed out, there are currently two federal funding mechanisms, one which favors PDMPs that are housed with law enforcement, which most experts feel discourages practitioner interaction, and one which favors those Programs residing with Departments of Health, Boards of Pharmacy, etc.

With regard to the pharmaceutical industry, we noted that you, as well as many organizations of the Forum, are working actively with the Food and Drug Administration on the Risk Evaluation and Mitigation Strategy for Certain Opioid Drugs. Many of our organizations collectively see this REMS as having the potential to incrementally improve the environment in which these medicines are used by educating prescribers and patients about the safe use, storage and disposal of opioid analgesics. The convening of a meeting of the various health care professional organizations mentioned above could facilitate, among other things, a uniform curriculum to train prescribers and other healthcare professionals on proper assessment and monitoring of patients being treated with controlled substances.

You had also mentioned attempting to garner support among the pharmaceutical companies for PDMPs. Some of our members have been actively involved for many years in supporting the implementation of well-designed Programs that promote their use by health care practitioners.

You suggested that industry could help in assuring that controlled substances do not reach the hands of purchasers who do not intend to use them for legitimate medical purposes. Over the last few years, several of our organizations have gone to great lengths to develop systems or strategies designed to help reach that objective. We would be pleased to discuss this with you as well as other potential measures to support this effort.

Certainly, as part of the impending REMS, or in addition to it, many of our industry organizations would be willing to engage on a public information campaign about the safe use, storage and disposal of these and other medicines.

In regard to your comments about discussions ONDCP has had with FDA regarding industry seeking formulation developments that could lead to medicines that are equally efficacious for patients to existing ones, but that are less desirable for abuse, we raised a concern about the potential unintended negative consequences that certain provisions of the health care reform legislation may have on persons whose quality of life relies on the medical use of these analgesics. Specifically, the legislation establishes a new calculation for the total Medicaid rebate for any “line extension” of an existing drug. This new provision will most likely result in higher Medicaid rebate liability for manufacturers of products that qualify as “line extensions”. However, the term “line extension” is vaguely defined in the legislation to mean “a new formulation of the drug, *such as an extended release formulation,*” (emphasis added) and some of our organizations are deeply concerned that, if this definition is construed broadly, it will discourage innovation, thereby limiting access to new formulations and new drugs that potentially result in material innovation and substantial advancement in treatment or patient safety, as opposed to minor changes designed to exploit less rebate liability, as we believe was the intent of the law.

Specifically, there is concern that during the rulemaking process that is currently underway, the Centers for Medicare and Medicaid Services (“CMS”) may interpret the definition broadly to cover new formulations and new drugs that reflect important new developments, such as a new formulation with the potential to decrease abuse of prescription drugs (thereby improving patient and public safety) or a new combination pain management drug that includes a new indication for addressing common pain

management side effects such as constipation (i.e., a clear advance in treatment). In both these examples, the Food and Drug Administration would require additional pre-approval or post-approval studies or clinical trials beyond those needed to establish bioequivalence to an existing formulation. Nonetheless, given the vague statutory definition of “line extension”, there is concern that CMS may not fully appreciate the distinction between slightly altered drugs (which can often be approved through bioequivalence studies or, occasionally, no additional studies at all) and those which are designed to improve treatment or patient safety as proven by one or more FDA-required pre-approval or post-approval studies or clinical trials. Accordingly, we urge ONDCP to recommend to CMS that it give careful consideration to the concerns of the community of persons in pain who use these medicines medically, and the public health in general, and ensure that the definition of “line extension” is implemented by CMS in a manner that protects new formulations and new drugs that represent a potential advancement in treatment or patient safety from the new line extension Medicaid rebate calculation.

Abuse-deterrent or abuse-mitigating formulations have been considered by the Food and Drug Administration (FDA) as a “helpful next step” in the overall effort against drug abuse. Clarifying the development and approval pathway for those companies involved in the creation and manufacturing of the newer formulations should be encouraged. It would be useful to enter into a dialogue with FDA about finding the appropriate incentives to develop new technologies that deter drug abuse.

Lastly, many of our organizations support ONDCP’s interest in achieving consensus about proper disposal of opioid analgesics, and all other medicines, when no longer needed. We pointed out that, under the current system, some of our company’s products have language in the FDA-approved Full Prescribing Information (package insert, or label) that mandate flushing down the toilet as the only recommended disposal method as, collectively, the federal government has determined that the toxicity of these few medicines when in the wrong hands outweighs any possible theoretical damage to the environment. We pointed out that human excretion of these medicines and their metabolites, both pharmacologically active and inactive, is the basis for urine drug testing, which you recommended as one tool practitioners employ. As long as the agency with primary regulatory jurisdiction recommends flushing of certain drug products when no longer needed, it makes it difficult for the sponsors of those products to endorse any other method, for fear of misbranding of the product under the federal Food, Drug and Cosmetic Act. We encouraged ONDCP to continue working with other federal and state agencies to develop workable, uniform recommendations for drug disposal that minimize both environmental impact and opportunities for diversion.

There was a consensus that a White House conference, similar to the one held over two decades ago to address much the same problems with achieving the balance between appropriate medical use and nonmedical use of these medicines is timely and could be very important in shifting practice and policy toward a new era of better use of these medicines with less harm to patients, abusers and society. Our organizations would be very willing to work with the executive branch on planning and participating in such a conference.

In sum, we were very encouraged by the vision for the future of US drug control policy that you shared and stand willing to work in a coordinated manner with ONDCP to improve the public health.

Thank you for taking the time to meet with us and to extend the offer to work together. We are anxious to find a way to continue to collaborate with you and the executive branch.

Sincerely,

Will Rowe- American Pain Foundation
Cyndi Miller Murphy, MSN, RN, CAE- Oncology Nursing Society
Marcia Lee Taylor- Partnership for a Drug-Free America
Judy Lentz, RN, MSN, NHA- Hospice and Palliative Care Nurses Association
Burt Rosen- Purdue Pharma
Rebecca A. Kirsh- American Cancer Society Cancer Action Network (ACS CAN)
Lisa A. Robin- Federation of State Medical Boards

Penney Cowan- American Chronic Pain Association
Theresa Grimes, MN,RN-BC,FNP-BC,CCRN- American Society for Pain Management Nursing
Adam M. Clark, Ph.D. - Lance Armstrong Foundation (LIVESTRONG)
Phil Saigh – American Academy of Pain Medicine
Mike Heffernan- Collegium Pharmaceuticals
Kevin Zacharoff, MD, FACPE, FACIP, FAAP- Inflexxion, Inc.
Joel Simon Hockman, MD- National Foundation for the Treatment of Pain
Brian Munroe- Endo Pharmaceuticals
Patrick Coyne, RN, MSN, APRN, FAAN - Virginia Cancer Pain Initiative
June Dahl- Alliance of State Pain Initiatives
Dr. Ian Buttfeld- International Association for Pain and Chemical Dependency
Stewart Leavitt, MA, PhD- Pain Treatment Topics
Myra Christopher- Center for Practical Bioethics
Marsha Stanton,PhD,RN- King Pharmaceuticals
Aaron M. Gilson,MS,MSSW,PhD- Pain & Policy Studies Group
J. Donald Schumacher,Psy.D- National Hospice and Palliative Care Organization
William J. Lorman, PhD, MSN, PMHNP-BC, CARN-AP- International Nurses Society on Addictions
Patrick Plues- Cephalon, Inc.
Anita Ducca- Healthcare Distribution Management Association
Jason Grove- Abbott Pharmaceuticals
Barbara Gordon, RD- Executive Director, Interstitial Cystitis Association