



Submitted via email to chronic_care@finance.senate.gov

June 22, 2015

Chronic Care Working Group
Senate Finance Committee
United States Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510

Re: Response to Chronic Care Reform Stakeholder Letter

Dear Senate Finance Committee Chronic Care Working Group:

Mallinckrodt Pharmaceuticals ("Mallinckrodt") appreciates the opportunity to provide comments to the Senate Finance Committee chronic care working group on efforts to improve and reform chronic care in the Medicare program. An independent company since July 2013, Mallinckrodt has deep expertise in the formulation and manufacture of specialty medications. As a company that provides a comprehensive suite of specialty pharmaceuticals, many of which treat chronic conditions, Mallinckrodt has a unique perspective about and appreciation of the complexities of appropriately and effectively treating patients with chronic conditions.

Mallinckrodt is a global specialty biopharmaceutical and medical imaging business that develops, manufactures, markets and distributes specialty pharmaceutical products and medical imaging agents. Our areas of focus include therapeutic drugs for autoimmune and rare disease specialty areas like neurology, rheumatology, nephrology and pulmonology; neonatal critical care respiratory therapies; and analgesics and central nervous system drugs for prescribing by hospital- and office-based physicians. Mallinckrodt's core strengths include the acquisition and management of highly regulated raw materials; regulatory expertise; and specialized chemistry, formulation and manufacturing capabilities. The company's Specialty Brands segment includes branded medicines; its Specialty Generics segment includes specialty generic drugs, active pharmaceutical ingredients and external manufacturing; and the Global Medical Imaging segment includes contrast media and nuclear imaging agents.

We greatly appreciate the Senate Finance Committee's creation of a chronic care working group. Although many of Mallinckrodt's products address chronic conditions, we want to focus our comments today on one, often intractable, chronic condition: chronic pain. Mallinckrodt is proud to manufacture opioid and non-opioid based medications for patients struggling with chronic and acute pain. We are committed to working with this working group to explore options to improve care for these patients, to reduce the incidence of opioid misuse and to address the pain treatment needs of chronic pain patients.

Based on this experience, Mallinckrodt offers the following suggestions for your consideration as you develop the legislative solutions that will be presented to the full Senate Finance Committee.

- Alternatives to Opioids. Although opioids are a necessary component of treatment for many patients suffering from chronic pain, we believe that the Medicare program can do more to encourage providers to consider alternatives to opioids for appropriate patients.
- The Potential for Better Treatment at Lower Costs. Non-opioids as a foundation for pain management, where appropriate, have a significant potential to reduce opioid misuse and abuse and produce cost savings in connection with the reduction of opioid related adverse drug events, unnecessary inpatient re-admissions, excessive length of stay, and other avoidable costs.
- Quality Metrics as a Key Policy Tool. A key component in encouraging providers, including hospitals, to explore alternatives to opioids will be the adoption by the Medicare program of an appropriate quality metric that requires providers to have a system in place to document their consideration of non-opioids as a foundation for pain management. Currently, the Medicare program has virtually no quality metrics in place that address opioid use and chronic pain.

I. Incidence of Chronic Pain

It is critical to remember at the outset that, sadly, pain often remains undiagnosed and is either untreated or under-treated.¹ The scope of the problem is disturbing. According to a 2011 Institute of Medicine (“IOM”) report, over 116 million adults in the United States live with chronic pain, costing the economy an estimated \$560 to \$635 billion annually.² Pain affects more individuals than diabetes, heart disease, and cancer combined,³ with over one-quarter of Americans over age 20 reporting a pain condition.⁴ Against this backdrop, it’s clear that patients experiencing chronic or acute pain need to have access to affordable, effective pain medications. An IOM report, for instance, has acknowledged that many Americans are not receiving adequate pain prevention, assessment, or treatment,⁵ and has called for an effort to “document rates of treatment or under treatment of pain.”⁶

¹ See Pizzo and Clark, Alleviating Suffering 101 – Pain Relief in the United States, *NEJM* 366:3 (Jan. 19, 2012); Institute of Medicine, *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research* (“IOM Report”) (June 29, 2011).

² IOM Report, at 1.

³ American Diabetes Association, <http://www.diabetes.org/diabetes-basics/diabetes-statistics/>; Heart Disease and Stroke Statistics—2011 Update: A Report From the American Heart Association, *Circulation* 2011, 123:e18-e209, 20, <http://circ.ahajournals.org/content/123/4/e18.full.pdf>; American Cancer Society, Prevalence of Cancer, http://www.cancer.org/docroot/CRI/content/CRI_2_6x_Cancer_Prevalence_How_Many_People_Have_Cancer.asp.

⁴ National Centers for Health Statistics, Chartbook on Trends in the Health of Americans 2006, Special Feature: Pain, <http://www.cdc.gov/nchs/data/hus/hus06.pdf>.

⁵ IOM Report, at 8.

⁶ IOM Report, at 6; see also *Id.* at 65.

Provider and patient groups have expressed concerns about the adequacy of pain management and treatment as well, particularly in the case of chronic pain; an example of which is neuropathic pain. Neuropathy results from nerve damage and is associated with a wide range of underlying diseases and conditions, including diabetes, trauma, autoimmune diseases (such as lupus, rheumatoid arthritis, and Guillain-Barre syndrome), tumors, kidney disease, liver disease, Lyme disease, and HIV/AIDS. Diabetic neuropathy alone accounts for between 15 and 20 million cases in the United States. These statistics make clear that chronic pain must be addressed in any consideration of how to improve chronic care treatment in the United States.

II. Alternatives to Opioids

Although opioid-based pain treatment is often essential in the appropriate management of chronic pain, Mallinckrodt is committed to encouraging the use of alternatives to opioids in pain management, where appropriate, in recognition, in part, of the serious concerns regarding opioid misuse and abuse. Various alternatives may exist for particular patients, such as anesthetic techniques, cooling pads, nonsteroidal anti-inflammatory drugs, COX-2 selective inhibitors, non-opioid sedatives and products like OFIRMEV[®] (acetaminophen) injection, Mallinckrodt's non-opioid pain medication.

Significantly, in considering alternatives to opioid use in chronic pain patients, it is critical to understand the link between acute and chronic pain, and that “a period of acute pain always precedes the development of chronic pain.”⁷ While not all individuals experience chronic pain after an acute injury, the link between acute and chronic pain is well-known.⁸ Multimodal pain treatment, meaning the use of more than one type of pain drug, is recommended by numerous medical societies and regulatory bodies to minimize the transition from acute to chronic pain.⁹ Given the link between acute and chronic pain, we see OFIRMEV as a means to help limit the problem of chronic pain. OFIRMEV is intravenous acetaminophen used primarily in the hospital inpatient setting. Its use may obviate the need to initiate opioids in surgical patients or significantly reduce the need for opioids, improving patient satisfaction and potentially reducing opioid-related adverse events.

Not surprisingly, many clinical guidelines support the use of alternatives to opioids where applicable. For example, the Joint Commission, in its pain management alert, has recognized the benefit of using an “individualized, multimodal treatment plan to manage pain,” which includes “non-opioid pain medications.”¹⁰ Additionally, the Centers for Disease Control reviewed eight guidelines for opioid prescribing and found that a common recommendation

⁷ Rathmell, *The Link Between Acute and Chronic Pain*, Inter Anesthesia Research Society, IARS Course Lectures, 2012.

⁸ McGreevy, et al. *Preventing Chronic Pain following Acute Pain: Risk Factors, Preventive Strategies, and their Efficacy*, *Eur J Pain Suppl.* 2011; 5(2): 365–372.

⁹ Voscopoulos and Lerna, *When Does Acute Pain Become Chronic?* *British J of Anesthesia.* 2010;105 (S1): i69–i85; American Society of Anesthesiologists (ASA) Committee on Standards and Practice Parameters, *Practice Guidelines for Acute Pain Management in the Perioperative Setting.* *Anesthesiology.* 2012; 116:248-73.

¹⁰ The Joint Commission, Sentinel Event Alert, *Safe Use of Opioids in Hospitals* (Aug. 8, 2012).

among all guidelines was to “[c]onsider[] all treatment options, weighing benefits and risks of opioid therapy, and using opioids when alternative treatments are ineffective.”¹¹

Incredibly, however, almost no quality metrics exist that encourage appropriate opioid management or the use of alternatives to opioids. For example, the Centers for Medicare and Medicaid Services (“CMS”) has a number of healthcare quality initiatives that are used for a variety of settings, such as the Home Health Quality Initiative, the Nursing Home Quality Initiative, the End-Stage Renal Disease Quality Initiative, the Physician Quality Reporting System and the Hospital Quality Initiative. But, to date, there are almost no applicable pain medication measures in place. A few measures reference pain, such as a pain-related measure for Median Time to Pain Management of Long Bone Fracture. There is not, for example, any CMS inpatient measure that could be used to encourage hospitals and their medical staffs to use, or even to consider the use of, alternatives to opioids in an effort to address the link between acute and chronic pain.

Similarly, the Healthcare Effectiveness Data and Information Set (“HEDIS”), which is used by health plans to measure performance on dimensions of care and service, presently fails to include adequate quality metrics tied to pain management. With regard to HEDIS, the only existing pain-specific measure relates to Use of Imaging Studies for Low Back Pain.

Thus, despite the attention that stakeholders have placed on addressing the important issue of opioid misuse and abuse, there are essentially no applicable existing quality measures that specifically address opioid use – and none that require the consideration of alternatives to opioids or that attempt to focus attention on connections between acute and chronic pain. We believe this must be changed.

a) Effective Use, Coordination and Costs of Prescription Drugs

Mallinckrodt believes that measures should be taken to consider and encourage the use of alternatives to opioids as part of ensuring that the Medicare program facilitates the effective, coordinated and cost-efficient pain management of chronic pain conditions. While opioids are appropriate for many patients with chronic conditions, some patients would clearly benefit from non-opioid pain management techniques and alternatives. Providing non-opioid pain medication after surgery, for example, may reduce the risk of subsequent misuse, abuse, or addiction. Notably, the Joint Commission has warned that opioids may not be appropriate for all patients, which underscores the need to explore the use of alternative pain medications.¹² In our view, the consideration of non-opioid alternatives is an essential component of ensuring the effective use and coordination of prescription drug medications in pain management.

The appropriate use of non-opioid alternatives in pain management also promises to be cost-effective. While opioid alternatives may cost more than certain opioids initially given the low unit

¹¹ CDC, Common Elements in Guidelines for Prescribing Opioids for Chronic Pain, available at http://www.cdc.gov/drugoverdose/pdf/common_elements_in_guidelines_for_prescribing_opioids-a.pdf.

¹² The Joint Commission, Sentinel Event Alert, *Safe Use of Opioids in Hospitals* (Aug. 8, 2012).

cost associated with some opioid treatments, the potential to minimize side effects from opioids and shorten hospital stays combined with future savings from avoiding opioid misuse and abuse can all easily outweigh the costs of the non-opioid alternatives (in avoided adverse events, emergency room visits, hospitalizations, and substance abuse program costs). Unfortunately, hospitals may not take into account these costs to the health care system or may not identify the connections between their opioid use decisions and these subsequent costs.

For example, a study showed that, across all surgery categories, the risk of an adverse event from opioid use was 2.6 times higher than the risk of an adverse event from all other drugs.¹³ This risk of adverse events was increased based on age, indicating the importance of this issue in the Medicare population.¹⁴ Further, the study found that an adverse event increased costs, on average, by 16%, which, when applied to the median cost patient for those without adverse events, resulted in an average opioid-related increase in costs in the amount of an adverse event of \$840.¹⁵

Another study also found that approximately 12% of patients treated with opioids experience an adverse event, and those who are elderly are particularly vulnerable to adverse events.¹⁶ Based on a review of four studies that examined the impact of opioid adverse events on hospital costs, the authors found that hospital costs increased with the development of such an adverse event.¹⁷

Yet another study concluded that there is a significant relationship between opioid adverse events and length of stay.¹⁸ Thus, reducing the use of opioids, and avoiding associated adverse events, presents a significant opportunity to reduce Medicare costs.

b) Care Coordination in Rural and Frontier Areas

Sadly, studies suggest that there is a higher incidence of opioid abuse in rural areas.¹⁹ Therefore, it is particularly important in these areas of the country to encourage consideration of non-opioid pain management options, where appropriate. Patient and provider isolation presents additional barriers to the meaningful consideration of and access to non-opioid alternatives.

III. Policy Options

Given the need to encourage non-opioid alternatives as a foundation for pain management, we believe that Medicare should take the lead in encouraging providers, including hospitals, to

¹³ Odera, et al. *Cost of Opioid-Related Adverse Drug Events in Surgical Patients*, J Pain and Symptom Management. 2003;25(3):276-283.

¹⁴ *Id.* at 278.

¹⁵ *Id.* at 279 - 280.

¹⁶ Odera, *Challenges in the Management of Acute Postsurgical Pain*, Pharmacotherapy. 2012;32(9 Pt 2):6S-11S.

¹⁷ *Id.*

¹⁸ Pizzi, et al. *Relationship Between Potential Opioid-Related Adverse Effects and Hospital Length of Stay in Patients Receiving Opioids After Orthopedic Surgery*, Pharmacotherapy. 2012;32(6):502-514.

¹⁹ Keyes, et al. *Understanding the Rural-Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States*, Am J Public Health. 2014;104(2):e52-e59.



explore alternatives to opioids in appropriate patients. Specifically, CMS should be directed by Congress to introduce quality ratings metrics that require providers to establish and report on the operation of programs to consider the use of alternatives to opioids. The quality metric should require that hospitals, for example, have a system in place to consider and implement alternatives to opioid use, including the consideration of non-opioid pain management techniques. As part of that system, CMS should encourage hospitals to discuss non-opioid pain management options with patients prior to relevant procedures such as surgery to ensure that the most appropriate pain care is provided. We believe that the current dearth of any meaningful pain-related measures reflects a disturbing gap in the Medicare program generally and its quality program in particular.

Creating a standard that requires the provider/patient discussions on pain management furthers the goals of patient-centered care and empowers patients, especially those with one or more chronic conditions, to manage their own care in a responsible manner. We strongly believe that facilitating such a dialogue will improve the management of care for patients with chronic conditions.

We do wish to emphasize that opioids are appropriate for many patients with chronic pain and we do not wish to discourage their use when appropriate for a given patient. At the same time, we believe that alternatives to opioids must be considered when appropriate.

* * *

Mallinckrodt appreciates the opportunity to provide the Senate Finance Committee chronic care working group with these comments and we greatly appreciate the Committee's work to ensure that chronic care is improved among this vulnerable population. We would welcome the opportunity to discuss these comments in greater detail.

Sincerely,

A handwritten signature in blue ink, appearing to read "Mark Tyndall", is positioned below the "Sincerely," text.

Mark Tyndall
Vice President, Government Affairs, Policy & Advocacy
Mallinckrodt Pharmaceuticals