



UCB, Inc. - 1950 Lake Park Drive - Smyrna, Georgia 30080

January 26, 2016

The Honorable Johnny Isakson
United States Senate
131 Russell Senate Office Building
Washington, DC 20510

The Honorable Mark Warner
United States Senate
475 Russell Senate Office Building
Washington, DC 20510

Submitted via email to Senate Finance Chronic Care mailbox: Chronic_Care@Finance.Senate.gov

Subject: Senate Finance Committee Chronic Care Working Group Policy Options Document

Dear Senator Isakson and Senator Warner,

UCB appreciates the critical leadership that you are providing as Co-Chairmen of the Senate Finance Committee's Chronic Care Working Group (CCWG). We thank you for the opportunity to participate in the development of policies that meet our common goal of improving the standard of care for individuals living with chronic disease.

UCB is a global biopharmaceutical company established in Belgium in 1928 focusing on severe diseases of the immune and central nervous systems. Our company is dedicated to developing medicines and other services for improving the lives of people with chronic diseases such as Epilepsy, Parkinson's Disease, Rheumatoid Arthritis, Crohn's Disease, Lupus, Osteoporosis, Psoriatic Arthritis and Ankylosing Spondylitis. UCB employs 8,500 people in over 40 countries, with our U.S. presence being concentrated at our U.S. headquarters in Atlanta, Georgia, and an additional facility in Raleigh, North Carolina.

At UCB, patients are at the heart of our business and are the reason for our existence. Everything we do starts with one question: "how can we create more value for people living with severe diseases?" We demonstrate our commitment to patients in many ways. UCB invests a substantial share of our revenue into research and development. In fact, this year we are investing an industry-leading 28% of our revenue into R&D. In addition, UCB is devoting significant resources to advancing personalized medicine that ensures the right medicine gets to the right patient at the right time- regardless of the manufacturer. Because the severe diseases on which we focus tend to be "silent diseases," people living with them may be reluctant to share their experiences and insights. We have become known for our innovative programs mapping the patient journey of living with severe disease to uncover opportunities for improving their experiences. UCB has also been a leader in fostering approaches that help patients and families connect with each other through virtual and live peer-to-peer interactions. For example, "Epilepsy Advocate" is a UCB-supported online community with over 200,000 followers that uses the

power of social media to support patients of all ages living with epilepsy. UCB's patient-centered culture results in innovations in new medicines as well as services "beyond the pill".

The CCWG Policy Options Document outlines a variety of proposals that have the potential to improve the standard of care for treating chronic disease. While these proposals focus most directly on health plans and providers, biopharmaceuticals manufacturers and the patients we treat will clearly be impacted. With this impact in mind, UCB offers the following overall comments.

Defining a Chronic Disease

UCB encourages any policies directed at improving access to care for patients with chronic disease to take a broad view of which conditions can qualify. Limiting the definition of what qualifies as a chronic condition can diminish a policy's impact on advancing care for patients. For example, Chronic Condition Special Needs Plans (C-SNPs) are only permitted to specialize in one of the 15 conditions recognized by the Centers for Medicare and Medicaid Services (CMS). This list fails to recognize several conditions that have high unmet burdens of disease in the Medicare population, such as osteoporosis.

To ensure that policies to improve care for chronic disease have maximum impact, policymakers should adopt a broad definition of what conditions will qualify. For example, rather than enumerating the conditions that will qualify, UCB suggests an approach similar to that for determining patient eligibility for services billed under the Chronic Care Management (CCM) code:

"Patients with multiple (two or more) chronic conditions expected to last at least 12 months or until the death of the patient, and that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline are eligible for the CCM service."

By appropriately focusing on the impact of a condition on a particular patient, this approach recognizes a broader spectrum of chronic conditions for which improved care is urgently needed. Conditions qualifying under this criteria could include commonly thought of examples such as Alzheimer's Disease, as well as less commonly thought of conditions such as Crohn's Disease and other flaring diseases.

Ensuring Patient Protection

UCB generally supports proposals to increase flexibility for Medicare Advantage (MA) plans and Accountable Care Organizations (ACOs) to better tailor benefits and services to patients with chronic disease, so long as adequate patient protections accompany such flexibility.

Specifically, any flexibility must continue to guarantee access to the six protected classes of drugs—Anticonvulsants, Antidepressants, Antineoplastic, Antipsychotics, Antiretrovirals, and Immunosuppressants. These drug classes have been recognized for protection based on the vulnerability of the patient populations that they treat and the uniquely impactful consequences of denied or delayed access to the full spectrum of drugs within the class. Without continued protection, care for Medicare beneficiaries with severe chronic conditions such as epilepsy, HIV-AIDS, cancer, mental illness and organ transplant could be disrupted potentially leading to worse health outcomes for patients and increased costs for the Medicare program.

Moreover, any flexibility to vary benefit designs and services based on health status must be accompanied by appropriate quality measurement. For example, the current Medicare Five-Star Rating System (Star Rating System) for Medicare Advantage and Part D plans fails to adequately target quality

measurement for the SNP plans that cover specialized patient populations today. Some Star Ratings measures may not be appropriate for very frail populations. Other measures are less meaningful for patients with chronic conditions, such as the measure for “improving or maintaining physical health” which fails to recognize that optimal care may be slowing—rather than “improving or maintaining”—the rate of decline for a patient with an irreversible, progressive chronic disease.

In order to ensure that patients enrolled in MA plans (including SNPs) or ACOs are receiving high quality care, CMS should be required to develop specialized quality measures for chronic conditions such as epilepsy, rheumatoid arthritis, Parkinson’s Disease, Crohn’s Disease, and other serious and potentially disabling conditions. This requirement should also include the development of quality measures appropriate for the approximately 9 million non-elderly Medicare beneficiaries who qualify based on a permanent disability and who have different needs that must be taken into account.

Finally, if MA plans and ACOs are to be adequately incentivized to take up any flexibility afforded to specialize on patients with chronic disease, they must be paid appropriately through an improved risk adjustment model. An effective risk adjustment model is also necessary to guard against the natural incentives that will otherwise exist to utilize flexibility to avoid enrolling and treating the sickest patients. As the CCWG recognizes in its Policy Options Document, research demonstrates that the current Medicare risk adjustment model significantly under-predicts costs for plans covering the sickest patients. UCB is generally supportive of the CCWG’s proposed improvements to the model, with the caveat that any such improvements be phased in to ensure that any unintended consequences for patients be minimized.

Transparency and Stakeholder Engagement

Finally, UCB supports the establishment of a robust and formal opportunity for stakeholders to provide comments during the regulatory implementation of any policies that ultimately gain adoption. A minimum of a 60-day notice and comment rulemaking process will ensure that stakeholders across the spectrum have the ability to engage in and advise implementation. Policymakers should pay particular attention to minimizing unintended consequences for patient access and care, for example by streamlining the regulatory burden on providers to ensure that they can focus more of their time on patient care.

Thank you again for shining such an important light on the need to improve access to quality care for patients with chronic disease. UCB applauds your leadership and your commitment the patients our medicines treat. Should you have any questions regarding our comments, please contact Director of Health Policy and Reimbursement, Alison Anway, at Alison.Anway@UCB.com or 404-295-0751.

Sincerely,

A handwritten signature in black ink, appearing to read "Patricia A. Fritz". The signature is fluid and cursive, with the first name "Patricia" being the most prominent.

Patty Fritz
Vice President, U.S. Corporate Affairs
UCB, Inc.