

United States Senate

WASHINGTON, DC 20510

June 6, 2011

Dr. Donald Berwick
Director
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Hubert Humphrey Building, Room 314
Washington, DC 20201

Dear Director Berwick:

I am writing to request that the Centers for Medicare and Medicaid Services (CMS) investigate the ramifications of URL Pharma's massive price increase of Colcrys – the branded version of colchicine.

According to the American College of Rheumatology, colchicine has been used for over 200 years as an inexpensive pain-reliever and anti-inflammatory for approximately 3 million Americans with gout. Prior to the approval of Colcrys, the Food and Drug Administration (FDA) was aware of 21 firms manufacturing oral colchicine – including URL Pharma – selling colchicine from for as little as \$0.04 a pill. After URL Pharma received FDA approval and became the sole source for colchicine, the price spiked to \$5.00 a pill.

The result is that the cost of colchicine for an individual requiring two pills a day, the monthly cost of colchicine soared from \$2.40 a month to \$300 a month. This cost only increases further when an individual suffers from a gout attack requiring additional colchicine to control the flare.

I understand the standard regimen for an individual living with gout – but not experiencing a gout flare-up – is two doses per day. With three million Americans living with gout – taking an average of two pills per day, – URL Pharma could sell \$10.9 billion in the first year alone. And the nearly \$11 billion in costs to seniors may be a conservative estimate since it does not account for the increased need for colchicine during a flare-up.

As the vast majority of patients with gout are over 65, the increased cost of colchicine places considerable burden on the Medicare system. As a result, I am interested in learning what impact the cost of Colcrys has had and will have on the system and – more importantly – what this cost increase means to seniors.

My overarching concern with this price increase is that this seems to be a new model for drug companies. As we saw recently with the drug Makena, companies are cherry-picking medications and treatments that have been widely used but have not gone through the FDA approval process. URL Pharma, KV Pharmaceutical, and others are taking these medications

through the approval process with minimal investment and are reaping disproportionate rewards for their work.

I urge CMS to evaluate what this price increase means for the Medicare budget for seniors who now have Colcrys as their only source of colchicines, and what it means for seniors themselves.

Sincerely,

A handwritten signature in blue ink that reads "Sherrod Brown". The signature is written in a cursive, flowing style.

Sherrod Brown
United States Senator