

February 5, 2018

The Honorable Rob Portman 448 Russell Senate Office Building Washington, D.C. 20510

Dear Senator Portman:

I am an ophthalmologist in Cincinnati who started the Cincinnati Eye Institute about 40 years ago. As you probably know, we are one of the largest groups of eye specialists in the country. My practice is limited to cataract surgery and my work has been recognized with the highest honors given from the American Society of Cataract & Refractive Surgery, the American Academy of Ophthalmology, and from multiple international societies where I have received awards abroad. I am also a professor at the University of Cincinnati and a longstanding supporter of yours.

I am writing to ask for your support in passing legislation to extend the duration of CMS's pass-through period for innovative drugs and devices from three to five years, which has the unqualified support of the American Society of Cataract and Refractive Surgery, the American Society of Retina Specialists, the Ophthalmic Outpatient Surgery Society, and the Society for Excellence in Eyecare. This legislation is needed to ensure appropriate continued reimbursement for products whose pass-through status has recently expired or will soon expire. This is important to ophthalmic surgeons with respect to Omidria, a product that we use during cataract surgery. As of the first of this year, when the pass-through period for Omidria ended, CMS began packaging its reimbursement into the payment code that covers cataract surgery. This policy makes Omidria – and other innovative products for which the pass-through period has expired – inaccessible to physicians and their patients.

CMS's packaging policy is problematic for two primary reasons. First, the allocation of reimbursement funds across all procedures in any given ambulatory payment classification results in, at best, nominal reimbursement for the drug. Second, pass-through has a maximum term of three years and, given that CMS reimbursement for a drug following expiration of the drug's pass-through period is derived from utilization data generated two years earlier, the post-pass-through reimbursement amount is driven only by use of the drug during the first year of its market availability. The collective result is that surgical facilities will not allow physicians, for their Medicare patients, to access products that are not adequately covered by CMS reimbursement. In the case of Omidria, this leads to increased risk of complications and worse

outcomes for Medicare patients undergoing cataract surgery. Extending the pass-through period to five years will yield utilization data that are more representative of the drug's actual use and, thereby, more equitable reimbursement.

I have used Omidria since its approval and coauthored the original article with Canada's leading cataract surgeon, Ike Ahmed, MD. The drug was developed to keep the pupil widely dilated throughout the cataract operation making the surgery more safe and effective. In addition, Omidria has proven to be invaluable when operating on the legions of patients who have used Flomax and other similar drugs to relieve the common urinary symptoms of prostate enlargement which are lethal to the pupil. It also reduces inflammation and postoperative pain. Alternative products do not work as well as Omidria and are not FDA-approved and, therefore, are not shown to be safe and efficacious and are not manufactured according to FDA's Good Manufacturing Practices. Indeed, alternative products are made in compounding pharmacies, which can expose patients and physicians to significant medical and legal risks.

I respectfully request your support for legislative action that quickly reinstates reimbursement for Omidria. In the interests of sound medical practice and the millions of seniors who undergo cataract surgery every year, it is imperative that you and your colleagues address this issue immediately. In the short-term, please support an extension to the pass-through period for innovative drugs and devices from three years to five years as part of Medicare extenders. I understand that this bill already has bipartisan and bicameral support. Once this urgent need is addressed, CMS's broader packaging policy should then be examined and modified appropriately.

Thank you for your leadership. The surgeons at the Cincinnati Eye Institute are proud of your track record as our Senator and we are confident that you will help us to help our surgical patients.

Sincerely,

Robert H. Osher, MD

Professor of Ophthalmology University of Cincinnati

Robert Osher MO

College of Medicine

Medical Director Emeritus

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RHO/tlr