# Congress of the United States
## Washington, DC 20515

September 13, 2017

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue SW
Washington, DC 20201

Re: Outcomes-Based Payment Contract for Kymriah

Dear Administrator Verma,

We write in regard to Novartis' new chimeric antigen receptor T-cell (CAR-T) treatment, known as Kymriah. As members strongly concerned with both rising prescription drug prices and the need to protect taxpayer access to therapies developed with public funding, we are watching closely the discussion around pricing for this treatment. Novartis announced that it is collaborating with the Centers for Medicare & Medicaid Services (CMS) on an outcomes-based payment approach, which may help defray the impact of the $475,000 price of this medication. Reports indicate that Novartis and CMS have reached an agreement to only reimburse for Kymriah if patients respond by the end of the first month of treatment. However, we are seeking additional information about this approach and the process by which it was developed.

We recognize that Kymriah is a promising treatment that may benefit cancer patients. However, an unaffordable drug is 100 percent ineffective. Already, 42 percent of insured cancer patients found their anticancer drugs represented a significant burden on their budget, according to a 2013 study. Earlier this year, a study found that more than one in four nonelderly cancer patients were not following their prescribed drug regimens because of high costs. This burden is only growing as cancer drug prices continue to soar and is exponentially more devastating for uninsured patients.

The issue of pricing is all the more critical because American taxpayers spent more than an estimated $200 million to develop the basic and translational science behind the CAR-T treatment. While Novartis purchased the exclusive global rights and contributed some additional resources, the American taxpayers' investment in CAR-T must be acknowledged and reflected in the price. Novartis also benefitted from the 50 percent orphan drug tax credit for clinical trials, which helped to offset the cost of approval and development. Dr. Carl June, who led the development of the CAR-T treatment, said that producing engineered T-cells costs around $20,000 per patient, and could get cheaper as the procedure is scaled up.

**We urge CMS to ensure that patients can access Kymriah and federal and state governments can afford to provide it to beneficiaries of Medicare, Medicaid, and other public programs.**

We also ask for your response to these questions on how you worked to develop an outcomes-based payment methodology for Kymriah:

1. How many Medicaid and Medicare beneficiaries do you expect will be eligible to take Kymriah next year, in five years, and in 10 years? Has Novartis provided CMS with any estimates of future patient population size? If so, please provide those estimates.
2. How was the one-month response period established? Were oncologists within or outside of CMS consulted on this decision? Will the federal government pay the full price ($475,000) if a patient relapses following that period?
3. What is the agreed-upon definition of success for the one-month outcome? What criteria will be evaluated in determining success? Who will be responsible for assessing these criteria? Did Novartis propose these criteria?
4. How does CMS plan to track whether outcomes-based pricing arrangements lower prices for taxpayers and patients? Will CMS track how many people ended up not being charged and how many people ended up paying for this therapy, by month or by quarter?
5. What are the metrics of success that will be used to determine whether this program will continue or be modified?
6. How will the patient data be collected by CMS for purposes of determining reimbursement? What resources will CMS be required to devote to determining patient outcomes?
7. Will this outcomes-based payment arrangement be ready to implement as soon as Kymriah reaches the market? If not, when does CMS anticipate its onset?
8. What mechanism will CMS use to implement this reimbursement arrangement? Does CMS anticipate that this arrangement will be established primarily through Medicaid or Medicare? If Medicaid, how will CMS enact these outcomes-based payments across different states and managed care plans?
9. Will Novartis be paid at the outset and then refund the money if the outcome is not determined successful, or will Novartis only be paid after the drug's success is proved?
10. Does CMS understand Novartis' profit margin on Kymriah, which could be significant if the production costs estimated by Dr. June are accurate? If not, how did CMS determine a fair price for taxpayers?
11. Did CMS ask Novartis how the company accounted for the fact that American taxpayers invested $200 million into the basic science behind CAR-T when pricing the drug?
12. Which CMS political appointees were involved in working on this arrangement? Were any CMS political appointees who worked on the arrangement previously employed by the pharmaceutical industry? Were any specifically employed by Novartis?
13. Does Novartis plan to charge US taxpayers the same amount as the company charges citizens of other countries? Did CMS ask Novartis about its pricing plans during discussions about the outcomes-based payment approach?
14. Is CMS willing to consider the use of royalty free rights on the various CAR-T patents to enable more supply and lower prices?

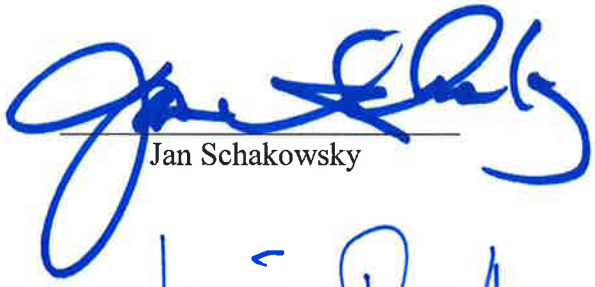
We look forward to the opportunity to learn more about how CMS established this outcomes-based payment agreement and how it will be enacted. We look forward to your reply and your continued engagement as the conversation around outcomes-based pricing moves forward.

Sincerely,

Lloyd Doggett

Mark Pocan

Carol Shea-Porter



Jan Schakowsky

Elijah Cummings

Jamie Raskin

Peter A. DeFazio

Keith Ellison

Peter Welch