PATIENTS FOR AFFORDABLE DRUGS™

Comments To The

Office for Civil Rights, Health and Human Services

On

Proposed Updates To Pertinent Provisions Of Section 504 To Promote Consistency With Title II Of The ADA

Offered By David Mitchell, Cancer Patient, Member of the Disability Community and President of Patients For Affordable Drugs

October 18, 2023

The Food and Drug Administration (FDA) protects patients by deciding if a drug seeking approval is safe and effective. But in the United States, we have no generally accepted process to answer this question for patients: “How effective?”

At the end of the day, there is no single factor more important in arriving at an appropriate price for a new drug than the value of the drug to patients. It is axiomatic that to stimulate and reward innovative new drug development, we should pay more for high value drugs, and less for low value drugs.

Every other wealthy nation relies on a process called Comparative Effectiveness Research (CER) to determine the value of a drug vis a vis other drugs or other approaches to treatment for a condition. But in the United States, the pharmaceutical industry has been successful in limiting the use of CER to analyze and assign value to its products. Why? Because at the end of the day, drug companies are determined to retain complete, unilateral power to dictate prices of their products to the American people without allowing independent, systematic analysis of their value.

I know the importance of this missing step in America’s drug pricing system first-hand. I have an incurable blood cancer, multiple myeloma, and the three main cancer drugs keeping me alive carry a list price of more than $960,000 per year. Are they priced fairly taking into account the value they deliver? I don’t know because there is no process in our country to develop and

provide that information to patients, health professionals and payers as there is in every other wealthy nation in the world.

One objection to value analysis as practiced around the world is that it often relies on a measure called the Quality Adjusted Life Year — or QALY. There is serious concern in the disability community that "the QALY metric puts a lower value on the life of an individual living with a disability, and, as such, value assessments using this metric devalue treatments for people with disabilities."

While I understand the value of QALYs, I also understand concerns within the disability community. As a 73-year-old man with a chronic, incurable disease, I myself am defined as having a disability. As such, I am extremely sensitive to any actions that would devalue a year of my life in any CER process.

Instead of promoting the use of the QALY, Patients For Affordable Drugs endorses the use of measures that explicitly value all lives equally, such as "the Equal Value of Life Years Gained" (evLYG.) We also strongly support protections such as those included in the recently passed Medicare negotiation provisions in the Inflation Reduction Act that state: "…the Secretary shall not use evidence from comparative clinical effectiveness research in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled or not terminally ill."

Unfortunately, there are efforts – spearheaded and funded by the pharmaceutical industry – to prevent the use of comparative effectiveness research or value analysis to inform prices of new drugs because brand-name drug companies resist any restraints on their ability to set prices as high as they want for any drug regardless of its value. The industry has cynically harnessed legitimate concerns of the disability community about QALYs to mobilize opposition to all forms of value measurement.

**We are deeply concerned that opposition to the use of QALYs could lead to broader proscriptions that could block any kind of value analysis, which would be a huge disservice to patients like me and millions of others who pay unjustified drug prices.**

As you consider protections to ensure we don't discriminate against people with disabilities, we must also bear in mind that high drug prices are themselves discriminatory: By consistently putting profit maximization ahead of public health, drug companies inflict the greatest pain on some of those who are most vulnerable — people with disabilities, low incomes, Black

Americans and other people of color. We need CER to help ensure we pay prices for drugs that maximize public health while providing fair return for manufacturers.

Value analysis is a key element for any process to arrive at fair prices for prescription drugs. There are other factors that should be considered in negotiation to arrive at appropriate prices including taxpayer investment in basic science the drug is based on, private investment in research and development, cost of manufacturing, price of existing therapies, prospective size of the market, and anticipated profits. But value is central.

To limit the analysis of value in new drugs in arriving at a fair price would be to exclude the most important factor — *how good is the drug for patients*? We must protect comparative effectiveness research and value analysis from an industry that would prohibit it for fear that basing prices on actual value will curb drug companies' pricing power over patients and all Americans.

We urge HHS to ensure non-discriminatory measures of value such as the Equal Value of Life Years Gained are permissible and employed in the best interests of all Americans, including those with disabilities.