Top 11 Market-Based Solutions for High Drug Prices

In the Overall Drug Marketplace:

1. **Reduce innovator biologic exclusivity to seven years.** Seven years of data exclusivity would still provide a sufficient return to manufacturers, while also speeding more affordable biosimilars to market.

2. **Eliminate "pay-for-delay" agreements.** Patent settlements, or "pay-for delay" agreements allow drug patent holders to pay off potential competitors who would otherwise produce a competing generic drug. These anti-competitive agreements should be eliminated.

3. **Allow for FDA accelerated approval of me-too brands.** Accelerated review is granted to new drug applications that address "unmet need." The economic need for competition to lower prices should be a criterion of unmet need.

4. **Eliminate the generic review backlog.** The Food and Drug Administration (FDA) should have the means to approve generic drugs faster. According to FDA reports, the median review time for a generic drug application is more than three years.

5. **Improve biosimilar labeling and naming.** Substitutable biosimilars should bear identical names and labels to their innovator analogs. Use of different names will only sow confusion among patients and providers and inhibit prescribing of biosimilars.

6. **Create a safe harbor for value-based drug price negotiations from Medicaid Best Price.** Today any drug manufacturer must offer state Medicaid programs the lowest price it offers any other payer. This provision is seen as a price floor and is inhibiting creative value-based pricing arrangements.

7. **Eliminate the tax deduction for direct-to-consumer (DTC) drug ads.** While DTC drug ads may encourage some people to see a doctor, they drive up unnecessary utilization and the cost of drug benefits. Tax deductions should end for ads mentioning a specific product.

In Medicare Part D:

8. **Remove Part D's protected classes.** Designating "classes of clinical concern" where all or substantially all drugs in a class must be covered allows drug manufacturers to name their price. CMS already applies careful plan formulary coverage checks to assure proper coverage.

9. **Make biosimilars subject to the 50% Part D coverage gap discount.** The ACA neglected to apply to biosimilars the 50% Part D coverage gap discount. This could have the unintended consequence of encouraging prescribing of more expensive innovator biologics when lower cost biosimilars are available.

10. **Encourage greater use of generics for Medicare LIS enrollees.** MedPAC recommended allowing the Secretary of HHS to lower cost sharing on generics and raise it for brands that have generic competition. Allowing plans to lower generic cost sharing would save money for enrollees and Medicare.

11. **Allow midyear changes in Part D formularies.** In the course of a year, new drugs become available and medical knowledge evolves. Not allowing plans to de-list drugs that are less effective allows manufacturers to exploit a de facto coverage mandate and unnecessarily raise and/or maintain high prices.