

Pharmaceutical Competition Act

1 BE IT ENACTED BY THE CONGRESS HERE ASSEMBLED THAT:

2 **SECTION 1.** The Food and Drug administration will no longer grant market exclusivity
3 periods for prescription drug products. All existing exclusivity periods for
4 prescription drug products will expire July 1, 2017. Further, the U. S.
5 Patent and Trademark office will no longer issue supplemental patents
6 for minor changes in formulation or administration.

7 **SECTION 2.** The definitions of “drug” and “drug product” will follow existing FDA
8 standards. “Market exclusivity” shall be defined as delays or prohibitions
9 on FDA approvals of competitor drugs. “Minor changes in formulation or
10 administration” shall be defined as any changes that do not materially
11 alter therapeutic effects, including but not limited to coatings and
12 combining two previously patented substances.

13 **SECTION 3.** This bill will be jointly implemented by the Food and Drug Administration
14 and the U. S. Patent and Trademark office.

15 **SECTION 4.** This bill will go into effect January 1, 2017.

16 **SECTION 5.** All laws in conflict with this legislation are hereby declared null and void.

Respectfully submitted to the Committee of Public Welfare

A Bill to Ensure Quality Health Plans

1 BE IT ENACTED BY THE CONGRESS HERE ASSEMBLED THAT:

2 **SECTION 1.** Health care plans that include burdensome prescription drug formularies
3 will no longer be certified as Quality Health Plans (QHPs) under the
4 Affordable Care Act.

5 **SECTION 2.** The definition of “drug” will follow existing FDA standards. “Burdensome
6 prescription drug formularies” shall be defined as any list of covered
7 drugs that excludes brand name drugs in favor of other brands, “generic”
8 or “therapeutic” equivalents. Exclusions for safety, cosmetic use, or non-
9 medical use shall not be considered “burdensome.”

10 **SECTION 3.** The Center for Consumer Information and Insurance Oversight, under the
11 direction of the Department of Health and Human Services, will continue
12 to oversee ACA insurance compliance and QHP certification.

13 **SECTION 4.** This bill will go into effect January 1, 2017.

14 **SECTION 5.** All laws in conflict with this legislation are hereby declared null and void.

Respectfully submitted to the Committee of Public Welfare

Pharmaceutical Integrity Act

1 BE IT ENACTED BY THE CONGRESS HERE ASSEMBLED THAT:

2 **SECTION 1.** No company may raise the price of a prescription drug product more
3 than 100% in any 2-year period. Violations of this statute will result in a
4 5-year tax penalty equal to 50% of gross revenue from sale of the drug
5 named in the violation. Three violations will result in regulatory approval
6 for production and distribution being revoked.

7 **SECTION 2.** The definitions of “drug” and “drug product” will follow existing FDA
8 standards.

9 **SECTION 3.** The Food and Drug Administration will receive \$5 billion annually to
10 monitor drug prices and notify violators of the appropriate penalty. The
11 FDA shall also oversee the revocation and reallocation of regulatory
12 approval. The Internal Revenue Service will administrate all relevant tax
13 penalties, which will then be added to the FDA budget.

14 **SECTION 4.** This bill will go into effect July 1, 2017.

15 **SECTION 5.** All laws in conflict with this legislation are hereby declared null and void.

Respectfully submitted to the Committee of Public Welfare