USC Schaeffer
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Comment Letter to the Office of the United States Trade Representative

Docket Number: USTR-2025-0011

Subject: Request for Comments Re Foreign Nations Freeloading on American-Financed Innovation

Executive Summary

As independent health economists and public policy researchers based at the USC Schaeffer Center for Health Policy & Economics, we submit these comments in response to the Office of the United States Trade Representative's (USTR) request for information regarding foreign acts, policies, or practices that result in American patients paying a disproportionate amount for global pharmaceutical research and development. Many foreign countries set prices using technology assessments measuring quality adjusted life years (QALYs). This practice is both outdated and discriminatory, in the sense that it systematically undervalues treatments for the disabled, aged, and those with rare or severe chronic conditions. As a consequence, foreign governments set prices below American standards of fair market value and place an inequitable burden on American patients—ultimately resulting in reduced access to treatment. We recommend a number of options USTR could pursue to ameliorate the impact of this situation. Our comments are our own and do not reflect the position of the University of Southern California or the USC Schaeffer Center for Health Policy & Economics.

I. Foreign Countries and Economies of Concern

The countries of primary concern are OECD member nations whose drug pricing decisions would directly impact U.S. prices under the Most-Favored-Nation (MFN) Executive Order, specifically:

Countries with 60 percent of U.S. GDP per capita:

- United Kingdom
- Germany
- Netherlands
- Canada
- Australia
- Denmark
- Norway
- Sweden
- Finland
- Belgium
- Austria
- Switzerland
- Ireland
- Luxembourg

Additional countries of concern (using purchasing power parity metrics):

- Italy
- Spain
- Japan
- South Korea
- Czech Republic
- Slovenia
- New Zealand
- Lithuania

II. Discriminatory Act, Policy, or Practice of Concern

The Systematic Use of Quality Adjusted Life Years (QALYs) in Health Technology Assessment

The discriminatory practice at issue is the systematic use of QALYs by foreign health technology assessment (HTA) bodies to determine pharmaceutical reimbursement and pricing decisions. Specifically:

- **United Kingdom:** The National Institute for Health and Care Excellence (NICE) extensively employs QALY thresholds (typically £20,000-£30,000 per QALY gained) to determine coverage and pricing recommendations.

- **Netherlands:** The National Health Care Institute uses cost-effectiveness thresholds based on QALY calculations for reimbursement decisions.

- **Canada:** The Canadian Agency for Drugs and Technologies in Health (CADTH) systematically applies QALY-based cost-effectiveness analysis with willingness-to-pay thresholds.

- **Australia:** The Pharmaceutical Benefits Advisory Committee (PBAC) uses incremental cost-effectiveness ratios based on QALYs for coverage determinations.

- **Nordic Countries:** Denmark, Norway, Sweden, and Finland all employ QALY-based health economic evaluations through their respective HTA bodies.

III. Why This Practice Is Unreasonable and Discriminatory

A. Inherent Discrimination Against Sick and Disabled Populations

The QALY methodology is fundamentally discriminatory because it:

1. **Devalues lives of people with disabilities and chronic conditions** by assigning lower value to life-years spent with disability
2. **Creates age-based discrimination** by implicitly valuing younger patients' life-years more highly than older patients'
3. **Systematically undervalues treatments** for rare diseases and conditions affecting vulnerable populations

B. Inconsistency with U.S. Legal and Ethical Standards

The use of QALYs by foreign countries is discriminatory against U.S. products and unreasonable because it conflicts with fundamental U.S. principles:

1. **Congressional Prohibition:** Section 1182(e) of the Social Security Act explicitly prohibits the Secretary of Health and Human Services from using QALYs or similar measures as thresholds to determine coverage, reimbursement, or incentive programs under Medicare.
2. **Americans with Disabilities Act Principles:** QALY-based pricing inherently violates the spirit of the ADA by systematically devaluing the lives of people with disabilities.
3. **Equal Protection Principles:** The discriminatory nature of QALYs conflicts with American principles of equal treatment regardless of health status or disability.

C. Market Distortion Through Artificial Price Suppression

Foreign countries' use of QALYs artificially suppresses pharmaceutical prices below American standards of fair market value by:

1. **Applying arbitrary cost-effectiveness thresholds** that bear no relationship to patients' actual willingness to pay or societal values
2. **Creating artificial scarcity** by denying access to treatments that fail QALY-based assessments
3. **Leveraging monopsony power** to force manufacturers to accept below-market prices
4. **Free-riding on U.S. innovation investment** by paying artificially low prices that do not reflect the true value of pharmaceutical innovation

IV. How This Practice Forces Americans to Pay Disproportionately

A. Cross-Subsidization of Global Healthcare Systems

The systematic use of QALYs by foreign countries forces American patients to bear a disproportionate share of global pharmaceutical R&D costs through several mechanisms:

1. **Price Discrimination:** Pharmaceutical companies must recoup R&D investments primarily from markets willing to pay prices reflecting true therapeutic value, predominantly the United State
2. **Innovation Tax on Americans:** Foreign countries' artificial price suppression effectively imposes an "innovation tax" on American patients, who subsidize global access to pharmaceutical advances.
3. **Reduced Access for Americans:** High U.S. prices resulting from foreign free-riding create affordability challenges for American patients and payers.

B. Importation of Discriminatory Pricing Through MFN Policy

The MFN Executive Order's approach of tying U.S. prices to foreign benchmarks would effectively import QALY-based discrimination into the American healthcare system by:

1. **Incorporating QALY-derived prices** as reference points for U.S. drug pricing
2. **Undermining Congressional intent** to prohibit QALY use in Medicare determinations
3. **Creating indirect discrimination** against American patients with disabilities and chronic conditions
4. **Legitimizing foreign countries' discriminatory practices** by accepting their artificially suppressed prices as appropriate benchmarks

V. Recommended Actions

A. Trade Policy Measures

USTR should consider policy options to address foreign countries' discriminatory use of QALYs, including:

1. **Initiate Section 301 investigations** into countries that systematically use QALYs to suppress pharmaceutical prices below American standards of fair market value

2. **Negotiate bilateral agreements** requiring foreign countries to abandon or modify QALY-based pricing methodologies
3. **Pursue WTO dispute resolution** where QALY-based practices constitute discriminatory treatment of U.S. pharmaceutical exports
4. **Implement targeted tariffs or trade sanctions** against countries that refuse to abandon discriminatory QALY practices

B. Coordination with Other Agencies

1. **HHS Collaboration:** Work with HHS to ensure that any MFN implementation excludes prices derived from QALY-based assessments
2. **Interagency Coordination:** Establish interagency working group to monitor and counter foreign discriminatory pricing practices
3. **Congressional Engagement:** Support legislative efforts to prevent importation of QALY-based pricing into U.S. healthcare programs

VI. Conclusion

Foreign countries' systematic use of QALYs represents a discriminatory trade practice that artificially suppresses pharmaceutical prices below American standards of fair market value and forces American patients to subsidize global healthcare systems. This practice is fundamentally inconsistent with American values of equal treatment and Congressional prohibitions on QALY use in Medicare.

USTR can take action to address these discriminatory practices through trade policy measures and ensure that any implementation of MFN pricing does not import QALY-based discrimination into the American healthcare system. American patients deserve pharmaceutical pricing that reflects true therapeutic value, not discriminatory foreign assessments that systematically devalue the lives of people with disabilities and chronic conditions.

Respectfully submitted by: Independent health economists and public policy researchers based at the USC Schaeffer Center for Health Policy & Economics

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