



Medicare Drug Price Negotiation Program Draft Guidance

Fred D. Ledley, Bentley University

This comment focuses on Section 50.1, provisions 1 & 3 of the draft guidance regarding the negotiation of a “maximum fair price” under the Inflation Reduction Act (IRA), research and development (R&D) costs of the primary manufacturer, and prior federal financial support for novel therapeutic discovery and development. Specifically, we argue that **a negotiated, “maximum fair price” must consider both public sector (federal) and private sector (manufacturer) investments and provide returns to both commensurate with the scale and risk of their investments.** This comment addresses three issues and makes specific recommendations regarding each:

- 1. In negotiating a “maximum fair price,” both parties may be expected to consider their investment and returns.**
- 2. Prior federal financial support for R&D may be estimated from the NIH investment in basic and applied research related to each product.**
- 3. The return on federal investment in discovery and development should be estimated as a social return on investment (SROI) based on elements of social value created by new drugs.**