January 20, 2021

Centers for Medicare and Medicaid Services

Department of Health and Human Services

CMS-5528-IFC

P.O. Box 8013

Baltimore, MD 21244-8013

Attention: CMS-5528-IFC – Most Favored Nation Model Interim Final Rule

Background

Citizens Against Government Waste (CAGW) is a private, nonpartisan, nonprofit, organization representing more than one million members and supporters nationwide. CAGW’s mission is to uncover, publicize, and eliminate waste, fraud, abuse, mismanagement, and inefficiency in the federal government. Founded in 1984 by the late industrialist J. Peter Grace and syndicated columnist Jack Anderson, CAGW was established to follow up on the work of the President’s Private Sector Survey on Cost Control, also known as the Grace Commission.

Comment

CAGW was disappointed when the Centers for Medicare and Medicaid (CMS) [announced](https://www.cms.gov/newsroom/fact-sheets/fact-sheet-most-favored-nation-model-medicare-part-b-drugs-and-biologicals-interim-final-rule) its new payment model for Medicare Part B drugs, Most Favored Nation Model (MFN), and the corresponding [Interim Final Rule](https://www.govinfo.gov/content/pkg/FR-2020-11-27/pdf/2020-26037.pdf) on November 20, 2020. While the rule became effective on November 27, 2020, CAGW appreciates that comments may be submitted until January 26, 2021.

CAGW has opposed this policy since it was first proposed. The organization stated in a November 20 [press release](https://www.cagw.org/media/press-releases/cagw-opposes-most-favored-nation-policy) that, “The MFN policy was always a bad idea and it is especially inappropriate as the pharmaceutical industry has produced safe and effective COVID-19 vaccines in record time. Implementing MFN for Medicare Part B will reduce future investment and innovation not just for pandemics but also for many other diseases.”

Adopting the MFN means the U.S. would pay no more than the lowest price for 50 pharmaceuticals found in 22 countries in the Organization for Economic Co-operation and Development. This may seem like a good idea on its face, but these countries all use price controls to keep costs down. Price controls never solve the problems they are intended to fix. This has been proven throughout history, as laid out in CAGW’s 2016 [issue brief](https://www.cagw.org/sites/default/files/pdf/Pharmaceutical%20Price%20Controls%20-%20A%20Prescription%20for%20Disaster.pdf), “Pharmaceutical Price Controls: A Prescription for Disaster.” The MFN will fail to eliminate global freeloading on U.S. biopharmaceutical research and development. Even worse, it imports socialized medicine policies that use rationing to keep costs down and stifle research and development.

In a November 20 *WasteWatcher* [blog](https://www.cagw.org/thewastewatcher/most-favored-nation-policy-unfavorable-us-biopharmaceutical-research), CAGW cited an NDP Analytics study, “Will U.S. Leadership in Biopharmaceutical R&D Continue?” The authors, Nam D. Pham, Ph.D. and Mary Donovan, wrote, “The positive and negative impacts that public policies can have on biopharmaceutical innovation can be seen in the movement in the balance of R&D investment from Europe to the U.S. in the late 1990s, and perhaps again with the rise of Asia as a biopharmaceutical innovation center very recently. Price controls and other interventions in the European medicines market decades ago – and the adoption in the U.S. of more market friendly drug policies – corresponded with the shift to the U.S. as the world leader in biopharmaceutical R&D.”

CAGW further wrote that in “1990, $16.7 billion was invested biopharmaceutical research, with European countries contributing 59.2 percent and the U.S. contributing 40.8 percent of those investments. But because Europe adopted strict price controls during the 1980s and 1990s, that investment began to shift. By 2017, of the $95.7 billion invested in biopharmaceutical research, the U.S. contributed 58.3 percent and Europe contributed 41.7 percent.”

Dr. Pham and Ms. Donavan discussed how this shift caught the attention of European policy makers and stated, “In its 2006 competitiveness report, the European Commission (EC) noted, ‘Since 2000, the U.S. has consolidated its central role as a locus of innovation in pharmaceuticals.’ Further, the EC observed, ‘Europe is lagging behind the U.S. in its ability to generate, organise, and sustain innovation processes and productivity growth in pharmaceuticals. Moreover, a disproportionate share of pharmaceutical R&D is performed in the U.S., with negative consequences [for Europe] in terms of both high value-added employment and complementary investments in clinical research.’ Günter Verheugen, Vice-President of the European Commission for Enterprise and Industry, stated ‘[W]e are confronted with a move of research and production of innovative drugs outside Europe.’”

The authors also pointed out that, “Over the last decade, various Asian nations have been advancing policy reforms to grow that region’s biopharmaceutical sector, including seeking to implement more science-based regulatory systems for the review and approval of new medicines, pricing and access reforms, and other policies to incent increases in biopharmaceutical R&D investments. For example, in 2017, China updated its National Reimbursement Drug List (NRDL) for the first time since 2009 to include additional new innovative medicines and is seeking to establish an innovative biopharmaceutical industry as a key development goal.”

This MFN policy is harmful to patients, research and development, and innovation, especially since it has been made clear that China is a growing threat to the United States and could soon overtake the U.S. in the development of new drugs. The U.S. should instead implement trade policies that would require Europe and our other allies to pay for their fair share of biopharmaceutical research and development and adopt policies that encourage more research and development in their countries. Not only would that help their biopharmaceutical industries, it also would lead to the creation of more new, innovative drugs and increase competition, which is a far more effective way to reduce costs.

Even though the government may see lower costs in the short term, the long-term results would be severely damaging to U.S. biopharmaceutical research. Fewer drugs would be developed that would benefit patients, especially those with chronic diseases. CAGW urges you to withdraw this harmful rule.

Sincerely,

