

**Pharmaceutical Industry Gears Up for Second Wave of Legal Challenges Against Medicare Drug Pricing**



**PhRMA CEO Stephen Ubl Anticipates Renewed Legal Offensive**

In a recent discussion with [Bloomberg Law](#), the CEO of the Pharmaceutical Research and Manufacturers of America (PhRMA), Stephen Ubl, hinted at the likelihood of a new wave of legal challenges against the Biden administration's Medicare drug pricing negotiation process. Pharmaceutical giants are preparing to intensify their legal assault on the Health and Human Services Department (HHS) over the program.

**The Ongoing Battle**

As it stands, the HHS is currently facing nine lawsuits related to the drug price negotiation program. Various entities have filed these lawsuits, including Merck & Co., Bristol-Myers Squibb Co., various other drug manufacturers, and industry associations. Notably, PhRMA itself is part of this legal crusade against the HHS.

**Challenging Constitutionality**

Until now, the legal challenges have predominantly centered on the assertion that Medicare negotiations violate the U.S. Constitution, specifically the First, Fifth, and Eighth Amendments.

**A New Phase of Legal Action**

Stephen Ubl shed light on what might be expected in the next phase of these legal battles. He suggested that upcoming attacks on the program might take the form of "applied challenges." In other words, companies could challenge specific aspects of the drug pricing law's application, such as fines imposed or other elements of the negotiation process.

**Legal Landscape**

AstraZeneca PLC and Boehringer Ingelheim have already launched lawsuits against the HHS, arguing that the agency's implementation of the drug pricing program through guidance instead of the formal regulatory process violated the Administrative Procedure Act.

The pharmaceutical industry has recruited prominent law firms to lead the charge against the HHS. These firms include legal heavyweights like King & Spalding and Jones Day. Some attorneys involved in these cases have previously served as Supreme Court clerks, Justice Department officials, and a former solicitor general.

**Potential Supreme Court Involvement**

The ongoing litigation is scattered across various federal courts, and there is a growing likelihood of a circuit split. This situation could ultimately push the United States Supreme Court to take up the case.

**A Changing Landscape**

Ubl underscored that, unless there are significant alterations or legal resolutions, the pharmaceutical industry is moving into a phase where the HHS is poised to play a much more substantial role in the pricing of pharmaceutical products. In response to this evolving landscape, PhRMA plans to assemble both in-house and external legal expertise to navigate the intricacies of the HHS and the Centers for Medicare & Medicaid Services as they gear up to implement the drug pricing law.

The Health and Human Services Department has not responded immediately to requests for comment regarding these legal challenges.

**Don't be a silent ninja! Let us know your thoughts in the comment section below.**