BIO ISSUE BRIEF

Biotechnology Innovation Organization

Pharmaceutical Information Sharing Improves Outcomes, Drives Value

Regulatory barriers prevent drug companies from sharing important health and economic information with population health decision makers

Current statutory and regulatory barriers hinder the sharing of information between biopharmaceutical innovators and population health decision makers, such as commercial insurers, pharmacy benefit managers, and Accountable Care Organizations (ACOs) about forthcoming new treatments and indications that have not yet received FDA approval.

Population health decision makers, such as commercial insurers, pharmacy benefit managers, and Accountable Care Organizations would all benefit from earlier access to medical and pharmacoeonomic data on promising potential new drugs and indications. This information is necessary well in advance of a new drug's FDA approval date in order to facilitate formulary coverage decisions, facilitate increased use of value-based payment models, and for rate-setting decisions, which must be submitted to federal and state regulators as early as 12-18 months prior to the start of a plan year.

Policy Position

BIO and its members have long-advocated for more regulatory certainty in the ability to converse with certain healthcare decisionmakers about new and soon-to-be-approved medicines. With the evolving landscape of alternative payment models, innovative formulary designs, and personalized medicines, more detailed – and earlier – information is crucial to ensuring immediate and robust patient access. And while the 21st Century Cures legislation in 2016 began the process of modifying rules on healthcare economic information exchange, there are areas where clarity still lacks.

H.R. 2026, the Pharmaceutical Information Exchange (PIE) Act of 2017, would create a "safe harbor" from laws and regulations that prevent the free flow of truthful and non-misleading health, scientific, and economic data about forthcoming new drugs.

This will allow population health decision makers to facilitate earlier access to breakthrough new therapies as soon as they receive FDA approval, as they will have the information necessary to make coverage decisions and conduct price negotiations with drug companies well in advance of FDA approval.

Key Points

- ✓ H.R. 2026 maintains requirements that information shared be both **truthful** and **non-misleading.**
- ✓ The safe harbor created by H.R. 2026 is **narrow in scope** to cover information exchanged between biopharmaceutical companies and population health decision makers (e.g. payers, provider sponsored health plans, pharmacy benefit managers, ACOs, and IDNs) only**.**
- ✓ The safe would apply only to **new molecules and expanded indications** with an intent to file.
- ✓ H.R. 2026 is supported by a **broad array of stakeholders**, including health insurers, biopharmaceutical and medical device manufacturers, patient advocacy groups, health care providers, health economists, and others.