Congress Expands Pathway for Drug & Device Manufacturers' Pre-Approval Communication of Health Care Economic Information to Payors, Formularies, & Similar Entities

The legislation previously introduced as the **Pre-Approval Information Exchange Act of 2022** ("PIE Act") was passed as part of Congress's December 23, 2022 omnibus spending bill. Once signed into law, this legislation will amend the Federal Food, Drug, and Cosmetic Act's (FDCA's) provisions on misbranded drugs and devices to formally allow drug and medical device manufacturers to proactively share investigational drug and device information, including health care economic information, with payors, health plans, formulary committees, and other similar entities *prior* to the clearance or approval of the drug or device or new use of the drug or device but with now-statutory strings attached.

The US Food and Drug Administration (FDA) has long had the authority to enforce against pre-approval *promotional* communications, and a pathway for pre-approval communication of health care economic information regarding the selection of drugs for coverage and reimbursement was enacted under the Food and Drug Administration Modernization Act of 1997. **Current guidance from FDA**, finalized in 2018, expressly permits drug and device companies to provide some details about investigational products or investigational uses of marketed products to payors, formulary committees, and similar entities prior to approval or clearance of the product or its new use; however, for device companies this has come in the form of non-binding guidance that lacks a formal anchor in the statutory language. The inclusion of the legislation previously known as the PIE Act in the omnibus spending bill formally establishes a statutory pathway built on FDA's 2018 final guidance for both drug and medical device companies to engage in pre-market communications about health care economic information with payors, formulary committees, and similar entities.

Read the client alert **here**.