
The Exclusion Illusion: Fixing a Flawed Health Care Fraud Enforcement System

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Year after year, the government announces historic settlements in the area of health care fraud. During the last decade, the annual fines imposed on pharmaceutical companies have increased more than 800 percent, approaching a total of \$25 billion. The federal exclusion regime, pursuant to which the government excludes pharmaceutical and other companies from federal health care programs, is particularly troubling: (1) The system leads to huge settlements that impose tremendous, unsustainable costs on health care manufacturers and on our economy; (2) enforcement almost invariably avoids the courts, and therefore companies and individuals lack clear rules for compliance; (3) those who can risk testing the government's case are often quite successful, demonstrating the weakness of the government's cases; and (4) prosecutors are going after employees even when the government admits they have played no role in the alleged wrongdoing committed by a company.

Magnifying the enormous leverage afforded by the threat of exclusion is the fact that numerous pharmaceutical and medical device companies sell a significant portion of their products to beneficiaries of federal health care programs—and exclusion therefore could be a death blow for a company. At the same time, exclusion is a sub-optimal outcome even for the government, because it would have the effect of depriving program participants of access to valuable medications and devices.

In "The Exclusion Illusion: Fixing a Flawed Health Care Fraud Enforcement System," WilmerHale lawyers David Ogden and Elisebeth Cook, with the assistance of Madhu Chugh and Daniel Aguilar, analyze the current system and propose a better way: Take exclusion off the table as a penalty option when a company has instituted a corporate integrity program that complies with comprehensive, rigorous standards certified by a third-party organization.

Read "[The Exclusion Illusion: Fixing a Flawed Health Care Fraud Enforcement System](#)."

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