Shift In Health Care Antitrust Prosecutions Is Likely

By **James Attridge, Daniel Oakes and Tasneem Chowdhury** (February 7, 2023, 1:45 PM EST)

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In December 2022, the Antitrust Division of the U.S. Department of Justice and the U.S. Department of Health and Human Services' Office of the Inspector General announced a memorandum of understanding[1] memorializing their partnership "to protect health care markets."[2]

This latest effort to "support the objectives of the President's Executive Order on Promoting Competition in the American Economy"[3] attracted little attention. But a closer look at the MOU reveals consequential and significant signals about the agencies' enforcement intentions going forward.

In several recent prosecutions of health care companies for price-fixing, bid-rigging and market allocation, the government was willing to resolve criminal charges short of conviction.

In doing so, prosecutors pointed to concerns that a criminal conviction could lead to the company's exclusion from key federal health care programs.

The government sought to avoid exclusion in these cases because it could harm continuity of care for innocent beneficiaries and reduce competition in health care markets.

The MOU is a significant departure from these prior cases. Instead of concern that exclusion would harm third parties, it proclaims a willingness to insist on criminal conviction — and thus exclusion — because of a new belief that the antitrust agencies can mitigate harm to innocents resulting from exclusion.

Considering the Collateral Consequences of Conviction

The Justice Manual requires prosecutors to consider 11 factors, in addition to those for charging an individual, "in determining whether to charge the corporation" and "how to resolve corporate criminal cases."[4]

These include consideration of the collateral consequences of conviction[5] because a charge or conviction often leads to significant collateral consequences for innocent third parties, such as employees, investors or customers.

Collateral consequences expressly include nonpenal sanctions resulting from conviction, such as "potential suspension or debarment from eligibility for government contracts or federally funded programs such as health care programs," according the the manual — e.g., Medicare and Medicaid.[6]

While prosecutors weigh suspension, debarment and exclusion, "[d]etermining whether or not such non-penal sanctions are appropriate or required" is a decision made by "the relevant agency" based on "applicable statutes, regulations, and policies."[7]

Indeed, in the context of negotiating a plea for a government contractor's fraud against the government, "a prosecutor may not negotiate away an agency's right to debar or delist the corporate defendant."[8]

On the one hand, in some circumstances "debarment may be deemed not collateral, but a direct and entirely appropriate consequence of the corporation's wrongdoing" if, for example, the crime was widespread, pervasive, long-term or top managers were involved in or aware of wrongdoing.[9]

On the other hand, a deferred prosecution agreement — which involves a criminal charge but no conviction because the charge is dismissed at the end of the DPA's term — may present an appropriate middle ground between indictment and declining prosecution when the "collateral consequences of a corporate conviction for innocent third parties would be significant."[10]

In that instance, a DPA "can help restore the integrity of a company's operations and preserve" its financial viability.[11]

Recent Health Care DPAs

In 2019 and 2020, the DOJ Antitrust Division charged several companies for conspiring to fix prices, rig bids and allocate customers for generic drugs, as well as an oncology practice for its role in a market allocation arrangement of medical and radiation services. While two generic drug companies were indicted, four generic drug companies and the oncology practice resolved criminal charges through DPAs that cite mandatory exclusion as a driving factor.[12]

Each DPA includes a recitation of the facts and circumstances that guided the Antitrust Division's decision to resolve the criminal charge by DPA rather than a guilty plea. For example, the announcement of Heritage Pharmaceuticals DPA — the first corporate resolution in the generic drug investigation — included a fact sheet explaining the Antitrust Division's rationale for using a DPA.

Its considerations included "the likelihood that a criminal conviction — including a guilty plea — would result in Heritage's mandatory exclusion from all federal health care programs for at least five years, under 42 U.S.C. § 1320a-7."[13]

As a result, the Antitrust Division "weighed the collateral consequences — including to customers outside of federal health care programs, as well as to Heritage's non-culpable employees — that would result if Heritage were to be excluded from federal health care programs."[14]

Subsequent resolutions included similar considerations. For example, Florida Cancer Specialists and Research Institutes' DPA noted:

[A] conviction (including a guilty plea) would likely result in FCS's mandatory exclusion from all federal health care programs ... for a period of at least five years, which would result in substantial consequences to patients covered by the federal healthcare programs, patients outside the federal healthcare programs, patients involved in ongoing clinical trials, and to the Company's employees.[15]

As the Heritage and FCS DPAs note, the potential for collateral consequences is particularly significant in the health care industry.

Beyond harm to innocent employees and investors, consumers of health care are patients. In the case of the generic drug investigation, the Antitrust Division noted the industry is "one of the most important markets for the health and wallets of American consumers," where charges allege antitrust crimes involving "essential generic drugs relied on by millions of American consumers, including the elderly and vulnerable, to treat a range of diseases and conditions."[16]

And in the case of FCS, the DPA considered harm to "current and future patients, including patients enrolled in ongoing clinical trials," and "cancer research generally."[17]

A Changing Tide

Since those resolutions, however, the tide seems to have turned. The Antitrust Division has not entered into a DPA since Jan. 19, 2021.[18]

As the use of DPAs dried up, the DOJ and Antitrust Division leadership declared their intent to usher in a new era of aggressive corporate criminal and antitrust enforcement. Despite their commitment to aggressive enforcement, questions arose about what Sen. Elizabeth Warren, D-Mass., and Sen. Ben Ray Lujan, D-N.M., referred to in a letter to the DOJ as the department's "inability or unwillingness to use its authority to suspend or debar" corporate criminals.[19]

Soon thereafter, the DOJ made a new commitment to "enhancing the effectiveness of the federal government's system for debarment and suspension."[20] This announcement suggested that the DOJ would use these tools more frequently, "to improve [the Department's] approach to corporate crime."[21] To that end, in early December 2022, the department announced it "is also reviewing the debarment and suspension process, including how to streamline information sharing between agencies."[22]

The MOU's Clear Message

Days after the Justice Department's declaration, the Antitrust Division and HHS OIG announced their MOU. The MOU includes general provisions about information sharing, consultation and coordination, but its most important provisions address the agencies' commitment to "work together to ensure that exclusions are imposed where appropriate."[23]

Although suspension, debarment, and exclusion remain collateral consequences rather than punitive tools, the recent MOU appears to preview prosecutors' greater willingness to deem debarment and other collateral consequences "a direct and entirely appropriate consequence of the corporation's wrongdoing,"[24] rather than one weighing heavily in favor of a DPA.

In fact, the MOU's commitment to "strengthen the enforcement of federal laws, including the full force of OIG's exclusion authorities and the antitrust laws enforced by the Justice Department's Antitrust Division" may be the first — and most concrete — example of the changing tide thus far.

Most significant, however, is the MOU's departure from recent health care DPAs where the potential for exclusion — and the view that exclusion would harm innocent beneficiaries of competition in critical health care markets — drove the division's willingness to enter into resolutions short of criminal conviction.

Again, the FCS DPA illustrates why the Antitrust Division previously credited concerns about the third-party collateral consequences of exclusion.

A Q&A accompanying the DPA explains:

The decision to resolve this matter with a DPA took into account the significant collateral consequences that likely would result from a criminal conviction, especially to FCS' current and future patients, including patients enrolled in ongoing clinical trials, its employees, and cancer research generally.[25]

The MOU announcement reaffirms the Antitrust Division's commitment to "ensuring the continuity of health care products and services"[26] and that "[f]ederal healthcare program beneficiaries maintain access to healthcare products and services."[27] But the MOU does not express concerns that exclusion (triggered by an antitrust conviction) would compromise continuity of health care and thus warrant a DPA.

In its place, the agencies assert that continuity of care can coexist with strengthened antitrust enforcement and "the full force of OIG's exclusion authorities."[28]

Perhaps most tellingly, the MOU signals that the Antitrust Division believes itself and HHS OIG are equipped and prepared to intercede in an excluded defendant's business "[t]o ensure health care assets remain in the market and competition is preserved and enhanced," even where it involves the "winding down or sales of assets by excluded health care entities."[29]

The import is clear: Whereas exclusion — which would likely result in removal of a competitor from a critical health care market and would cause significant disruption for current and future patients — was something the division avoided and previously weighed heavily in favor of a DPA, that may not be the case going forward.

It is not just that the agencies think they can obtain a conviction and impose exclusion in a manner that addresses harm to competition and mitigates risks to patients and research, the agencies now argue that together they can impose exclusion in a way that restores, or even increases, competition.[30]

Implications

For health care companies in the Antitrust Division's crosshairs, the MOU signals a sea change with considerable consequences. Parties willing to resolve price-fixing, bid-rigging and market allocation charges should no longer expect a sympathetic ear when arguing that the collateral consequences of conviction weigh heavily in favor of a resolution short of conviction, as was the case in five recent DPAs received by health care companies that cite mandatory exclusion as a driving factor.[31]

Given the agencies' willingness to insist upon a guilty plea that would result in mandatory exclusion, on top of corporate fines and individual incarceration, compliance is an even more worthy investment, and the carrot of leniency — which avoids a criminal conviction and thus exclusion — looks more attractive, too.

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Disclosure: James Attridge advised on the Antitrust Division's criminal investigations and litigation while serving as counsel to the assistant attorney general from November 2018 to August 2022, including certain cases mentioned in this article.

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[1] Mem. of Understanding Between the Antitrust Division of the U.S. Department of Justice and the Office of the Inspector General of the U.S. Department of Health and Human Services (Dec. 9, 2022) [hereinafter MOU], https://www.justice.gov/opa/press-release/file/1556856/download.

[2] Press Release, U.S. Dep't Of Justice, Justice Department's Antitrust Division and the Office of the Inspector General of the Department of Health and Human Services Announce Partnership to Protect Health Care Markets (Dec.9, 2022) [hereinafter MOU Press Release], https://www.justice.gov/opa/pr/justice-department-s-antitrust-division-and-office-inspector-general-department-health-and.

[3] Id.

[4] U.S. Dep't Of Just., Just. Manual § 9-28.1100 (2020), https://www.justice.gov/jm/jm-9-28000-principles-federal-prosecution-business-organizations.

[5] See id. at § 9-28.300.

[6] Just. Manual § 9-28.1100 (2020).

[7] Id.

[8] Just. Manual § 9-28.1600 (2015).

[9] Just. Manual § 9-28.1100.

[10] Id.

[11] Id.

[12] See U.S. v. Heritage Pharm. Inc., No. 2:19-cr-00316 (E.D. Pa. May 30, 2019); U.S. v. Sandoz Inc., No. 2:20-cr-00111 (E.D. Pa. Mar. 2, 2020); U.S. v. Apotex Corp., No. 2:20-cr-00169 (E.D. Pa. May 6, 2020); U.S. v. Taro Pharma. U.S.A., Inc., 2:20-cr-00214 (E.D. Pa. July 23, 2020); U.S. v. Florida Cancer Specialists & Research Inst., No. 2:20-cr-00078-TPB-MRM (M.D. Fla. Apr. 30, 2020); Second Superseding Indictment, U.S. v. Teva Pharm. USA Inc. and Glenmark Pharm. Inc, No. 2:20-cr-00200-RBS (E.D. Pa. Aug. 25, 2020).

[13] Press Release, U.S. Dep't Of Just., Heritage Pharmaceutical Fact Sheet, at 2 (May 31, 2010), https://www.justice.gov/opa/press-release/file/1188386/download.

[14] Id.

[15] Florida Cancer Specialists & Research Inst., at Dkt. No. 3 ¶ 5.

[16] U.S. Dep't of Just. Antitrust Div., Spring 2021 Update, Generic Drugs Investigation Targets Anticompetitive Schemes (Mar. 24, 2021), https://www.justice.gov/atr/division-operations/division-update-spring-2021/generic-drugs-investigation-targets-anticompetitive-schemes.

[17] Press Release, U.S. Dep't of Just., Florida Cancer Specialists & Research Institute, LLC Deferred Prosecution Agreement – Q&A, at 2 (Apr. 30, 2020), [hereinafter FCS DPA Q&A], https://www.justice.gov/opa/press-release/file/1272556/download.

[18] See U.S. v. Berlitz Languages, Inc., No. 3:21-cr-00051-FLW (D.N.J. Jan. 19, 2021); U.S. v. Comprehensive Language Center, Inc., No. 3:21-cr-00050-FLW (D.N.J. Jan. 19, 2021).

[19] Letter from Sen. Elizabeth Warren and Sen. Ben Ray Luján to Merrick Garland, Att'y General, and Lisa O. Monaco, Deputy Attorney General, at 1 (Aug. 11, 2022), https://www.warren.senate.gov/imo/media/doc/2022.08.10%20Letter%20to%20DOJ%20on%20use%20of%20suspension%20and%20debarment%20authority.pdf.

[20] Lisa O. Monaco, Deputy Att'y General, U.S. Dep't of Just., Deputy Attorney General Lisa O. Monaco Delivers Remarks on Corporate Criminal Enforcement (Sept. 15, 2022), https://www.justice.gov/opa/speech/deputy-attorney-general-lisa-o-monaco-delivers-remarks-corporate-criminal-enforcement.

[21] Id.

[22] Marshall Miller, Principal Associate Deputy Att'y General, U.S. Dep't of Just., Principal Associate Deputy Attorney General Marshall Miller Delivers Remarks at the American Bankers Association Financial Crimes Enforcement Conference (Dec. 6, 2022), https://www.justice.gov/opa/speech/principal-associate-deputy-attorney-general-marshall-miller-delivers-remarks-american.

[23] MOU at 3.

[24] Just. Manual § 9-28.1100.

[25] FCS DPA Q&A at 1-2.

[26] MOU Press Release.

[27] MOU at 3.

[28] MOU Press Release.

[29] Id.

[30] MOU at 4.

[31] See supra n.12.